Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

December 17, 2018</br></br>

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Executive Summary Information

Executive Summary:	See 510(k) Summary
Classification:	See Form FDA 3514
Common Name:	See Form FDA 3514
Trade/Proprietary Name:	See Form FDA 3514
Establishment Registration Number:	See Form FDA 3514
Labelling/Promotional Material:	See Section 13
Substantial Equivalence:	See Section 12
Compliance with special controls or Performance standards:	See Form FDA 3514 & Form FDA 3654

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

We have received your response and will continue our review of k182651. Thank you for providing the additional information so quickly. We will let you know we have any questions.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D4121F.6E3ACB20	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

Firstly apologies for not responding sooner.

Thank you for letting me know.

Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 25 January 2019 21:19

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: CLIA categorization for k182651

Dear Catriona,

(b)(4)

Warm regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=jqn5jrGJUEfVh4nZojP0xTe1TpIK52EN8yq_QyIl3Bc&s=gn_YGsJwZ8e1AiQp3OCwOfXKDepKzb87eq3-wx3NjEY&e=>

From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Sent: Wednesday, January 16, 2019 11:28 AM

To: chourigan@beckman.com<mailto:chourigan@beckman.com>

Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

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Declaration of Conformity to a Recognized Standard

I certify that, in my professional capacity at Beckman Coulter Ireland Inc.

All utilized standards indicated within the enclosed FORM FDA 3514 have conformed to the extent defined in FORM FDA 3654.

(b)(6)

Catriona Hourigan
Regulatory Affairs Specialist

19th Sept 2018
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Form Approved: OMB No. 0910-0120; Expiration Date: 6/30/2020

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP05-A3: 2014 "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition"

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 7-251		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP05-A3: 2014 "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Multisite Precision Evaluation Study	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Multisite Precision Evaluation Study

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Multisite Precision Evaluation Study	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0120; Expiration Date: 6/30/2020

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP06-A: "Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline"

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 7-193		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP06-A: "Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope/Introduction/Time Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Evaluating Experiment Conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Demonstration of the Linear Range - Data Evaluation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP09-A3: "Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition"

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 7-245		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP09-A3: "Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Measurement Procedure Comparison Studies	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-8	Considerations for Clinical Laboratories, Visual Data Review	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9-10	Quantitative Analysis, Comparisons Within a Measurement Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0120; Expiration Date: 6/30/2020

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP07 3rd Edition "Interference Testing in Clinical Chemistry"

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 7-275	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP07 3rd Edition "Interference Testing in Clinical Chemistry"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Interference Screening Testing (Paired difference testing)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Characterizing Interference effects (Dose-Response experiment)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Evaluating Interferences using Patient Calculations	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0120; Expiration Date: 6/30/2020

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP37 1st Edition "Supplemental tables for Interference testing in Clinical Chemistry" - First edition

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 7-284	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP37 1st Edition "Supplemental tables for Interference testing in Clinical Chemistry" - First edition

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Table 1	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0120; Expiration Date: 6/30/2020

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EP25-A: "Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline"

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 7-235		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EP25-A: "Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Overview of the Stability Testing Process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5-7	Real time Stability Study Protocol	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Accelerated Stability Testing	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

(b)(4) Draft

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,
Thank you for your holiday schedule update (b)(4) (b)(4). I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 17, 2018 12:33 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 19, 2018 11:03 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update. We will need re (b)(4)
(b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
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Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

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I look forward to hearing from you.

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Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

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FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an

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Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

I am writing to acknowledge receipt of the review of K182651 HbA1c Advanced. We are working on our response and will be in contact on or before 10th December.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4). My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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cid:image002.jpg@01D41 21F.6E3AC820

Catriona Hourigan

REGULATORY AFFAIRS SPECIALIST
Office: 353.65.683.1417
CHourigan@beckman.com www.beckmancoulter.com
Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Hi Rosemary,

Thank you so much for the quick responses also.

Please see below our response to your query on the (b)(4)

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 13 December 2018 17:11

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Thursday, December 13, 2018 11:16 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 18:27

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 12, 2018 11:33 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

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Warm Regards

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

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Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4)

(b)(4)

I look forward to working with you.

Thanks and Kind Regards

Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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Hi Rosemary,

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Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Best regards,
Rosemary

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

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I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D41 21F.0E5AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Catriona

cid:image002.jpg@01D41 21F.0E3AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

Excellent customer service is important to us. Please take a moment to provide feedback HERE regarding the customer service you have received.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Financial Certification or disclosure statement

– NOT APPLICABLE

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Hi Rosemary,

(b)(4)

If you need any further information, please let us know.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 19:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

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Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

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Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

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Catriona

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To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

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Form Approved: OMB No. 0910-0616. Expiration Date: 3/31/2021. See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Catriona Hourigan

2. Date of the Application/Submission
TO ADD

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
Beckman Coulter Ireland Inc.

Address 2 *(Apartment, suite, unit, building, floor, etc.)*
Lismeehan,

City
O' Callaghan's Mills,

State/Province/Region
Co. Clare

Country
Ireland

ZIP or Postal Code
V94 PP63

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): +353-65-683-1417

(Fax): +353-65-683-1122

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

HbA1c Advanced, Class II, B93009

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Catriona Hourigan	Regulatory Affairs Specialist

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* Beckman Coulter Ireland Inc.		
Address 2 *(Apartment, suite, unit, building, floor, etc.)* Lismeehan,		
City O' Callaghan's Mills,	State/Province/Region Co. Clare,	
Country Ireland	ZIP or Postal Code V94 PP63	

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): +353-65-683-1417

(Fax): +353-65-683-1122

14. Date of Certification

09/19/2018

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

(b)(6)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

(b)(4)

We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Monday 14 January 2019 19:06
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Subject: RE: K182651 additional information request
Importance: High

Dear Catriona,

K182651 is under division review and we have the following requests for additional information.

(b)(4)

Kind regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, January 07, 2019 2:17 PM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Best wishes for the New Year! We do not anticipate any delay in the review of k182651 as it is MDUFA funded. I will be sending it for division review this week and will let you know if we have additional questions.

Kind regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, January 07, 2019 9:06 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

Happy New to you, I hope you had a good holiday.
I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

I hope this email finds you well.

Thanks & Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 20 December 2018 18:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,
Rosemary

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Hi Rosemary,

(b)(4)

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Subject: RE: K182651 review will proceed via interactive review

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Catriona

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Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update. We will need (b)(4)
(b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

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December 17, 2018

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Hi Rosemary,

Many happy returns. I hope you have a great holiday and it has been lovely working with you over the last few weeks.

I will regularly check my email over the holiday also and I look forward to hearing from you.

Thanks again and happy holidays!!

Catriona

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=yRF7AbnlWwrwzaO-Pztaf-txiK2oet3WDKgKov1OS28&s=wAghdHyHHHZGPy_-Q_4k2ktEOWKu1W2eNtbeNyCIQ3E&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

I am writing to acknowledge receipt of the review of K182651 HbA1c Advanced. We are working on our response and will be in contact on or before 10th December.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=MfdBWbdoT1qbxVwTN4k-T0keL9pYA8ia2qVifEkDCG0&s=AVeHKX9Bucg4C_jZ9WhiBV9-XnpqjLJDt6yXG2RELl0&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024
Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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[cid:image003.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=https-3A__twitter.com_US-5FFDA&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=S0HXpvC31hdTr842eqtOx-plyrJARrdFgf__jTBrvdM&e=>
[cid:image004.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.youtube.com_user_USFoodandDrugAdmin&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=MhVE9pPRkqTMadsUUybKEbapFJeV1rZLPwPqZ83sUJ4&e=>
[cid:image005.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.flickr.com_photos_fdaphotos_&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=oepR2tEHXKGuYYrTiLEutrYlF--e0-9c5AQnn4jwKxk&e=>
[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJr1Q9TDlMqTXQ&e=>

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Dear Catriona,

(b)(4)

Warm regards,
Rosemary

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From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Sent: Wednesday, January 16, 2019 11:28 AM
To: chourigan@beckman.com
Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
TO ADD	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Beckman Coulter Ireland Inc.	9680746		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+353-65-6831417		
Street Address	FAX Number *(including area code)*		
Lismeehan,	+353-65-6831122		
City	State / Province	ZIP/Postal Code	Country
O' Callaghan's Mills,	Co. Clare	V94 PP63	Ireland
Contact Name			
Catriona Hourigan			
Contact Title	Contact E-mail Address		
Regulatory Affairs Specialist	chourigan@beckman.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	PDJ	2	LCP	3	JIT	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [X] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K151321	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	Bio-Rad Laboratories., Inc.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

HbA1c Advanced

	Trade or Proprietary or Model Name for This Device		Model Number
1	HbA1c Advanced	1	B93009
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 (b)(4)	2	3	4	5	6
7	8	9	10	11	12

Data included in Submission

- [X] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
PDJ, LCP, JIT	862.1373, 864.7470, 862.1150 - 510(K) exempt	[ ] Class I [X] Class II [ ] Class III [ ] Unclassified

Classification Panel

Clinical Chemistry, Hematology, Clinical Chemistry

Indications *(from labeling)*

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1000206808	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name: Beckman Coulter Ireland Inc.		Establishment Registration Number: 9680746			
Division Name *(if applicable)*		Phone Number *(including area code)*: +353-65-6831417			
Street Address: Lismeehan,		FAX Number *(including area code)*: +353-65-6831122			
City: O' Callaghan's Mills	State / Province: Co. Clare	ZIP Code: V94 PP63	Country: Ireland		
Contact Name: Catriona Hourigan	Contact Title: Regulatory	Contact E-mail Address: chourigan@beckman.com			

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)*			
Street Address		FAX Number *(including area code)*			
City	State / Province	ZIP Code	Country		
Contact Name	Contact Title	Contact E-mail Address			

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number			
Division Name *(if applicable)*		Phone Number *(including area code)*			
Street Address		FAX Number *(including area code)*			
City	State / Province	ZIP Code	Country		
Contact Name	Contact Title	Contact E-mail Address			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	EP05	CLSI	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition"	A3	08/14/2015
2	EP06	CLSI	Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline	A	01/30/2014
3	EP09	CLSI	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition	A3	08/01/2013
4	EP07	CLSI	Interference Testing in Clinical Chemistry	3rd edition	09/17/2018
5	EP37	CLSI	Supplemental tables for Interference testing in Clinical Chemistry	1st edition	09/17/2018
6	EP25	CLSI	Evaluation of Stability of In Vitro Diagnostic Reagents, Approved Guideline	A	01/15/2013
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k182651

B. Purpose for Submission:

New Device

C. Measurand:

Glycosylated Hemoglobin (HbA1c)

D. Type of Test:

Quantitative turbidimetric inhibition immunoassay

E. Applicant:

Beckman Coulter Ireland Inc.

F. Proprietary and Established Names:

HbA1c Advanced

G. Regulatory Information:

Regulation Description	Product Code	Device Class	Regulation	Panel
Hemoglobin A1c Test System	PDJ	II	21 CFR § 862.1373	Chemistry, 75
Glycosylated Hemoglobin Assay	LCP	II	21 CFR 864.7470	Hematology, 81

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

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2. Indication(s) for use:

The HbA1c (Hemoglobin A1c) Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For In vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription use only.

For in vitro diagnostic use.

This assay is designed only for the measurement of mmol/mol HbA1c (IFCC) and %HbA1c (NGSP). Individual results for T-Hb and A1c concentration should not be reported.

This test should not replace glucose testing for patients with Type 1 diabetes, pediatric patients or pregnant women.

In cases of rapidly evolving Type 1 diabetes, the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions, diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms.

HbA1c should not be used to diagnose diabetes during pregnancy or to diagnose gestational diabetes. HbA1c reflects the average blood glucose levels over the preceding 3 months (the average life of a red blood cell), and therefore may be falsely low during pregnancy or any other condition associated with recent onset of hyperglycemia.

The HbA1c Advanced assay allows its use in patients with hemoglobin variants S, C, D and E traits. However, hemoglobinopathies might affect the red blood cell turnover or the in vivo glycation rates, and these patients may suffer from anemia and undergo transfusion. Therefore, results reported correctly by the assay may not reflect the same level of glycemic control as would be expected in patients with normal hemoglobin. In these cases, even analytically correct results do not reflect the same level of glycemic control that would be expected in patients with normal hemoglobin. Whenever, it is suspected that the presence of a Hb variant (e.g. HbSS, HbCC or HbSC) affects the correlation between the HbA1c value and glycemic control, HbA1c must not be used for the diagnosis of diabetes mellitus.

This test is not intended for analysis of samples collected from newborns.

Glycated HbF is not detected by the assay as it does not contain the β-chain that

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characterizes HbA1c. However, HbF is measured in the T-Hb assay and as a consequence, specimens containing high amounts of HbF may result in lower than expected mmol/mol HbA1c values (IFCC) and% HbA1c values (DCCT/NGSP). HbA1c results are invalid for patients with abnormal amounts of HbF including those with known Hereditary Persistence of Fetal Hemoglobin. The following warning is included in the labeling;

> **"WARNING: The Hemoglobin A1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin. Refer to Limitations section."**

HbA1c should not be used to diagnose or monitor diabetes in patients with any conditions resulting in decreased erythrocyte survival, decrease in mean erythrocyte age or abnormal red blood cell turnover (e.g., hemolytic anemia, including hereditary spherocytosis, iron deficiency, thalassemias, malignancies, recovery from acute blood loss and severe chronic hepatic and renal disease). Shortened red cell survival time will reduce the exposure of red cells to glucose, with a resultant decrease in HbA1c values. The altered red blood cell turnover interferes with the relationship between mean blood glucose and HbA1c values.

4. Special instrument requirements:

   Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer (k161837)

I. Device Description:

The HbA1c Advanced reagent kit is provided in a liquid format and is ready to use. It contains HbA1c R1 and HbA1c R2, Total Hemoglobin R1 and Hemolyzing reagent R1.

HbA1c R1	Anti-human HbA1c Antibody (sheep)
	MES (2-morpholino-ethanesulphonic acid) Buffer
	TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)
HbA1c R2	HbA1c Polyhapten
	MES (2-morpholino-ethanesulphonic acid) Buffer
	TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)
Total Hemoglobin R1	Phosphate Buffer, pH 7.4
Hemolyzing reagent R1	0.9% Tetradecyltrimethylammonium bromide

The HbA1c calibrator is supplied with the reagent, in a liquid, ready to use format and contains 5 x 2 mL calibrator levels (levels 2 - 6). The sample hemolysis is automated on the DxC 700 AU Clinical Chemistry analyzer.

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J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad D-100™ HbA1c

2. Predicate 510(k) number(s):

   k151321

3. Comparison with predicate:

Similarities		
Item	Candidate Device HbA1c Advanced	Predicate Device Bio-Rad D-100™ HbA1c k151321
Intended Use	Intended for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus.	Same
Specimen Type	Venous whole blood K2-EDTA K3-EDTA Lithium Heparin Sodium Heparin	Same
Reporting Units	NGSP Equivalent Units (% HbA1c) IFCC Equivalent Units (mmol/mol)	Same

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Differences		
Item	Candidate Device HbA1c Advanced	Predicate Device Bio-Rad D-100™ HbA1c k151321
Platform	DxC 700 AU Clinical Chemistry Analyzer	D-100TM Hemoglobin Testing System
Methodology	Quantitative turbidimetric inhibition immunoassay	Ion-exchange Quantitative high performance liquid chromatography (HPLC)
Measuring Range	HbA1c: 4.0 – 15% HbA1c (NGSP) 20 – 140 mmol/mol (IFCC)	HbA1c: 3.5 to 20% HbA1c (NGSP) 15 - 195 mmol/mol (IFCC)

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition

CLSI EP-37 1st Edition: Supplemental tables for Interference testing in Clinical Chemistry - First edition

CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

L. Test Principle:

The HbA1c Advanced assay is a turbidimetric inhibition immunoassay. The DxC 700 AU Clinical Chemistry analyzer automatically performs the whole blood hemolysis.

Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. The hemolyzed venous whole blood is then added to both the Total Hemoglobin and HbA1c assay cuvettes according to their defined assay parameters.

Total Hemoglobin reagent (R1) is used to measure Total Hemoglobin (T-Hb) concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent (R1 and R2) is used to measure hemoglobin A1c (A1c) concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies in the reagent combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting

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agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

The concentrations of both T-Hb and A1c are determined, and are used in the calculation of the reported HbA1c (A1c/T-Hb ratio), which is expressed either as mmol/mol (IFCC) or % (DCCT/NGSP).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision of the HbA1c Advanced reagent on the DxC 700 AU Clinical Chemistry Analyzer was evaluated based on CLSI guideline EP05-A3, *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Third Edition*. Studies were carried out at a single site by three operators over 20 days on three DxC 700 AU systems using three lots of HbA1c Advanced reagent, four levels of HbA1c K2 EDTA human venous whole blood patient samples at HbA1c concentrations of approximately 5.0%, 6.5%, 8.0% and 12%, one level of K2 EDTA human venous whole blood spiked with human based high HbA1c material at a HbA1c concentration of approximately 14% and two levels of control materials (QC) resulting in 720 measurements for each sample. The summary of precision performance results are shown in the tables below.

DxC 700 AU Clinical Chemistry Analyzer Instrument 1, % HbA1c (NGSP) units

Sample ID	Mean HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
	%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	5.06	0.04	0.88	0.04	0.80	0.03	0.64	0.05	0.92	0.08	1.63
Pool 2	6.72	0.07	1.01	0.04	0.60	0.04	0.65	0.06	0.93	0.11	1.64
Pool 3	8.06	0.06	0.77	0.04	0.47	0.06	0.73	0.09	1.06	0.13	1.57
Pool 4	11.70	0.09	0.79	0.06	0.48	0.10	0.84	0.02	0.19	0.15	1.26
Pool 5	14.02	0.10	0.74	0.07	0.49	0.10	0.72	0.04	0.32	0.17	1.19
QC 1	5.32	0.06	1.19	0.04	0.84	0.03	0.66	0.07	1.34	0.11	2.08
QC 2	9.88	0.08	0.77	0.05	0.48	0.06	0.65	0.11	1.07	0.15	1.54

DxC 700 AU Clinical Chemistry Analyzer Instrument 2, % HbA1c (NGSP) units

Sample ID	Mean HbA1c	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
	%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	5.03	0.06	1.15	0.02	0.37	0.03	0.57	0.05	1.02	0.08	1.68
Pool 2	6.69	0.08	1.14	0.01	0.20	0.03	0.50	0.06	0.83	0.10	1.51
Pool 3	8.05	0.07	0.86	0.04	0.48	0.04	0.49	0.06	0.70	0.11	1.31
Pool 4	11.69	0.08	0.71	0.04	0.33	0.07	0.61	0.07	0.56	0.13	1.14
Pool 5	14.04	0.11	0.75	0.08	0.58	0.05	0.34	0.10	0.69	0.17	1.22

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Sample ID	Mean HbA1c %	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
QC 1	5.28	0.06	1.23	0.02	0.41	0.04	0.75	0.07	1.32	0.11	1.99
QC 2	9.88	0.08	0.77	0.04	0.42	0.05	0.54	0.09	0.95	0.14	1.40

DxC 700 AU Clinical Chemistry Analyzer Instrument 3, % HbA1c (NGSP) units

Sample ID	Mean HbA1c %	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	5.03	0.04	0.83	0.02	0.45	0.04	0.70	0.05	1.02	0.08	1.55
Pool 2	6.66	0.06	0.82	0.02	0.31	0.03	0.48	0.09	1.31	0.11	1.65
Pool 3	7.98	0.06	0.73	0.05	0.58	0.04	0.47	0.14	1.68	0.16	1.98
Pool 4	11.68	0.08	0.71	0.03	0.21	0.08	0.67	0.06	0.54	0.13	1.14
Pool 5	13.99	0.09	0.66	0.06	0.44	0.08	0.56	0.09	0.66	0.17	1.18
QC 1	5.25	0.05	0.93	0.05	0.97	0.03	0.60	0.07	1.37	0.11	2.01
QC 2	9.72	0.06	0.65	0.03	0.36	0.06	0.65	0.14	1.45	0.17	1.75

DxC 700 AU Clinical Chemistry Analyzer Instruments Combined, % HbA1c (NGSP) units

Sample ID	Mean HbA1c %	Repeat-ability		Between Run		Between Day		Between Lot		Between Instrument		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	5.07	0.05	0.96	0.03	0.57	0.03	0.64	0.05	0.99	0.04	0.74	0.09	1.78
Pool 2	6.72	0.07	1.00	0.03	0.41	0.04	0.55	0.07	1.05	0.04	0.56	0.11	1.69
Pool 3	8.07	0.06	0.79	0.04	0.51	0.05	0.58	0.10	1.22	0.05	0.57	0.14	1.74
Pool 4	11.71	0.09	0.74	0.04	0.36	0.08	0.71	0.05	0.46	0.04	0.32	0.14	1.22
Pool 5	14.03	0.10	0.72	0.07	0.51	0.08	0.56	0.08	0.58	0.02	0.12	0.17	1.20
QC 1	5.29	0.06	1.12	0.04	0.78	0.04	0.67	0.07	1.34	0.03	0.50	0.11	2.09
QC 2	9.84	0.07	0.73	0.04	0.43	0.06	0.61	0.12	1.17	0.07	0.70	0.17	1.72

DxC 700 AU Clinical Chemistry Analyzer Instrument 1, mmol/mol (IFCC) units

Sample ID	Mean HbA1c %	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	31.84	0.48	1.51	0.46	1.43	0.34	1.08	0.51	1.60	0.90	2.84
Pool 2	49.92	0.75	1.49	0.45	0.90	0.48	0.97	0.68	1.36	1.21	2.41
Pool 3	64.65	0.68	1.06	0.40	0.61	0.65	1.01	0.93	1.43	1.38	2.14
Pool 4	104.38	1.37	1.31	0.00	0.00	1.07	1.03	0.24	0.23	1.76	1.68
Pool 5	129.76	1.13	0.87	0.74	0.57	1.11	0.86	0.49	0.37	1.82	1.40
QC 1	34.65	0.70	2.01	0.44	1.28	0.41	1.18	0.77	2.22	1.20	3.46
QC 2	84.53	0.83	0.98	0.51	0.61	0.69	0.82	1.15	1.36	1.66	1.96

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DxC 700 AU Clinical Chemistry Analyzer Instrument 2, mmol/mol (IFCC) units

Sample ID	Mean HbA1c %	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	31.51	0.63	2.01	0.37	1.19	0.24	0.77	0.57	1.81	0.96	3.05
Pool 2	49.59	0.81	1.63	0.21	0.42	0.37	0.74	0.59	1.18	1.08	2.18
Pool 3	64.48	0.76	1.18	0.43	0.66	0.43	0.67	0.62	0.96	1.15	1.79
Pool 4	104.29	0.91	0.88	0.40	0.38	0.78	0.75	0.73	0.70	1.46	1.40
Pool 5	129.92	1.15	0.88	0.85	0.66	0.56	0.43	1.06	0.82	1.87	1.44
QC 1	34.24	0.72	2.09	0.25	0.74	0.42	1.23	0.76	2.23	1.16	3.38
QC 2	84.52	0.83	0.98	0.46	0.54	0.58	0.69	1.03	1.22	1.52	1.80

DxC 700 AU Clinical Chemistry Analyzer Instrument 3, mmol/mol (IFCC) units

Sample ID	Mean HbA1c %	Repeatability		Between Run		Between Day		Between Lot		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	31.46	0.46	1.41	0.38	1.18	0.42	1.31	0.58	1.78	0.93	2.88
Pool 2	49.27	0.61	1.21	0.23	0.46	0.35	0.70	0.97	1.93	1.22	2.42
Pool 3	63.68	0.65	1.00	0.52	0.79	0.41	0.63	1.49	2.29	1.75	2.69
Pool 4	104.18	0.92	0.87	0.26	0.25	0.85	0.81	0.70	0.66	1.46	1.39
Pool 5	129.37	1.02	0.79	0.67	0.52	0.86	0.66	1.01	0.87	1.81	1.39
QC 1	33.83	0.54	1.58	0.55	1.61	0.35	1.02	0.79	2.32	1.16	3.40
QC 2	82.77	0.69	0.83	0.38	0.46	0.69	0.83	1.55	1.86	1.87	2.24

DxC 700 AU Clinical Chemistry Analyzer Instruments Combined, mmol/mol (IFCC) units

Sample ID	Mean HbA1c %	Repeat-ability		Between Run		Between Day		Between Lot		Between Instrument		Total Precision	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Pool 1	31.91	0.53	1.66	0.41	1.27	0.34	1.08	0.55	1.73	0.42	1.31	1.02	3.20
Pool 2	49.95	0.72	1.45	0.31	0.63	0.41	0.81	0.76	1.53	0.41	0.82	1.24	2.49
Pool 3	64.75	0.70	1.08	0.45	0.69	0.51	0.79	1.07	1.66	0.50	0.77	1.53	2.37
Pool 4	104.51	1.09	1.04	0.24	0.23	0.91	0.87	0.60	0.57	0.42	0.40	1.61	1.54
Pool 5	129.84	1.10	0.85	0.76	0.58	0.87	0.67	0.89	0.69	0.19	0.14	1.84	1.42
QC 1	34.32	0.66	1.91	0.43	1.26	0.39	1.15	0.78	2.26	0.30	0.87	1.21	3.52
QC 2	84.10	0.78	0.93	0.46	0.54	0.66	0.78	1.26	1.50	0.76	0.90	1.85	2.20

b. Linearity/assay reportable range:

Linearity testing was conducted based on CLSI EP06-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.* A dilution series consisting of ten levels across the assay range was prepared by mixing high HbA1c and low HbA1c venous whole blood pools. Samples levels evaluated were 3.94, 4.67, 6.14, 7.60, 9.07, 10.54, 12.00, 13.47, 14.94 and 15.37% HbA1c (19.51, 29.53, 43.56, 59.59, 75.62, 91.65, 107.68, 123.71, 139.74 and 144.49 mmol/mol HbA1c) and each was run in quadruplicate with two reagent lots on

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the DxC 700 AU Clinical Chemistry Analyzer. The measured values were compared to the expected values. The regression parameters (slope, intercept, and r) are shown below for one representative lot:

NGSP:

Slope	Intercept	R	Concentration Range Tested
1.030	-0.14	1.000	3.94 to 15.37 % HbA1c

IFCC:

Slope	Intercept	R	Concentration Range Tested
1.020	-0.64	1.000	19.51 to 144.49 mmol/mol HbA1c

The results of the linearity study support the claimed assay measuring range of 4-15% HbA1c (20 – 140 mmol/mol HbA1c (IFCC)).

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The HbA1c Advanced assay standardization is traceable to the International Federation of Clinical Chemistry (IFCC) reference material. The HbA1c Advanced assay is certified through the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification expires in one year. See NGSP website for current certification at http://www.ngsp.org. The International Federation of Clinical Chemistry (IFCC) units of mmol/mol are calculated using the Master Equation:

NGSP (%) = 0.09145 x IFCC (mmol/mol) + 2.152
IFCC Formula= (A1c / T-Hb) * 1000 = HbA1c (mmol/mol)

Results for calculated HbA1c may be reported from the DxC 700 AU analyzer in either NGSP (%) units or IFCC (mmol/mol).

d. *Detection limit:*

The claimed measuring range of 4-15% HbA1c (NGSP) and 20 – 140 mmol/mol HbA1c (IFCC) for HbA1c Advanced reagent is based on the linearity studies above in M.1.b.

e. *Analytical specificity:*

Testing to determine the interference bias of various endogenous and exogenous interferents on the HbA1c Advanced Assay was performed according to CLSI EP07-A2, *Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition*; CLSI EP37 *Supplement Tables for Interference Testing in Clinical Chemistry, 1st Edition* was used in conjunction with EP07-A2.

The interfering substances analyzed were tested at two % HbA1c concentrations; approximately 6.5% HbA1c (low level human venous whole blood K2 EDTA

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sample) and approximately 8.0% HbA1c (high level human venous whole blood K2 EDTA sample) using one lot of reagent on one DxC 700 AU Clinical Chemistry Analyzer.

The whole blood samples were tested at a minimum of five concentration levels for each interferent with 10 replicates tested per level on the DxC 700 AU Clinical Chemistry Analyzer to determine the magnitude of the interference. The difference in mean recovery of the samples with and without the potential interfering substances was determined.

The sponsor defines significant interference as ≥ ±7% change in the HbA1c measurements from the initial value (sample containing no interferent). The following substances demonstrated no significant interference at the concentrations described below:

Endogenous Interference Summary

Potential Interfering Substance	**Highest Concentration Tested without Significant Interference**
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	500 mg/dL
Ascorbic Acid	300 mg/dL
Rheumatoid Factor	1000 IU/mL
Total Protein	21 g/dL
Glucose	2000 mg/dL

Exogenous Interference Summary

Potential Interfering Substance	**Highest Concentration Tested without Significant Interference**
Glyburide	0.12 mg/dL
Salicyclic Acid	4.76 mg/dL
Sitagliptin	0.2 mg/dL
Rosiglitazone	0.33 mg/dL
Metformin	5 mg/dL
Cyclosporine	0.5 mg/dL
Heparin	5500 IU/L
Calcium Dobesilate	20 mg/dL
Metronidazole	200 mg/dL
Levodopa	20 mg/dL

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Potential Interfering Substance	Highest Concentration Tested without Significant Interference
Acetylsalicyclic acid	1000 mg/dL
Acarbose	0.05 mg/dL
Acetaminophen	26 mg/dL
Acetylcystein	166 mg/dL
Ampicillin-Na	1000 mg/dL
Cefoxitin	2500 mg/dL
Doxycyclin	50 mg/dL
Ibuprofen	50 mg/dL
Methyldopa	20 mg/dL
Phenylbutazone	53.5 mg/dL
Rifampicin	8 mg/dL
Theophylline	10 mg/dL

Cross reactivity with Hemoglobin derivatives

Hemoglobin derivatives and potential cross reactants were tested at two %HbA1c concentrations, approximately 6.5% and 8.0% HbA1c, using one lot of reagent on one DxC 700 AU Clinical Chemistry Analyzer. Hemoglobin derivatives and potential cross reactants were tested at a minimum of five concentration levels with 10 replicates tested per level to determine the magnitude of any interference effect. The sponsor defined significant interference as recovery > 7% of the initial value (sample containing no cross reactant).

The following substances demonstrated no significant cross reactivity at the concentrations described below:

Potential Cross reacting Substance	Highest Concentration Level without Significant Cross Reactivity
Labile Hemoglobin	2000 mg/dL (Glucose)
Acetylated Hemoglobin	0.5 mg/mL (Acetylsalicylic acid)
Carbamylated Hemoglobin	1.5 mg/mL (Potassium Cyanate)
Glycated Albumin	5mg/mL
HbA0	12 mg/mL
HbA1a + b	0.16 mg/mL

Hemoglobin Variant Interference

A study was performed to assess hemoglobin variant interference with major hemoglobin variants in the HbA1c Advanced assay. Results from singlicate measurements of K2EDTA human venous whole blood samples tested using the HbA1c Advanced assay on the DxC 700 AU Clinical Chemistry Analyzer were compared to results from a FDA cleared method demonstrated to be free from

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hemoglobin interference; Trinity Premier Hb9210 and Trinity Ultra Primus 2 were used to verify %HbA1c concentrations in samples containing HbC, HbD, HbE, HbS, and HbA2 variants. The Menarini HA8180V and Tosoh G8 were used to verify %HbA1c concentrations in samples containing HbF variant. Significant interference was defined by the sponsor as ≥ ±7% change in HbA1c value in the presence of the hemoglobin variant relative to control. The following tables show the samples that were measured and the range of biases that were observed.

Hemoglobin Variant Sample Ranges

Hb Variant	Number of Samples	% Concentration of Variant in Sample	%HbA1c Concentration Range
HbC	28	28.5 - 38.2	4.8 - 14.7
HbD	23	31.1 – 42.0	5.0 - 10.6
HbE	24	20.1 - 36.1	5.4 - 10.8
HbS	29	31.0 – 42.0	5.0 - 12.7
HbA2	28	3.3 - 6.2	5.4 - 7.5
HbF	22	3.2 – 34.0	4.9 - 12.8

Relative Bias Summary

Hb Variant	Relative % Bias (Range of % Bias) observed relative to Comparator Method	
	HbA1c ~6.5% A1c	HbA1c ~9% A1c
HbC	-2.57 (-4.30% to -1.80%)	-3.19 (-6.48% to 0.41%)
HbD	-0.77 (-4.81% to 2.99%)	-1.22 (-6.30% to -0.22%)
HbE	-1.12 (-9.16% to 2.48%)	0.47 (-1.76% to 4.21%)
HbS	-1.18 (-2.17% to 3.04%)	-1.04 (-3.33% to 4.41%)
HbA2	0.48 (-1.92% to 5.60%)	2.49 (-0.98% to 3.60%)
HbF	Specimens containing high amounts of HbF (> 7%) may yield lower than expected HbA1c Values	

The results show there is no significant interference for HbS (≤ 42.0%), HbC (≤ 38.2%), HbD (≤ 42.0%), HbE (≤ 36.1%), and HbA2 (≤ 6.2%). The labeling states:

"WARNING: The Hemoglobin A1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin. Refer to Limitations section."

f. Assay cut-off:

Not applicable.

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2. Comparison studies:

a. Method comparison with predicate device:

Method comparison testing was performed using 138 frozen human venous whole blood samples in K2EDTA with values spanning the assay range of 4.70 to 14.2% HbA1c. Samples were evaluated using the HbA1c Advanced assay on the DxC 700 AU Clinical Chemistry Analyzer. The HbA1c Advanced assay first replicate results were compared to results obtained for the same samples from testing at an NGSP secondary reference laboratory (SRL) on the Menarini HA8180V, a HPLC method (cleared in k162822). The distribution of samples spanning the measuring interval follows:

Distribution of Samples

% HbA1c Level	n	% of Samples tested
<5	6	4.35%
5-6	18	13.04%
6-6.5	32	23.19%
6.5-7	35	25.36%
7-8	25	18.12%
8-9	12	8.7%
>9	10	7.25%
Total	138	100%

Deming (weighted) and Passing-Bablok regression analyses were performed for the HbA1c Advanced assay versus the comparator method. A summary of the results are provided below:

NGSP

	Slope	95 % CI	y-intercept	95% CI	R
Deming	0.990	(0.978-1.002)	0.01	(-0.070-0.089)	0.998
Passing-Bablok	0.980	(0.964-0.992)	0.090	(-0.006-0.187)	0.998

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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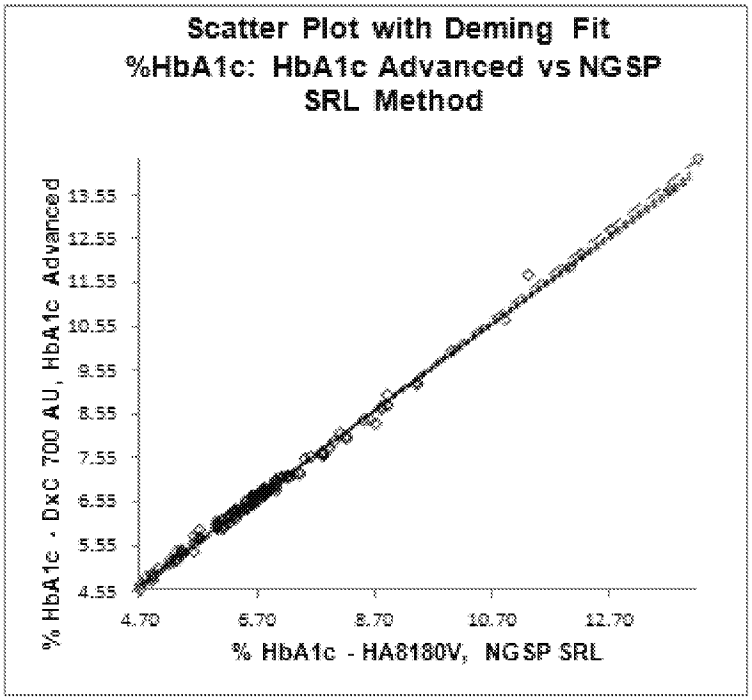
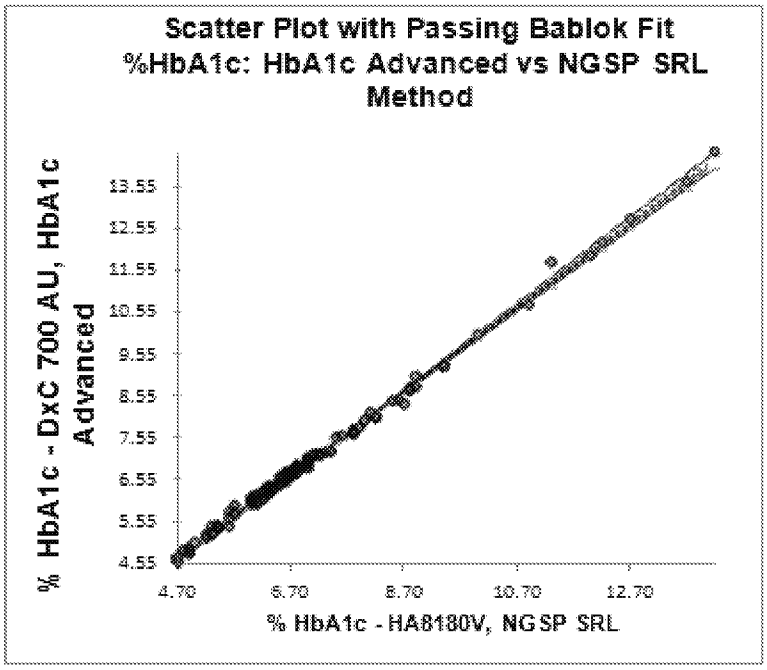
Scatter Plot using Deming Fit, %HbA1c, HbA1c Advanced vs. NGSP SRL



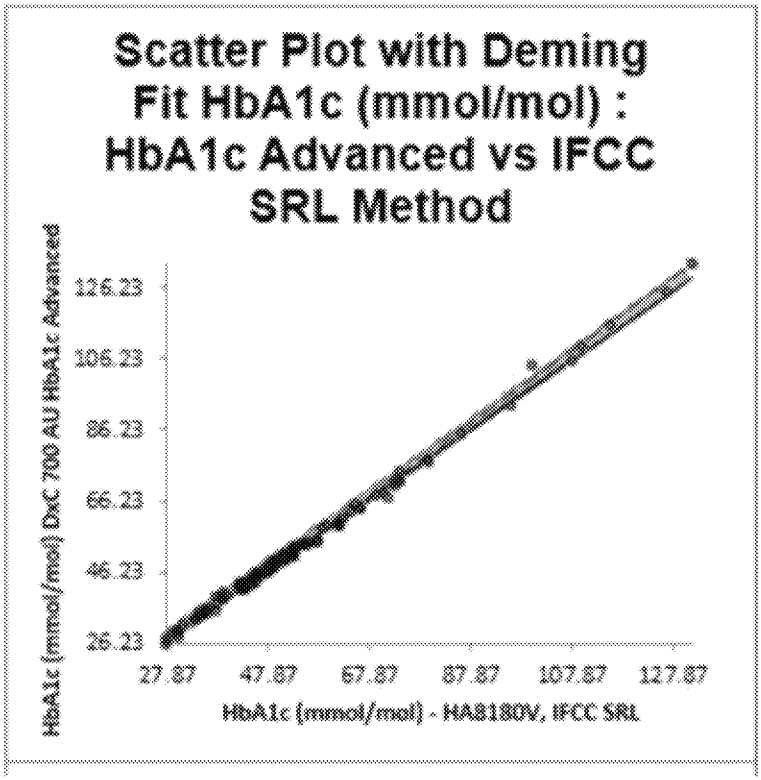
Scatter Plot using Passing-Bablok Fit, %HbA1c, HbA1c Advanced vs. NGSP SRL



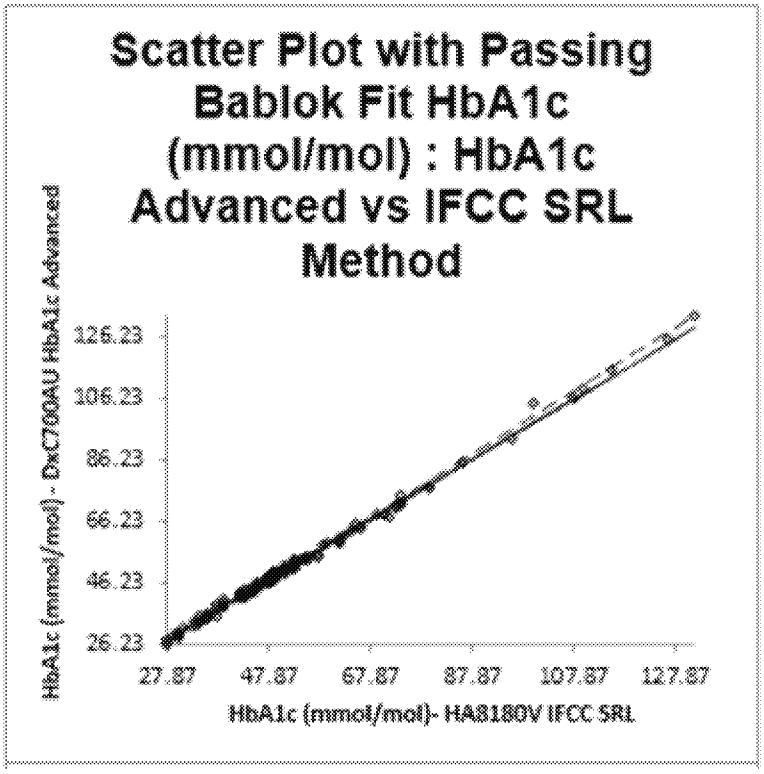
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Scatter Plot using Deming Fit, %HbA1c, HbA1c Advanced vs. IFCC SRL



Scatter Plot using Passing-Bablok Fit, %HbA1c, HbA1c Advanced vs. IFCC SRL



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Summary of Bias Estimation table (medical decision points) Weighted Deming Analysis

Bias Estimation:

%HbA1c	Automated (Whole Blood)	
	Bias	% Bias
5.00	-0.04	-0.80
6.50	0.06	-0.85
8.00	-0.07	-0.88
12.00	-0.11	-0.92

Total Error calculations and estimation

The bias estimation values determined in the method comparison study and precision estimates determined in the precision study were used to determine the total error at each of the levels listed in the tables below. Total error was calculated by the following equation:

%TE = |%Bias| + (1.96 x %CV) x (1 + %Bias/100)

Total Error Summary:

%HbA1c	% Bias	%CV	%TE
5.00	-0.80	1.78	4.3
6.50	-0.85	1.69	4.2
8.00	-0.88	1.74	4.2
12.00	-0.92	1.22	3.3

b. *Matrix comparison:*

Testing was performed to validate the use of different anticoagulants in primary collection tubes for the HbA1c Advanced reagent on the DxC 700 AU Clinical Chemistry Analyzer. The study was carried out using one lot of HbA1c Advanced and K2 EDTA, K3 EDTA, Lithium Heparin and Sodium Heparin anticoagulant tube types. K2 EDTA values were used as the reference method for K3 EDTA, Lithium Heparin and Sodium Heparin.

Fifty native venous human whole blood specimens were drawn from each donor into each of the intended anticoagulant tube types. Values of K2-EDTA whole blood, ranging from 4.86% HbA1c to 9.83% HbA1c, were compared with values for K3-EDTA whole blood, lithium heparin whole blood and sodium heparin whole blood, yielding the following regression results:

Anticoagulant	Deming Regression Analysis
K3-EDTA	y = 1.000x + 0.043 ; r = 0.997
Lithium Heparin	y = 1.004x + 0.013; r = 0. 994
Sodium Heparin	y = 1.002x - 0.009; r = 0.997

These results support the use of the HbA1c Advanced assay with samples collected in

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K2-EDTA, K3-EDTA, Lithium Heparin or Sodium Heparin tubes.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable.

   b. Clinical specificity:

   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   Hemoglobin A1c Expected Values:

Hemoglobin A1c		Suggested Diagnosis
NGSP %	**IFCC mmol/mol**	
>6.5	>48	Diabetic
5.7 – 6.4	39-47	Pre-Diabetic
<5.7	<39	Non-Diabetic

   The expected HbA1c range for non-diabetic adults is 4-6%.

   The following references were cited in the labeling:

   - American Diabetes Association. Position Statement: Standards of medical care in diabetes – In: Diabetes Care 2018; 41 (Suppl 1): S13-S27.
   - Panteghini M, John WG. Implementation of Hemoglobin A1c results traceable to the IFCC reference system: the way forward. Clin Chem Lab Med 2007; 45(8): 942-944.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10 and the special controls for this device type under 21 CFR 862.1373.

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O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

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11. Reason for Premarket Notification and Device Description

Reason for Premarket Notification:
The proposed HbA1c Advanced assay and the predicate Bio-Rad (D-100™ HbA1c, D-100™ HbA1c Calibrator pack) methods are both for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human venous whole blood and support the diagnosis of diabetes, long term monitoring blood glucose in individulas with diabetes mellitus and identify patients who may be at risk for developing diabetes mellitus.

It is the intention in this section to highlight the following:

(1) Beckman Coulter is submitting a traditional 510(k) for the new HbA1c Advanced reagent against a predicate device.
(2) Demonstrate the comparability of the two methods for hemoglobin A1c (IFCC mmol/mol and NGSP %) determination thus establishing substantial equivalence.
(3) Determine suitability of the HbA1c Advanced kit using human venous whole blood on the Beckman Coulter AU Clinical Chemistry analyzer DxC700 AU.

Device Description:

HbA1c Advanced, B93009:

(b)(4)

Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. The hemolyzed whole blood is then added to the Total Hemoglobin and HbA1c assay cuvettes according to their defined assay parameters.

Total Hemoglobin reagent (R1) is used to measure Total Hemoglobin (Thb) concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent (R1 and R2) is used to measure hemoglobin A1c (A1c) concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies in the reagent combine with HbA1c from the sample to form soluble antigen-antibody

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complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700mm.

The concentrations of both THb and A1c are determined, and are used in the calculation of the reported A1c/THb ratio, which is expressed either as mmol/mol (IFCC) or %HbA1c (DCCT/NGSP).

(b)(4)

The HbA1c Advanced reagent kit (part number B93009) shall consist of 2 x 41.4 mL HbA1c R1 reagent vials, 2 x 9.9 mL R2 reagent vials, 2 x 38.3 mL Total Hemoglobin R1, 5 x 2 mL HbA1c Calibrator (Levels 2-6) and 2 x 54.7mL Hemolyzing R1 reagent vials.

1. Total Hemoglobin R1, HbA1c R1 and R2 and Hemolyzing reagent are liquids, ready for use and can be placed directly on board the analyzer.

Below is an image of the HbA1c Advanced reagent kit:

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HbA1c Advanced, B93009

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Reactive Ingredients

The concentrations of the reactive ingredients of the HbA1c Advanced R1 & R2, Total Hemoglobin R1 and Hemolyzing reagent vials are outlined in the tables below.

Table 1: Concentration of the reactive ingredients as per the kit label in the individual R1/R2 bottles.

HbA1c R1 Antibody Reagent		**HbA1c R2 Polyhapten Reagent**	
Anti-human HbA1c Antibody (sheep)	≥ 0.5 mg/mL	HbA1c Polyhapten	≥ 8 µg/mL
MES (2-morpholino-ethanesulphonic acid) Buffer	0.025 mol/L	MES (2-morpholino-ethanesulphonic acid) Buffer	0.025 mol/L
TRIS (tris(hydroxymethyl)amino methane) Buffer (pH 6.2)	0.015 mol/L	TRIS (tris(hydroxymethyl)aminome thane) Buffer (pH 6.2)	0.015 mol/L
Non-reactive chemicals necessary for optimum system performance			

Total Hemoglobin Reagent	
Phosphate Buffer, pH 7.4	0.02 mol/L
Non-reactive chemicals necessary for optimum system performance	

Hemolyzing Reagent
0.9% tetradecyltrimethlyammonium bromide 26.75 mmol/L

Table 2: Final Concentration of the reactive ingredients in the reaction cuvette.

HbA1c R1 Antibody Reagent		**HbA1c R2 Polyhapten Reagent**	
Anti-human HbA1c Antibody (sheep)	≥0.403 mg/mL	HbA1c Polyhapten	≥ 1.29 µg/mL
MES (2-morpholino-ethanesulphonic acid) Buffer	0.020 mol/L	MES (2-morpholino-ethanesulphonic acid) Buffer	0.004 mol/L
TRIS (tris(hydroxymethyl)aminometh ane) Buffer (pH 6.2)	0.012 mol/L	TRIS (tris(hydroxymethyl)am inomethane) Buffer (pH 6.2)	0.002 mol/L
Non-reactive chemicals necessary for optimum system performance			

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Total Hemoglobin Reagent	
Phosphate Buffer, pH 7.4	0.018 mol/L
Non-reactive chemicals necessary for optimum system performance	

Hemolyzing Reagent
0.9% tetradecyltrimethlyammonium bromide 26.5mmol/L

Warnings and Precautions

The calibrator is manufactured from human material; each donor used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to HIV-1/2 and HCV as well as for hepatitis B surface antigen and was not repeatedly reactive. Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis B virus or other infectious agents are absent from biological materials, this product should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control and Prevention/National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories.

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

Calibrator Traceability

The HbA1c calibrator values are traceable to the IFCC HbA1c reference method via IFCC HbA1c reference material. The relationship between results from the NGSP network (DCCT aligned) and the IFCC network has been evaluated and a Master Equation has been developed for interconversion of results from IFCC (mmol/mol) to NGSP (%) units.

(b)(4)

The HbA1c Advanced kit is designed for optimal performance on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, in a clinical laboratory setting to generate IVD results. The device is for in-vitro diagnostic use only.

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FDA clearance of DxC 700 AU Clinical Chemistry analyzer is described below:

Device Name:	ISE Reagent, Glucose, CRP Latex, DxC 700 AU Clinical Chemistry Analyzer
Device Manufacturer:	Beckman Coulter, Inc.
Device 510(k) #:	K161837

Device Name:	DxC 700 AU Clinical Chemistry Analyzer, AU IgG Reagent
Device Manufacturer:	Beckman Coulter, Inc.
Device 510(k) #:	K162208

This 510(k) submission will demonstrate the ability of the DxC 700 AU Clinical Chemistry Analyzer to perform online pre-treatment of human venous whole blood samples.

Image of the DxC 700 AU analyzer:

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Hi Rosemary,

(b)(4)

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 19:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reagent

Acceptance Criteria

Results

Pass/ Fail

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=22YUQmxLcErJaU2IMWbfwfOvcuFKNZiuGtBsbOBKu8U&s=gKi_wE9-Tcmz9oq6_uS_nZzXcwhIA2ofWUCSztDi8m8&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 19, 2018 11:03 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Thank you for your holiday schedule update. (b)(4) (b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=yRF7AbnlWwrwzaO-Pztaf-txiK2oet3WDKgKov1OS28&s=wAghdHyHHHZGPy_-Q_4k2ktEOWKu1W2eNtbeNyCIQ3E&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

cid:image002.jpg@01D41 21F.0E3AC820

Catriona Hourigan

REGULATORY AFFAIRS SPECIALIST
Office: 353.65.683.1417
CHourigan@beckman.com www.beckmancoulter.com
Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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14. Stability

Accelerated Shelf Life

Shelf life for the new proposed HbA1c Advanced reagent components was assessed in accordance with an internal test protocol for shelf life stability prediction with principles for CLSI EP25-A "*Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline"* with the aim to establish an initial claim of 21 months.

(b)(4)

Shelf life stability was conducted using three lots of HbA1c Advanced reagent on one DxC 700 AU representative platform, using the Kennon accelerated stability model.

(b)(4)

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, December 20, 2018 12:17 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 19:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 19, 2018 11:03 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

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(b)(4)

Thanks and Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update (b)(4)
(b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 17, 2018 12:33 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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(b)(4) Draft Package Insert

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Dear Catriona,

(b)(4)

Best regards,

Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Wednesday, December 12, 2018 11:33 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

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Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

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(b)(4)

Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office: 353.65.683.1417

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www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

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Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

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Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

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Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

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Sent: Monday, November 19, 2018 11:27 AM

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

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Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

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Importance: High

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Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

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K182651

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Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

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U.S. Food and Drug Administration,
Center for Devices and Radiological Health,
Document Control Center - WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002.

Re: 510(k) Notification [21 CFR 807.90(e)] for HbA1c Advanced

Dear Director,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended (the Act), Beckman Coulter Ireland Inc. proposes to introduce into interstate commerce for commercial distribution a device intended for human use and hereby report to the Food and Drug Administration as required by law. This 510(k) report is being submitted at least ninety days prior to the date upon which we propose to begin introduction of the device herein described. There have been no prior submissions for this device. Beckman Coulter has submitted a Pre-Submission for this 510(k) - Reference No. Q170940. Please provide CLIA categorization.

1. Submission Type: Traditional 510(k)

2. Basis: New Reagent and Calibrator

3. Device Name: Common Name: HbA1c Advanced
Trade Name: HbA1c Advanced

4. Submitter: Beckman Coulter Ireland Inc.
Contact: Catriona Hourigan
Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.,
Lismeehan,
O' Callaghan's Mills,
Co. Clare,
Ireland.
V94 PP63

Phone: +353-65-6831417
FAX: +353-65-6831122

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Beckman Coulter Ireland Inc.,
Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

Email: chourigan@beckman.com

5. Recommended Reagent Classification:

Name: Hemoglobin A1c Test System
Regulation: 862.1373
Class: II
Panel: Clinical Chemistry
Product Code: PDJ

Name: Assay Glycosylated Hemoglobin
Regulation: 864.7470
Class: II
Panel: Hematology
Product Code: LCP

Recommended Calibrator Classification: Name: Calibrator, Secondary
Regulation: 862.1150
Class: II
Panel: Clinical Chemistry
Product Code: JIT

Beckman Coulter has provided two electronic copies "eCopies" of this submission.

Beckman Coulter has included the Table of Contents in the cover letter.

We believe the foregoing information and referenced enclosures are sufficient for CDRH to make a substantial equivalence determination for this device. However, should additional information be required, it will be furnished upon request to the contact person listed above.

Sincerely,

(b)(6)

Catriona Hourigan
Beckman Coulter Ireland Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Beckman Coulter Ireland Inc.,
Lismeehan,
O'Callaghan's Mills,
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Tel. +353-65-6831100.
Fax. +353-65-6831122.

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Fax. +353-65-6831122.

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Fax. +353-65-6831122.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Suantak, Ngocinthawng * [Ngocinthawng.Suantak@fda.hhs.gov]
Sent: 10/18/2018 9:47:20 PM
To: chourigan@beckman.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K182651/CR180714 Acknowledgment Notification
Attachments: Acknowledgment%20Letter.pdf; CR180714 Acknowledgment Letter.pdf

Greetings,

Your submission is now Under Review.

Thanks,
Thawng-DCC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Acknowledgment Letter

10/18/2018

Catriona Hourigan, Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.
Lismeehan
O' Callaghan's Mills, Co. Clare V94 PP63
IRELAND

Dear Catriona Hourigan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K182651
Received: 9/24/2018
Applicant: Beckman Coulter Ireland Inc.
Device: HbA1c Advanced

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

10/18/2018

Catriona Hourigan, Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.
Lismeehan
O' Callaghan's Mills, Co. Clare V94 PP63
IRELAND

Dear Catriona Hourigan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: (b)(4)
Received: 9/24/2018
Applicant: Beckman Coulter Ireland Inc.
Device: HbA1c Advanced

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Dear Catriona,

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Thursday, December 13, 2018 11:16 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 18:27

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 12, 2018 11:33 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Best regards,

Rosemary

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26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=MfdBWbdoT1qbxVwTN4k-T0keL9pYA8ia2qVifEkDCG0&s=AVeHKX9Bucg4C_jZ9WhiBV9-XnpqjLJDt6yXG2RELl0&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

[cid:image004.jpg@01D4121F.6E3ACB20]<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.linkedin.com_company_beckman-2Dcoulter&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=MfdBWbdoT1qbxVwTN4k-T0keL9pYA8ia2qVifEkDCG0&s=aRbch6dD_G5UZFYCZGYly3hTcUue8AWJEOwDxFCcihI&e=>[cid:image006.jpg@01D4121F.6E3ACB20]<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.youtube.com_user_beckmancoulter&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=MfdBWbdoT1qbxVwTN4k-T0keL9pYA8ia2qVifEkDCG0&s=jFCvF8oSlog3b9bu9jJc38w4lXSlL2EPT0Ka1GZ0DoA&e=>

Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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[cid:image002.jpg@01D1C57E.DFA022A0]<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.facebook.com_FDA&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=FLtX9EE2tsdMr2o5nwi8gXQkyiEBRgfd0MWVOgmsWpg&e=>
[cid:image003.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=https-3A__twitter.com_US-5FFDA&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=S0HXpvC31hdTr842eqtOx-plyrJARrdFgf__jTBrvdM&e=>
[cid:image004.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.youtube.com_user_USFoodandDrugAdmin&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=MhVE9pPRkqTMadsUUybKEbapFJeV1rZLPwPqZ83sUJ4&e=>
[cid:image005.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.flickr.com_photos_fdaphotos_&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=oepR2tEHXKGuYYrTiLEutrYlF--e0-9c5AQnn4jwKxk&e=>
[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJr1Q9TDlMqTXQ&e=>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

(b)(4) Draft

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510(k) Summary

HbA1c Advanced

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Performance Testing Animal – NOT APPLICABLE

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182651

Device Name
HbA1c Advanced

Indications for Use *(Describe)*
The HbA1c (hemoglobin A1c) Advanced assay on the Beckman Coulter DxC700 AU Clinical Chemistry Analyzer, is inteded for the quantitative determination of mmol/mol HbA1c (IFCC) or % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term glucose control in indicidulas with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Hi Rosemary,

(b)(4)

Thanks and Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update **(b)(4)**
(b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 17, 2018 12:33 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Hi Rosemary,

Many happy returns. I hope you have a great holiday and it has been lovely working with you over the last few weeks.
I will regularly check my email over the holiday also and I look forward to hearing from you.

Thanks again and happy holidays!!

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 20 December 2018 18:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,
Rosemary

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Biocompatibility – NOT APPLICABLE

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Dear Catriona,
Thank you for the update. We appreciate that you will respond later today.

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 12, 2018 8:58 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

We have received your email. (b)(4)

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

clclimage002.jpg@01D41 21F.6E3AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,

Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Thursday, December 20, 2018 12:17 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 19:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 19, 2018 11:03 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Thank you for your holiday schedule update. (b)(4) (b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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510(k) Summary

HbA1c Advanced

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Hi Rosemary,

Please see our responses below.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 18:27
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 12, 2018 11:33 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

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Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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(b)(4)

Best regards,
Rosemary

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on thi (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

clclimage002.jpg@01D41 21F.6E3AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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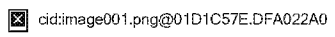
(b)(4)

Please confirm receipt of this correspondence and provide your response to me by email today if possible but no later than noon (EST) Monday, 19 November, 2018. If you have any questions or will need additional time to respond, please let me know. Thank you.

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov



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Hi Rosemary,

(b)(4)

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

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Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

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I look forward to working with you.

Thanks and Kind Regards

Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

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Subject: k182651 HbA1c Advanced Additional information request

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(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJr1Q9TDlMqTXQ&e=>

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510(k) Summary

HbA1c Advanced

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

We acknowledge receipt of your request below.

(b)(4)

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 18:27

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Best regards,

Rosemary

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GgA9B2t6zEqfp1jIpJq7Tbie8baNpJCnQ&s=CkutGrT0IdB1PtIFEJK0OEkcQV1LiIfq97O4SpWxcCk&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 12, 2018 11:33 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Best regards,

Rosemary

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

I look forward to working with you.

Thanks and Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16.1 Software

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

16.2 Cybersecurity

(b)(4)

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Performance Testing Clinical – NOT APPLICABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. Substantial Equivalence Comparison and Discussion

Predicate

Proposed Device	Predicate Device	Manufacturer	Docket Number
HbA1c Advanced, Model No. B93009	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	Bio-Rad Laboratories., Inc.	K151321

Comparison to Predicate(s):
The following tables show similarities and differences between the predicate and the proposed device.

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Comparison with Predicate

Similarities between the Predicate Device and the Proposed Device:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Based on the similarities, the Beckman Coulter HbA1c Advanced are equivalent to the predicate device. The differences between the analyzer platforms, applications, and features have been further tested to ensure that they do not present any new safety or effectiveness concerns. This is detailed within Section 14 (Stability) and Section 18 (Performance Testing).

The HbA1c Advanced kit has data to support the proposed Instructions For Use claims. The data was generated from a DxC 700 AU analyzer platform with specific claims for: analytical range (linearity), precision, method comparison, interferences (analytical specificity), anticoagulants and sample stability. The new claims utilized current, recognized standards from industry practice.

The following describes in more detail the differences between the proposed and predicate device and how these differences do not introduce any new safety or efficacy issues.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating Principle

(b)(4)

Sample Types

The predicate has additional sample types of: Potassium Oxalate / Sodium Fluoride and Sodium Citrate. Beckman Coulter are not intending for this reagent to be used with these sample types and therefore have not performed any testing on these sample types.

Analytical Range (Linearity)

(b)(4)

are raised.

Interferences (Analytical Specificity)

(b)(4)

Endogenous Interference:

(b)(4)

Hemoglobin Variant Interference:

(b)(4)

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Table 1: Hemoglobin Variant Interference comparison

Hemoglobin variant	Biorad	HbA1c Advanced
HbF	HbF concentrations up to 30% do not interfere with the test	Samples containing ≥7% HbF may result in lower than expected HbA1c results

Hemoglobin Derivative and Cross Reactant Interference:
When compared to the predicate the interference claims are equivalent or were tested to an increased concentration of interferent. Three additional cross reactant/ hemoglobin derivates were also tested.

Table 2: Hemoglobin Derivates and Cross Reactant Interference differences.

Cross Reactant Interferent	Biorad	HbA1c Advanced
HbA0	N/A	NSI up to 12 mg/mL
HbA1a+b	N/A	NSI up to 0.16 mg/mL
Glycated Albumin	N/A	NSI up to 5 mg/mL
Carbamylated Hemoglobin	NSI up to 5%	NSI up to 1.5 mg/mL
Labile Hemoglobin	NSI up to 1200 mg/dL of glucose	NSI up to 2000 mg/dL

Drug Interference:

(b)(4)

The following table outlines the differences in drug interfences between Biorad and HbA1c Advanced. Drug interferents not included have the same level of no significant interference.

Table 3: Difference in drug interferents between Biorad predicate and HbA1c Advanced

Drug Interferent	Biorad	HbA1c Advanced
Heparin	5000U/L	5500IU/L
Rifampicin	64 mg/L	8 mg/dL
Acetaminophen	200 mg/L	26 mg/dL
Phenylbutazone	400 mg/L	53.5 mg/dL
Sitagliptin	N/A	0.2 mg/dL
Glyburide	N/A	0.12 mg/dL
Salicyclic acid	N/A	4.76 mg/dL
Rosiglitazone	N/A	0.33 mg/dL
Metformin	N/A	5 mg/dL
Calcium Dobsilate	N/A	20 mg/dL
Acarbose	N/A	0.05 mg/dL

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In conclusion, the data contained within the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the predicate chemistry test system already in commercial distribution. The conclusions drawn from the non-clinical tests demonstrate that the HbA1c Advanced reagent is as safe and effective and performs as well as the predicate Biorad device. The Beckman Coulter HbA1c Advanced reagent is substantially equivalent to the predicate device and any differences do not demonstrate additional safety or effectiveness concerns.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

Happy New to you, I hope you had a good holiday.
I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

I hope this email finds you well.

Thanks & Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 20 December 2018 18:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, December 20, 2018 12:17 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 19:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

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(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 19, 2018 11:03 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update (b)(4)
(b)(4) I will provide the revisions needed later today. Can we expect to receive a revised version before COB Friday the 21st December?

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 17, 2018 12:33 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Sent: Wednesday, December 19, 2018 11:03 AM

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

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Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

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Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

We acknowledge receipt of your request below.

(b)(4)

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 18:27
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 12, 2018 11:33 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

(b)(4)

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D4121F.6E3ACB20	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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BECKMAN COULTER

AU

Instructions For Use

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HbA1c Advanced
HbA1c

REF B93009 2 x 41.4 mL HbA1c R1
2 x 9.9 mL HbA1c R2
2 x 38.3 mL Total Hemoglobin R1
2 x 54.7 mL Hemolyzing Reagent R1
5 x 2 mL HbA1c Calibrator (Levels 2-6)

APPROVAL C NOT FOR PUBLICATION

For *In Vitro* Diagnostic Use

For Rx use only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The HbA1c (hemoglobin A1c) Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or %HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

SUMMARY AND EXPLANATION

Diabetes mellitus is a condition characterized by hyperglycemia resulting from the body's inability to use blood glucose for energy. In Type 1 diabetes, the pancreas no longer makes insulin and therefore, blood glucose cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly[1,2]. The direct and indirect effects on the human vascular tree are the major source of morbidity and mortality in both type 1 and type 2 diabetes. Generally, the injurious effects of hyperglycemia are separated into macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy)[3].

HbA1c is the major species of glycohemoglobin found in human blood, and is formed by the non-enzymatic glycation of the free amino group at the N-terminal of the hemoglobin A0 β-chain[4]. HbA1c testing has been recommended for the diagnosis of Type 2 diabetes by the International Expert Committee (IEC), the American Diabetes Association (ADA), and the World Health Organization (WHO), which recommended a diagnostic threshold of ≥ 6.5% (≥ 48 mmoL/moL) HbA1c[5,6,7]. HbA1c testing has also been recommended for the identification of individuals at increased risk for developing diabetes (pre-diabetic). The ADA has defined the HbA1c range for pre-diabetes as 5.7% - 6.4% (39 – 46 mmoL/moL) HbA1c[2,5,8,9,10].

Detection and treatment of prediabetes may reduce or eliminate the risk of developing Type 2 diabetes and related complications[5].

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HbA1c determinations are useful for monitoring long-term blood glucose control in individuals with diabetes mellitus. Determination of HbA1c provides an important tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus. Therapy for diabetes requires the long term maintenance of a blood glucose level as close as possible to normal levels, minimizing the risk of long-term vascular consequences[11]. A single fasting blood glucose measurement is an indication of the patient's immediate past condition (hours), but may not represent the true status of blood glucose regulation[12,13].

The measurement of HbA1c every two to three months has been accepted as a measure of glycemic control in the care and treatment of patient with diabetes mellitus. Long term treatment of the disease emphasizes control of blood glucose levels in preventing the acute complications of ketosis and hyperglycemia. In addition, long term complications such as retinopathy, neuropathy and cardiovascular disease can be minimized if blood glucose levels are effectively controlled.

The HbA1c Advanced assay reflects the average blood glucose levels over the preceding 3 months (i.e. the average life span of a red blood cell) and therefore may be falsely low during any condition associated with the recent onset of hyperglycemia (including gestational diabetes) and/or decreased red blood cell survival[14,15,16,17]. Refer to Limitations section for additional information.

METHODOLOGY

The HbA1c Advanced assay (B93009) involves the use of three reagents: Total Hemoglobin (R1), HbA1c (R1 and R2), and Hemolyzing Reagent (R1). The DxC 700 AU Clinical Chemistry analyzer automatically performs the whole blood hemolysis using 200 µL of Hemolyzing reagent (R1) and 2 µL of whole blood in a cuvette.

Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. The hemolyzed whole blood is then added to both the Total Hemoglobin and HbA1c assay cuvettes according to their defined assay parameters.

Total Hemoglobin reagent (R1) is used to measure Total Hemoglobin (T-Hb) concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent (R1 and R2) is used to measure hemoglobin A1c (A1c) concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies in the reagent combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

The concentrations of both T-Hb and A1c are determined, and are used in the calculation of the reported HbA1c (A1c/T-Hb ratio), which is expressed either as mmol/mol (IFCC) or % (DCCT/NGSP).

SPECIMEN

SPECIMEN STORAGE AND STABILITY

Reference[18,19]

Whole blood samples are stable for up to 8 hours when stored at 20°C to 25°C, 7 days when stored at 2°C to 8°C and up to 1 month when frozen at -20°C and -70°C. Frozen samples should be thawed only once.

Each laboratory should evaluate sample handling procedures to avoid variable results.

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

Additional handling conditions as designated by this laboratory:

APPROVAL COPY NOT FOR PUBLICATION

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SPECIMEN COLLECTION AND PREPARATION

K_2-EDTA, K_3-EDTA, Li-Heparin or Na-Heparin whole blood (freshly drawn blood treated with EDTA is the preferred specimen). Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of the chemistry information sheet.

HbA1c Advanced should be programmed using "WHOLE BLOOD" as the sample type. Thoroughly mix the whole blood sample to ensure a uniform distribution of erythrocytes IMMEDIATELY before loading onto the analyzer. Settling of the erythrocytes may cause an elevated total hemoglobin result. Ensure there are no bubbles in the sample and remove any visible clots. Samples should not be centrifuged prior to analysis.

SAMPLE VOLUME

When using a primary sample tube for the whole blood sample, refer to the manufacturer's recommendations for minimum/maximum fill volume. When using a 2.5 mL sample cup (MU853200), the minimum volume for patient whole blood samples is 250µL.

Additional instructions for patient sample preparation as designated by this laboratory:

Additional type conditions as designated by this laboratory:

REAGENTS

CONTENTS

HbA1c Advanced Reagent

Reagent storage location in this laboratory:

WARNING AND PRECAUTIONS

Reference[20]

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.

The calibrator is manufactured from human material; each donor used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to HIV-1/2 and HCV as well as for hepatitis B surface antigen and was not repeatedly reactive. Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis

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B virus or other infectious agents are absent from biological materials, this product should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control and Prevention/National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories.*

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

HbA1c R1 Antibody Reagent		**HbA1c R2 Polyhapten Reagent**	
Anti-human HbA1c Antibody (sheep)	≥ 0.403 mg/mL	HbA1c Polyhapten	≥ 1.29 µg/mL
MES (2-morpholino-ethanesulphonic acid) Buffer	0.020 mol/L	MES (2-morpholino-ethanesulphonic acid) Buffer	0.004 mol/L
TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)	0.012 mol/L	TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)	0.002 mol/L
Non-reactive chemicals necessary for optimum system performance			

Total Hemoglobin Reagent	
Phosphate Buffer, pH 7.4	0.018 mol/L
Non-reactive chemicals necessary for optimum system performance	

Hemolyzing Reagent
0.9% Tetradecyltrimethylammonium bromide 26.5 mmol/L

The concentrations of the reactive ingredients of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 bottles. The reagent composition which is shown in this Instructions For Use is the final concentration of these ingredients in the reaction cuvette after the addition of the applicable components required for the reaction (R1, Sample, R2).

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GHS HAZARD CLASSIFICATION

HbA1c Calibrator (Levels 2 - 6)	WARNING	
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P337+P313	If eye irritation persists: Get medical advice/attention.
		Tetradecyltrimethylammonium bromide 1 - 2%
Hemolyzing Reagent	WARNING	
	H316	Causes mild skin irritation.
	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tetradecyltrimethylammonium bromide 0.1 - 1%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

0.9% Saline solution.

At least two levels of control material

Storage location of the saline solution in this laboratory:

EQUIPMENT AND MATERIALS

DxC 700 AU Beckman Coulter Analyzers.

Sample cups 2.5mL, REF MU853200

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Storage location of test tubes or sample cups in this laboratory:

REAGENT PREPARATION

Total Hemoglobin (R1), HbA1c (R1 and R2) and Hemolyzing Reagent (R1) are ready for use, and can be placed directly on board the analyzer.

REAGENT STORAGE AND STABILITY

1. The unopened reagents are stable, up to the stated expiration date when stored at 2 to 8°C.
2. Opened bottles of reagent are stable for 30 days when stored in the refrigerated compartment of the analyzer.
3. Do not freeze

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, gross turbidity, precipitate, or change in color in the HbA1c, Total Hemoglobin or Hemolyzing reagents may indicate degradation and warrant discontinuation of use.

Additional storage requirements as designated by this laboratory:

CALIBRATION

CALIBRATOR PREPARATION

1. For each individual level of calibrator, carefully remove the cap and stopper, avoiding any loss of lyophilized material. Ensure each level of calibrator is reconstituted individually to remove the possibility of cap and stopper mix up.
2. Add 2.00 mL of sterile deionized water at 15 to 25°C (room temperature) to the lyophilized material using a calibrated pipette or gravimetrically using an analytical balance. Ensure the deionized water being used for reconstitution is at room temperature for accurate aspiration and dispensing into the calibrator bottle. Failure to accurately measure 2.00 mL for each level of calibrator will lead to variability in test results.
3. Replace the cap and stopper.
4. Invert to ensure any material on the stopper is in solution. Dissolve the contents completely by gently mixing for 30 minutes. Vortex each bottle for 5 seconds at medium speed. Avoid foaming. Ensure that all lyophilized material is reconstituted.
5. Record the date the calibrator was reconstituted on the bottle label.

CALIBRATOR STORAGE AND STABILITY

Unopened, the calibrators should be stored at 2 to 8°C until the expiration date printed on the calibrator bottle.

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After reconstitution, calibrators are stable for up to 8 hours stored at 15°C to 25°C or up to 30 hours stored at 2°C to 8°C. Calibrators that are aliquoted immediately after reconstitution and stored at -20°C are stable for up to 60 days, as long as it has not exceeded the expiration date printed on the original calibrator bottle. Frozen calibrators should be thawed only once. After thawing, vortex each bottle for 5 seconds at medium speed[19]. Avoid foaming.

Calibration Stability

Recalibrate the assay every 15 days or when the following occur:

1. Change in reagent lot or significant shift in control values.
2. Major preventative maintenance was performed on the analyzer or a critical part was replaced.

   Following calibration, the resulting curve should be visually reviewed on the Beckman Coulter DxC 700 AU Analyzer for acceptability using the software options to access the Calibration Monitor.

   Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

CALIBRATION INFORMATION

Calibrators are included in the kit.

CALIBRATOR ASSIGNED VALUES

Refer to table below for information on calibrator levels. Refer to table of assigned values included in the kit.

NOTE: Calibrators are lot-specific and provided as a set for a specific lot of reagent. They should not be interchanged.

Calibration of Total Hemoglobin: Two Point Calibration

- Level 1 (0.9% Saline) (not supplied with kit)
- HbA1c Calibrator Level 3

Calibration of A1c: Multi-point Calibration

- HbA1c Calibrator Levels 2 to 6 only are used for the calibration of the A1c assay

Cup Sequence Order	Assay Name: A1c	Assay Name: T-Hb
1	Not Applicable	0.9% Saline
2	Calibrator 2	Not Applicable
3	Calibrator 3	Calibrator 3
4	Calibrator 4	Not Applicable
5	Calibrator 5	Not Applicable
6	Calibrator 6	Not Applicable

TRACEABILITY

Reference[21]

The HbA1c calibrator values are traceable to the IFCC HbA1c reference method via IFCC HbA1c reference material. The relationship between results from the NGSP network (DCCT aligned) and the IFCC network has been evaluated and a Master Equation has been developed for conversion of results from IFCC (mmol/mol) to NGSP (%) units.

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MASTER EQUATION

NGSP = (0.0915 x IFCC (mmol/mol)) + 2.15

IFCC Formula = (A1c / T-Hb) * 1000 = HbA1c (mmol/mol)

The definition of the relationship between the two networks links IFCC traceable results to clinically meaningful HbA1c results from the DCCT and the United Kingdom Prospective Diabetes Study (UKPDS). The Master Equation also provides these DCCT results with traceability to a higher order reference method.

Results

Results for calculated HbA1c may be reported from the DxC 700 AU analyzer in either IFCC (mmol/mol) or NGSP (%) units. To change reporting units, please contact your Beckman Coulter representative.

QUALITY CONTROL

At least 2 levels of control material should be analyzed. Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

Confirm that a volume of QC material sufficient for analysis plus the required dead volume is in the recommended 2.5 mL sample cup.

Location of controls used at this laboratory.

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

Refer to the Beckman Coulter DxC 700 AU Chemistry Analyzer Instrument Instructions For Use (IFU) and Reference Manual for analyzer-specific instructions.

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Note: The DxC 700 AU cannot process whole blood patient samples from the STAT table. Calibrators and controls in 2.5 mL sample cups (REF MU853200) only, may be loaded directly onto the STAT table.

REPORTING RESULTS

Data contained within this section is representative of performance on the Beckman Coulter DxC 700 AU Chemistry Analyzer. Data obtained in your laboratory may differ from these values.

REFERENCE INTERVALS

Reference[5,6,7,19,22,23]

The following HbA1c ranges recommended by the American Diabetes Association (ADA) may be used as an aid in the diagnosis of diabetes mellitus:

HbA1c Advanced		
NGSP %	**IFCC mmol/mol**	**Suggested Diagnosis:**
≥ 6.5	≥ 48	Diabetic
5.7 - 6.4	39 - 47	Pre-Diabetic
< 5.7	< 39	Non-Diabetic

The expected HbA1c range for non-diabetic adults is 4-6%[24]. This reference interval was taken from the literature. Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. Results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

ANALYTICAL MEASURING RANGE

The reportable range for the calculated HbA1c is 20 – 140 mmol/mol HbA1c (IFCC) and 4 – 15% HbA1c (NGSP). Note: a calculated HbA1c result may be outside the reportable range based on either the T-Hb or the A1c result being outside of their respective analytical ranges (refer to the Limitations section).

Expected reference ranges in this laboratory:

INTERVALS	SAMPLE TYPE	UNITS

Additional reporting information as designated by this laboratory:

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PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

Reference[19]

The following anticoagulants were assessed by Deming regression analysis with paired EDTA and heparin whole blood samples. Values of K2-EDTA whole blood (X), ranging from 4.9% HbA1c to 10% HbA1c, were compared with values for K3-EDTA whole blood, lithium heparin whole blood and sodium heparin whole blood (Y), yielding the following results:

ANTICOAGULANT	CONCENTRATION OF ANTICOAGULANT TESTED	DEMING REGRESSION ANALYSIS
K_3-EDTA	1.8 mg/mL	Y = 1.000X + 0.043 ; r = 0.997
Lithium Heparin	17 I.U./mL	Y = 1.004X + 0.013 ; r = 0.994
Sodium Heparin	17 I.U./mL	Y = 1.002X - 0.009 ; r = 0.997

LIMITATIONS

1. The result from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
2. This assay is designed only for the measurement of mmol/mol HbA1c (IFCC) and %HbA1c (NGSP). Individual results for T-Hb and A1c concentration should not be reported.
3. The analytical range for T-Hb is 3.7 - 17.0 mmol/L (5.97 - 27.4 g/dL). The analytical range for A1c is 0.19 mmol/L (0.3 g/dL) to the concentration of Calibrator 6[19]. When the result for T-Hb and/or A1c is outside the analytical range a “Tx” flag is generated. This could indicate that settling of the whole blood sample has occurred, which will be indicated by an “F” flag on the individual T-Hb or A1c results. In this instance this sample should be inverted to re-suspend the erythrocytes and analyzed immediately. If on repeat the “Tx” flag is repeated, the calculated HbA1c should not be reported.
4. This test should not replace glucose testing for patients with Type 1 diabetes, pediatric patients or pregnant women.
5. In cases of rapidly evolving Type 1 diabetes, the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions, diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms [6].
6. HbA1c should not be used to diagnose diabetes during pregnancy or to diagnose gestational diabetes. HbA1c reflects the average blood glucose levels over the preceding 3 months (the average life of a red blood cell), and therefore may be falsely low during pregnancy or any other condition associated with recent onset of hyperglycemia[6].
7. The HbA1c Advanced assay allows its use in patients with hemoglobin variants S, C, D and E traits. However, hemoglobinopathies might affect the red blood cell turnover or the in vivo glycation rates, and these patients may suffer from anemia and undergo transfusion. Therefore, results reported correctly by the assay may not reflect the same level of glycemic control as would be expected in patients with normal hemoglobin. In these cases, even analytically correct results do not reflect the same level of glycemic control that would be expected in patients with normal hemoglobin. Whenever, it is suspected that the presence of a Hb variant (eg HbSS, HbCC or HbSC) affects the correlation between the HbA1c value and glycemic control, HbA1c must not be used for the diagnosis of diabetes mellitus.
8. This test is not intended for analysis of samples collected from newborns. Glycated HbF is not detected by the assay as it does not contain the β-chain that characterizes HbA1c. However, HbF is measured in the T-Hb assay and as a consequence, specimens containing high amounts of HbF (>7%) may result in lower than expected

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mmol/mol HbA1c values (IFCC) and % HbA1c values (DCCT/NGSP)[25,26]. HbA1c results are invalid for patients with abnormal amounts of HbF including those with known Hereditary Persistence of Fetal Hemoglobin.

9. HbA1c should not be used to diagnose or monitor diabetes in patients with any conditions resulting in decreased erythrocyte survival, decrease in mean erythrocyte age or abnormal red blood cell turnover (e.g. hemolytic anemia, including hereditary spherocytosis, iron deficiency, thalassemias, malignancies, recovery from acute blood loss[27] and severe chronic hepatic and renal disease). Shortened red cell survival time will reduce the exposure of red cells to glucose, with a resultant decrease in HbA1c values. The altered red blood cell turnover interferes with the relationship between mean blood glucose and HbA1c values[6,28].
10. The HbA1c Advanced Assay requires the use of Contamination Prevention Parameters. Please refer to the latest version of the DxC 700 AU Reagent Contamination Prevention Parameters on the Beckman Coulter Website.

INTERFERENCES

Reference[19,27,29,30,31]

Drugs and Endogenous Substances

Results of studies conducted to evaluate the susceptibility of the method to interference from common or known drugs and endogenous substances that could interfere with the assay are listed below. The criteria for no significant interference is recovery within 7% of the initial value (sample containing no interferent).

No significant interference is observed from substances up to the following concentrations:

Acarbose	0.05 mg/dL
Acetaminophen	26 mg/dL
Acetylcystein	166 mg/dL
Acetylsalicylic Acid	1000 mg/dL
Ampicillin-Na	1000 mg/dL
Ascorbic Acid	300 mg/dL
Calcium Dobsilate	20 mg/dL
Cefoxitin	2500 mg/dL
Conjugated Bilirubin	60 mg/dL
Cyclosporine	0.5 mg/dL
Doxycyclin	50 mg/dL
Glucose	2000 mg/dL
Glyburide	0.12 mg/dL
Heparin	5500 IU/L
Ibuprofen	50 mg/dL
Levodopa	20 mg/dL
Lipemia	500 mg/dL
Metformin	5 mg/dL
Methyldopa	20 mg/dL
Metronidazole	200 mg/dL
Phenzylbutazone	53.5 mg/dL
Rheumatoid Factor	1000 IU/mL

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Rifampicin	8 mg/dL
Rosiglitazone maleate	0.33 mg/dL
Salicyclic Acid	4.76 mg/dL
Sitagliptin	0.2 mg/dL
Theophylline	10 mg/dL
Total Protein	21 g/dL
Unconjugated Bilirubin	60 mg/dL

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Hemoglobin Derivatives and Cross Reactants

Results of studies conducted to evaluate the susceptibility of the method to interference from common hemoglobin variants are listed below. The criteria for no significant interference is recovery within 7% of the initial value (sample containing no interferent).

No significant interference is observed from substances up to the following concentrations:

HbA0	12 mg/mL
HbA1a+b	0.16 mg/mL
Acetylated hemoglobin	0.5 mg/mL
Carbamylated hemoglobin	1.5 mg/mL
Glycated albumin	5 mg/mL
Labile HbA1c	2000 mg/dL

Hemoglobin Variants

Results of studies conducted to evaluate the susceptibility of the method to interference from common hemoglobin variants are listed below. The criteria for no significant interference is recovery within 7% of the reference value (value assigned in a Secondary Reference Laboratory).

HbC	38%
HbD	42%
HbE	36%
HbA2	6.2%
HbS	42%

No significant interference is observed from the following variants: HbC, HbD, HbE, HbS and HbA2.

The following representative data was generated using the HbA1c advanced assay on the DxC 700 AU:

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Hemoglobin Variant	No. of samples	% Variant	Range in % HbA1c Concentration	Relative % Bias (Range % Bias) 6.5% HbA1c	Relative % Bias (Range % Bias) 9.0% HbA1c
HbC	28	28.5 - 38.2	4.8 - 14.7	-2.57 (-4.30 to -1.80)	-3.19 (-6.48 to 0.41)
HbD	23	31.1 - 42.0	5.0 - 10.6	-0.77 (-4.81 to 2.99)	-1.22 (-6.30 to -0.22)
HbE	24	20.1 - 36.1	5.4 - 10.8	-1.12 (-9.16 to 2.48)	0.47 (-1.76 to 4.21)
HbS	29	31.0 - 42.0	5.0 - 12.7	-1.18 (-2.17 to 3.04)	-1.04 (-3.33 to 4.41)
HbA2	28	3.3 - 6.2	5.4 - 7.5	0.48 (-1.92 to 5.60)	2.49 (-0.98 to 3.60)

Note: Samples containing ≥7% HbF may result in lower than expected HbA1c results.

WARNING: The Hemoglobin A1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin. Refer to Limitations section.

Refer to references for further information on interfering substances.

Laboratory specific procedure notes:

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PERFORMANCE CHARACTERISTICS

METHODS COMPARISON

Reference[32]

A correlation study was performed using guidance document CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Human K2 EDTA whole blood specimen results from the HbA1c Advanced (B93009) assay on the DxC 700 AU were compared with those from an NGSP secondary reference laboratory method. Results of Deming regression in %HbA1c units were as follows:

Slope = 0.99	Intercept = 0.01 %HbA1c	r = 0.998	n = 138	Sample range = 4.7 – 14.2% HbA1c

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Using the results of the bias estimation (%bias) in the method comparison study and total precision estimates in the precision study, Total Error (TE) at four HbA1c concentrations was calculated as follows: %TE = |%Bias| + 1.96*%CV*(1+%Bias/100)[33]

% HbA1c	% Bias	% CV	% TE
5.00	-0.80	1.78	4.3
6.50	-0.85	1.69	4.2
8.00	-0.88	1.74	4.3
12.00	-0.92	1.22	3.3

PRECISION

Reference[34]

Estimates of imprecision, based on CLSI recommendations, are consistent with typical performance. Testing was conducted using 3 lots of the HbA1c Advanced kit and 3 DxC 700 AU analyzers, analyzed over 20 days. Comparative performance data for the DxC 700 AU Chemistry Analyzers evaluated using the CLSI approved guideline EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures appears in the table below. Each laboratory should characterize their own instrument performance for comparison purposes.

DxC 700 AU Chemistry Analyzer - % HbA1c (NGSP) units

HbA1c Advanced, B93009	Mean % HbA1c	Repeatability (Within-run)		Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	5.07	0.96	0.05	0.57	0.03	0.64	0.03	0.99	0.05	0.74	0.04	1.78	0.09
Human Whole Blood 2	6.72	1.00	0.07	0.41	0.03	0.55	0.04	1.05	0.07	0.56	0.04	1.69	0.11
Human Whole Blood 3	8.07	0.79	0.06	0.51	0.04	0.58	0.05	1.22	0.10	0.57	0.05	1.74	0.14
Human Whole Blood 4	11.71	0.74	0.09	0.36	0.04	0.71	0.08	0.46	0.05	0.32	0.04	1.22	0.14
Spiked Human Whole Blood	14.03	0.72	0.10	0.51	0.07	0.56	0.08	0.58	0.08	0.12	0.02	1.20	0.17
Whole Blood Control 1	5.29	1.12	0.06	0.78	0.04	0.67	0.04	1.34	0.07	0.50	0.03	2.09	0.11
Whole Blood Control 2	9.84	0.73	0.07	0.43	0.04	0.61	0.06	1.17	0.12	0.70	0.07	1.72	0.17

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DxC 700 AU Chemistry Analyzer - mmol/moL HbA1c (IFCC) units

HbA1c Advanced, B93009	Mean HbA1c mmol/moL	Repeatability (Within-run)		Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	31.91	1.66	0.53	1.27	0.41	1.08	0.34	1.73	0.55	1.31	0.42	3.20	1.02
Human Whole Blood 2	49.95	1.45	0.72	0.63	0.31	0.81	0.41	1.53	0.76	0.82	0.41	2.49	1.24
Human Whole Blood 3	64.75	1.08	0.70	0.69	0.45	0.79	0.51	1.66	1.07	0.77	0.50	2.37	1.53
Human Whole Blood 4	104.51	1.04	1.09	0.23	0.24	0.87	0.91	0.57	0.60	0.40	0.42	1.54	1.61
Spiked Human Whole Blood	129.84	0.85	1.10	0.58	0.76	0.67	0.87	0.69	0.89	0.14	0.19	1.42	1.84
Whole Blood Control 1	34.32	1.91	0.66	1.26	0.43	1.15	0.39	2.26	0.78	0.87	0.30	3.52	1.21
Whole Blood Control 2	84.10	0.93	0.78	0.54	0.46	0.78	0.66	1.50	1.26	0.90	0.76	2.20	1.85

ADDITIONAL INFORMATION

DxC 700 AU has a standard format for abbreviated Test Name for each reagent application. Refer to the table below for the abbreviated Test Name assigned to each application for this assay.

Test Name	Description
A1c	HbA1c
T-Hb	Total Hemoglobin
Denat	Hemolysate

Setting Sheet Footnotes
User defined

It is recommended to set Critical Limits where an audible alarm and a pl or ph flag for results outside the Analytical Measuring Range (AMR) for HbA1c% or HbA1c mmol/mol is required.

Ψ Unit for T-Hb and A1c components is shown in mmol/L. To change unit to g/dL, contact your local Beckman Coulter Representative.

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Ω HbA1c Calibrators are included in the kit and are lot specific. The concentrations (Conc.) will vary by lot number. Values set for working in mmol/l or g/dL as defined in CONFIGURATION PARAMETERS > SPECIFIC TEST PARAMETERS >TEST VOLUME AND METHODS > HBA1C>UNIT.

* Concentration of HbA1c Advanced Calibrator Level 6.

For the T-Hb Level 1 (zero) calibrator, saline should be used.

The calculation used for HbA1c% or HbA1c mmol/mol is hardcoded into the software and is not visible or editable in the Calculated Test tab.

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Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

(b)(5) FDA drafts

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Appendix A

Contains Nonbinding Recommendations

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments: IVD Device			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments: CDRH			

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3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4. Is the submission for a combination product that contains as a constituent part an approved drug that is under exclusive marketing rights? (503(g)(5)) If "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.	☐	☒	☐
Comments:			
5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments: (b)(4)			
6. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.	☐	☐	☒

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If no clinical studies have been submitted, mark "N/A."			
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.**
- **If the answer to 4 is "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.**
- **If the answer to 5 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.**
- **If the answer to 7 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☒	☐	3-1
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	3-1
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed

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- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☒	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☒	☐		2-1
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒	☐		2-1
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☒	☐		4-1
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☒	☐		5-1

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		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☒	☐		6-1
		Comments:					
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*		☐		☒	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☒	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☐	☐	☒	8-1
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☒	☐	☒ N/A	21-1
		Comments:					

Catherine Houseyan
19th Sept 2018

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	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*	☒	☐		23-1
		a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☒	☐	☐	23-1
		Comments:				
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison.				☒	
	9.	Submission identifies the product as a combination product.	☐	☐		

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	10.	The combination product contains as a constituent part an approved drug as defined in 21 USC 503(g)(5)(B). Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.		☐		☐	
		a.	The submission includes appropriate patent statement or certification and a statement that the applicant will give notice, as applicable. 21 USC 503(g)(5)(A)&(C).	☐	☐		
		Comments:					
B.	**Device Description**						
	11.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☒		☐	11-1
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☒	☐	☐	
		Comments:					
	12.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒	☐		11 - 1
		Comments:					
	13.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		11 - 1
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		11 - 1
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☒	☐	☐	11 - 1

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☒	☐		11 – 1
		Comments:					
	14.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☒		☐	11 – 1
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒	☐		11 – 1
		b.	Submission includes a description (as detailed in item 13a., 13b., and 13d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☒	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☒	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						

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	15.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	☒	☐		
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		12-1
		Comments:					
	16.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☒	☐		12-1

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		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☒	☐		12 - 1
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☒	☐		13 - 1
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒	☐		13 - 1
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐		13 - 1
		Comments:					
	18.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☒	☐		13 - 1
		Comments:					

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	19.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☒	☐	☐	13 - 1
		Comments:					
	20.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☒		☐	13 - 1
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐	13 - 1

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		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☒	☐	☐	13 - 1
		Comments:					
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.		☒	☐	☐	13 - 1
		Comment:					
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☒	

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				Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*						☐		
	Comments:								
	22.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.							
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*			☐	☐	☐	

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		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☐	☐	☐	
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☐	☐	☐	
		Comments:					
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐	
		Comments:					

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	24.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*					☐	
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*		☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*		☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*		☐	☐	☐	
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*		☐		☐	
			i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☐	
		Comments:						

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	25.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
F.	**Shelf-Life**						

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	26.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐		14 - 1.
		Comments:				
	27.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☒	
		Comments:				
	28.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		14 - 1.
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☒	

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	Submission states that there: (*one of the below must be checked*) ☐ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*			☐		
	Comments:						
	29.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.		☐	☐		
		Comments:					
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).		☐	☐		
		Comments:					

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	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☐		
		Comments:				
H.	**Software**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ⊟ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*			⊟		
	Comments:	**(b)(4)**				
	32.	Submission includes a statement of software level of concern and rationale for the software level of concern	⊟	☐		16 - 1
		Comments:				

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	33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☒	☐		16-1.
		Comments:				
I.	**Electrical Safety and EMC**					
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*		☒		
	Comments:					

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	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☒		13 - 1
		Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☒		13 - 1
	Comments:					

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	35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		☐	☒		17-1
		Comments:					
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*					☐	
	Comments:						
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒	☐	☐	18-1-18-120
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☒	☐	☐	
		Comments:					

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	37.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☒		☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☒	☐	☐	
		Comments:					

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	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*		☐	☐	☐	18-31
		a.	Legible reprints or a summary of each article.	☐	☒		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☒		
		Comments:					
	39.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☒	19-1
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						

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Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	Submission indicates that device: (*one of the below must be checked*) ☒ Is an in vitro diagnostic device ☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☒	☐	☐	18-1
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☒	☐	☐	18-9
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☒	☐	☐	18-119
		d.	Analytical specificity	☒	☐	☐	18-32
		Comments:					
	41.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☒	☐	☐	

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Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☒	☐	☐	
		Comments:					

Decision: **Accept**_____ **Refuse to Accept**_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	

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Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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510(k) Summary

HbA1c Advanced

1.0 Submitted By:

Catriona Hourigan
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2.0 Date Submitted:

15th January 2019

3.0 Device Name(s):

Proprietary Name: HbA1c Advanced
K182651

4.0 Predicate Device:

Table 1: Predicate Details

Candidate(s)	Predicate	Manufacturer	Docket Number
HbA1c Advanced	D-100™ HbA1c, D-100™HbA1c Calibrator Pack	Bio-Rad Laboratories, Inc;	K151321

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5.0 Recommended Reagent Classification:

Name: Hemoglobin A1c Test System
Regulation: 862.1373
Class: II
Panel: Clinical Chemistry
Product Code: PDJ

.

Name: Assay Glycosylated Hemoglobin
Regulation: 864.7470
Class: II
Panel: Hematology
Product Code: LCP

6.0 Description:

The HbA1c Advanced reagent kit is in a liquid format and is ready to use. It contains four reagents HbA1c R1 and HbA1c R2, Total Hemoglobin R1 and Hemolyzing reagent R1. The HbA1c calibrator is supplied with the reagent, in a liquid, ready to use format and contains 5 x 2mL calibrator levels. The sample hemolysis is automated on the DxC700 AU Clinical Chemistry analyzer. Sample handling is performed as follows: 200 µL of hemolyzing reagent is aspirated from the Hemolyzing Reagent R1and dispensed into a cuvette. Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. 2 µL of whole blood sample is then aspirated from the patient sample and added to the hemolyzing reagent in the cuvette. This hemolyzed whole blood is then added to the THb assay cuvette and HbA1c assay cuvette as per the assay parameters.

The concentrations of both HbA1c and Total Hemoglobin are determined. The HbA1c/Total Hemoglobin ratio is expressed either as mmol/mol (IFCC) or %HbA1c (DCCT/NGSP).

Total Hemoglobin Reagent is used to measure total hemoglobin concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent is used to measure hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

The calibrator is manufactured from human material; therefore should be handled as though capable of transmitting infectious disease. Each donor used in the preparation of this material was tested by the United States Food and Drug Administration (FDA), approved method and found to be negative for the presence of the antibodies for HIV-1/2, HCV, Hepatitis B surface antigen and was determined to not be repeatedly reactive.

Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis B virus

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or other infectious agents are absent from biological materials, this product should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control and Prevention/National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories.

7.0 Intended Use:

HBA1c Advanced

The HbA1c Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For In vitro diagnostic use only.

8.0 Comparison to the Predicate(s):

Table 2: Similarities between the Predicate Device and the Proposed Device:

Test System	HbA1c Predicate	Proposed New System
Proprietary and Established Names	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	HbA1c Advanced
Similarities		
Intended use	The D-100™ HbA1c test is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood using ion-exchange high performance liquid chromatography (HPLC) on the D-100 Hemoglobin testing system. Hemoglobin A1c measurements are used as an aid in the diagnosis of diabetes mellitus, as an aid to identify patients who may be at risk for developing diabetes mellitus, and for the monitoring of long-term	The HbA1c (Hemoglobin A1c) Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

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	blood glucose control in individuals with diabetes mellitus. Calibrators: The D-100^{Tm} HbA1c Calibrator pack is for the calibration of the D-100 Hemoglobin Testing System used for the quantitative determination of hemoglobin A1c (HbA1c) in human whole blood.	
Reporting Units	HbA1c results are provided to the customers using two different units: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol).	Same
Sample Types	Whole blood K2-EDTA K3-EDTA Lithium Heparin Sodium Heparin	Whole blood K2-EDTA K3-EDTA Li-Heparin Na-Heparin
Reagent Stability	**Unopened** 2° - 8^{0}C until expiration date	**Unopened** 2° - 8^{0}C until expiration date
Reference Range	Literature reference: Diabetic ≥6.5 NGSP %, ≥48 IFCC mmol/mol; Pre-Diabetic 5.7 – 6.4 NGSP%, IFCC 39 – 47 mmol/mol;: Non--Diabetic<5.7 NGSP%, <39 IFCC mmol/mol	Same
Traceability	Traceable to the Diabetes Control and Complications trial (DCCT) reference	Same

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	method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	
Sensitivity	Not stated	Not stated
Specificity (Interference - Hb Variants)	Significant interference was defined as ≥ 7% change in HbA1c value in the presence of the hemoglobin variant relative to control. HbC, HbD, HbE, HbS HbA2, HbF	No Significant interference (NSI) is recovery within 7% of the reference value from Hb variants C, S, D, E, A2. Hemoglobin F interference shall be displayed as a disclaimer on package insert.
Specificity (Interferences - Endogenous)	NSI is observed from the following endogenous substances up to the stated concentrations (Significant interference is defined as ≥7% change in HbA1c value of the mean test value relative to mean of the reference samples): • Conjugated Bilirubin: NSI up to 60 mg/dL • Unconjugated Bilirubin: NSI up 60 mg/dL • Glucose: NSI up 2000 mg/dL • Total Protein: NSI up to 21 g/dL	The criteria for NSI is recovery within 7% of the initial value (sample containing no interferent). Similar for: • Conjugated Bilirubin: NSI up to 60 mg/dL • Unconjugated Bilirubin: NSI up to 60 mg/dL • Glucose: NSI up to 2000 mg/dL • Total Protein: NSI up to 21 g/dL
Specificity (Interference - Hb Derivatives and Cross Reactants)	Significant interference defined as % recovery of ±7% change in % HbA1c value from the control • Acetylated Hb: up to 50 mg/dL	NSI is recovery within 7% of the initial value (sample containing no interferent). • Acetylated Hb: NSI up to 0.5 mg/mL

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Specificity (Interference - Drug)	Significant interference was defined as a ≥7% change in %HbA1c value from the control. Acetylcysteine: 166 mg/dL Ampicillin-Na: 1000 mg/dL Acetylsalicylic Acid: 1000 mg/dL Ascorbic Acid: 300 mg/dL Cefoxitin: 2500 mg/dL Levodopa: 20 mg/dL Methyldopa: 20 mg/dL Metronidazole: 200 mg/dL Doxycyclin: 50 mg/dL Cyclosporine: 5 mg/L Theophylline: 100 mg/L Ibuprofen: 500 mg/L Theophyline: 100mg/L	The criteria for no significant interference (NSI) is recovery within 7% of the initial value (Sample containing no interferent): Acetylcystein:166 mg/dL Ampicillin-Na: 1000 mg/dL Acetylsalicylic Acid: 1000 mg/dL Ascorbic Acid: 300 mg/dL Cefoxitin: 2500 mg/dL Levodopa: 20 mg/dL Methyldopa: 20 mg/dL Metronidazole: 200 mg/dL Doxycyclin: 50 mg/dL Cyclosporine: 0.5 mg/dL Theophylline: 10 mg/dL Ibuprofen: 50 mg/dL
Total Allowable Error	≤6%	≤6%

Table 3: Differences between the Predicate Device and the Proposed Device:

Feature	Predicate	Proposed New System
Proprietary and Established Names	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	HbA1c Advanced
Instrument Platform	D-100™ Hemoglobin Testing System	DxC 700 AU Clinical Chemistry Analyzer
Control	Commercially available Bio-Rad Lyphocheck Diabetes control materials	2 Levels of control material
Operating Principle	Ion-exchange Quantitative high performance liquid chromatography (HPLC)	Quantitative turbidimetric inhibition immunoassay

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Sample Types	Capillary blood Acceptable anticoagulants are Potassium Oxalate/ Sodium Fluoride Sodium Citrate	Not Applicable for HbA1c Advanced
Analytical Range (Linearity)	HbA1c: 3.5 to 20% HbA1c (NGSP) 15 - 195 mmol/mol (IFCC)	HbA1c: 4.0 – 15% HbA1c (NGSP) 20 – 140 mmol/mol (IFCC)
Specificity (Interferences - Endogenous)	Significant interference defined as a ±7% change in % HbA1c value from the control • Lipemia (Intralipid): NSI up to 6000 mg/dL • Rheumatoid Factor: NSI up to 750 IU/mL	NSI is recovery within 7% of the initial value (sample containing no interferent). Lipemia: NSI up to 500 mg/dL Rheumatoid Factor (RF): NSI up to 1000 IU/mL
Specificity (Interference - Hb Derivatives and Cross Reactants)	Significant interference defined as % recovery of ±7% change in % HbA1c value from the control • Carbamylated Hb: up to 5% • Labile Hb: up to 1200 mg/dL of glucose does not interfere with this assay	NSI is recovery within 7% of the initial value (sample containing no interferent). • Carbamylated Hb: NSI up to 1.5 mg/mL • Labile Hb; NSI up to 2000 mg/dL • Glycated Albumin: NSI up to 5 mg/mL • HbA0: NSI up to 12 mg/mL

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		• HbA1a+b: NSI up to 0.16 mg/mL
Drug Interference	Significant interference was defined as a ±7% change in %HbA1c value from the control. • Acetaminophen: 200 mg/L • Heparin: 5000 U/L • Rifampicin: 64 mg/L • Phenzylbutazone – 400 mg/L	NSI is recovery within 7% of the initial value (sample containing no interferent): • Acetaminophen: 26 mg/dL • Heparin: 5500 IU/L • Rifampicin: 8 mg/dL • Phenzylbutazone: 53.5 mg/dL • Glyburide: 0.12 mg/dL • Salicyclic Acid: 4.76 mg/dL • Sitagliptin: 0.2 mg/dL • Rosiglitazone: 0.33 mg/dL • Metformin: 5 mg/dL • Calcium Dobsilate: 20mg/dL • Acarbose: 0.05 mg/dL
Specificity (Interference - Hb Variants)	Significant interference was defined as ≥ 7% change in HbA1c value in the presence of the hemoglobin variant relative to control. HbF concentrations up to 30% do not interfere with the test.	No Significant interference is recovery within 7% of the reference value (value assigned in Secondary Reference Laboratory). Samples containing ≥7% HbF may result in lower than expected HbA1c results

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9.0 Performance Characteristics – Analytical Performance:

Precision

Precision of the HbA1c Advanced reagent on the DxC 700 AU was evaluated based on CLSI guideline EP05-A3: *"Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Third Edition".* Studies were carried out on 3 lots of HbA1c Advanced by testing four levels of HbA1c K2 EDTA human venous whole blood patient samples at HbA1c concentrations of approximately 5.0%, 6.5%, 8.0%, 12% and 14%. The experimental design used duplicate sample analysis, twice daily, over the course of twenty working days (n=2) in random order. NGSP results are shown in Tables 4 – 7. IFCC results are shown in Tables 8 – 11.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 4: DxC 700 AU: Instrument 1: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.06	0.88	0.04	Pass	0.80	0.04	0.64	0.03	0.92	0.05	1.63	0.08	Pass
Human Whole Blood 2	6.72	1.01	0.07	Pass	0.60	0.04	0.65	0.04	0.93	0.06	1.64	0.11	Pass
Human Whole Blood 3	8.06	0.77	0.06	Pass	0.47	0.04	0.73	0.06	1.06	0.09	1.57	0.13	Pass
Human Whole Blood 4	11.70	0.79	0.09	Pass	0.48	0.06	0.84	0.10	0.19	0.02	1.26	0.15	Pass
Spiked Human Whole Blood	14.02	0.74	0.10	Pass	0.49	0.07	0.72	0.10	0.32	0.04	1.19	0.17	Pass
Whole Blood Control 1	5.32	1.19	0.06	Pass	0.84	0.04	0.66	0.03	1.34	0.07	2.08	0.11	Pass
Whole Blood Control 2	9.88	0.77	0.08	Pass	0.48	0.05	0.65	0.06	1.07	0.11	1.54	0.15	Pass

Table 5: DxC 700 AU Instrument 2: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.03	1.15	0.06	Pass	0.37	0.02	0.57	0.03	1.02	0.05	1.68	0.08	Pass
Human Whole Blood 2	6.69	1.14	0.08	Pass	0.20	0.01	0.50	0.03	0.83	0.06	1.51	0.10	Pass
Human Whole Blood 3	8.05	0.86	0.07	Pass	0.48	0.04	0.49	0.04	0.70	0.06	1.31	0.11	Pass
Human Whole Blood 4	11.69	0.71	0.08	Pass	0.33	0.04	0.61	0.07	0.56	0.07	1.14	0.13	Pass
Spiked Human Whole Blood	14.04	0.75	0.11	Pass	0.58	0.08	0.34	0.05	0.69	0.10	1.22	0.17	Pass
Whole Blood Control 1	5.28	1.23	0.06	Pass	0.41	0.02	0.75	0.04	1.32	0.07	1.99	0.11	Pass
Whole Blood Control 2	9.88	0.77	0.08	Pass	0.42	0.04	0.54	0.05	0.95	0.09	1.40	0.14	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 6: DxC 700 AU Instrument 3: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.03	0.83	0.04	Pass	0.45	0.02	0.70	0.04	1.02	0.05	1.55	0.08	Pass
Human Whole Blood 2	6.66	0.82	0.06	Pass	0.31	0.02	0.48	0.03	1.31	0.09	1.65	0.11	Pass
Human whole Blood 3	7.98	0.73	0.06	Pass	0.58	0.05	0.47	0.04	1.68	0.14	1.98	0.16	Pass
Human Whole Blood 4	11.68	0.71	0.08	Pass	0.21	0.03	0.67	0.08	0.54	0.06	1.14	0.13	Pass
Spiked Human Whole Blood	13.99	0.66	0.09	Pass	0.44	0.06	0.56	0.08	0.66	0.09	1.18	0.17	Pass
Whole Blood Control 1	5.25	0.93	0.05	Pass	0.97	0.05	0.60	0.03	1.37	0.07	2.01	0.11	Pass
Whole Blood Control 2	9.72	0.65	0.06	Pass	0.36	0.03	0.65	0.06	1.45	0.14	1.75	0.17	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 7: Instruments Combined (Instrument 1, 2, 3): NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.07	0.96	0.05	Pass	0.57	0.03	0.64	0.03	0.99	0.05	0.74	0.04	1.78	0.09	Pass
Human Whole Blood 2	6.72	1.00	0.07	Pass	0.41	0.03	0.55	0.04	1.05	0.07	0.56	0.04	1.69	0.11	Pass
Human Whole Blood 3	8.07	0.79	0.06	Pass	0.51	0.04	0.58	0.05	1.22	0.10	0.57	0.05	1.74	0.14	Pass
Human Whole Blood 4	11.71	0.74	0.09	Pass	0.36	0.04	0.71	0.08	0.46	0.05	0.32	0.04	1.22	0.14	Pass
Spiked Human Whole Blood	14.03	0.72	0.10	Pass	0.51	0.07	0.56	0.08	0.58	0.08	0.12	0.02	1.20	0.17	Pass
Whole Blood Control 1	5.29	1.12	0.06	Pass	0.78	0.04	0.67	0.04	1.34	0.07	0.50	0.03	2.09	0.11	Pass
Whole Blood Control 2	9.84	0.73	0.07	Pass	0.43	0.04	0.61	0.06	1.17	0.12	0.70	0.07	1.72	0.17	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 8: DxC 700 AU Instrument 1: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.84	1.51	0.48	Pass	1.43	0.46	1.08	0.34	1.60	0.51	2.84	0.90	Pass
Human Whole Blood 2	49.92	1.49	0.75	Pass	0.90	0.45	0.97	0.48	1.36	0.68	2.41	1.21	Pass
Human Whole Blood 3	64.65	1.06	0.68	Pass	0.61	0.40	1.01	0.65	1.43	0.93	2.14	1.38	Pass
Human Whole Blood 4	104.38	1.31	1.37	Pass	0.00	0.00	1.03	1.07	0.23	0.24	1.68	1.76	Pass
Spiked Human Whole Blood	129.76	0.87	1.13	Pass	0.57	0.74	0.86	1.11	0.37	0.49	1.40	1.82	Pass
Whole Blood Control 1	34.65	2.01	0.70	Pass	1.28	0.44	1.18	0.41	2.22	0.77	3.46	1.20	Pass
Whole Blood Control 2	84.53	0.98	0.83	Pass	0.61	0.51	0.82	0.69	1.36	1.15	1.96	1.66	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 9: DxC 700 AU Instrument 2: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.51	2.01	0.63	Pass	1.19	0.37	0.77	0.24	1.81	0.57	3.05	0.96	Pass
Human Whole Blood 2	49.59	1.63	0.81	Pass	0.42	0.21	0.74	0.37	1.18	0.59	2.18	1.08	Pass
Human Whole Blood 3	64.48	1.18	0.76	Pass	0.66	0.43	0.67	0.43	0.96	0.62	1.79	1.15	Pass
Human Whole Blood 4	104.29	0.88	0.91	Pass	0.38	0.40	0.75	0.78	0.70	0.73	1.40	1.46	Pass
Spiked Human Whole Blood	129.92	0.88	1.15	Pass	0.66	0.85	0.43	0.56	0.82	1.06	1.44	1.87	Pass
Whole Blood Control 1	34.24	2.09	0.72	Pass	0.74	0.25	1.23	0.42	2.23	0.76	3.38	1.16	Pass
Whole Blood Control 2	84.52	0.98	0.83	Pass	0.54	0.46	0.69	0.58	1.22	1.03	1.80	1.52	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 10: DxC 700 AU Instrument 3: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specifications
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.46	1.41	0.46	Pass	1.18	0.38	1.31	0.42	1.78	0.58	2.88	0.93	Pass
Human Whole Blood 2	49.27	1.21	0.61	Pass	0.46	0.23	0.70	0.35	1.93	0.97	2.42	1.22	Pass
Human Whole Blood 3	63.68	1.00	0.65	Pass	0.79	0.52	0.63	0.41	2.29	1.49	2.69	1.75	Pass
Human Whole Blood 4	104.18	0.87	0.92	Pass	0.25	0.26	0.81	0.85	0.66	0.70	1.39	1.46	Pass
Spiked Human Whole Blood	129.37	0.79	1.02	Pass	0.52	0.67	0.66	0.86	0.87	1.01	1.39	1.81	Pass
Whole Blood Control 1	33.83	1.58	0.54	Pass	1.61	0.55	1.02	0.35	2.32	0.79	3.40	1.16	Pass
Whole Blood Control 2	82.77	0.83	0.69	Pass	0.46	0.38	0.83	0.69	1.86	1.55	2.24	1.87	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 10: Instruments Combined (Instrument 1, 2, 3): IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concen-tration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.91	1.66	0.53	Pass	1.27	0.41	1.08	0.34	1.73	0.55	1.31	0.42	3.20	1.02	Pass
Human Whole Blood 2	49.95	1.45	0.72	Pass	0.63	0.31	0.81	0.41	1.53	0.76	0.82	0.41	2.49	1.24	Pass
Human Whole Blood 3	64.75	1.08	0.70	Pass	0.69	0.45	0.79	0.51	1.66	1.07	0.77	0.50	2.37	1.53	Pass
Human Whole Blood 4	104.51	1.04	1.09	Pass	0.23	0.24	0.87	0.91	0.57	0.60	0.40	0.42	1.54	1.61	Pass
Spiked Human Whole Blood	129.84	0.85	1.10	Pass	0.58	0.76	0.67	0.87	0.69	0.89	0.14	0.19	1.42	1.84	Pass
Whole Blood Control 1	34.32	1.91	0.66	Pass	1.26	0.43	1.15	0.39	2.26	0.78	0.87	0.30	3.52	1.21	Pass
Whole Blood Control 2	84.10	0.93	0.78	Pass	0.54	0.46	0.78	0.66	1.50	1.26	0.90	0.76	2.20	1.85	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Linearity:

Dynamic Range/ Analytical Measuring Range studies were designed using CLSI Guideline EP06-A: *"Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"*. High and low pools were prepared as per Table 1. A linearity series was prepared by inter-diluting the high and low pools to achieve a % HbA1c concentration spanning the required analytical range. The samples were mixed together in varying ratios.

Data was analyzed using Polynomial regression analysis (for first, second and third order polynomials) to determine the statistical significance of non-linearity. Where data generated was non-linear, the best fitting polynomial was applied to the data and difference between this best fitting, non-linear polynomial and the linear polynomial was calculated. Regression parameters for slope, intercept and R value were calculated.

The results of the study provides data to support the dynamic range/analytical measuring range claim for HbA1c Advanced reagent 4 – 15% (NGSP) HbA1c and 20 – 140 mmol/mol HbA1c (IFCC).

Table 12: Linearity Results Summary

Reagent	Acceptance Criteria	Results		Pass/ Fail	Acceptance Criteria	Pass/Fail
	Linear Range	Linear From	Linear To		Regression Parameters	
HbA1c Advanced	4-15% HbA1c	3.94% HbA1c	15.37% HbA1c	Pass	Slope: 1.0 ± 0.05 Intercept: ≤ ± 0.5 % HbA1c R: ≥ 0.990 N: ≥ 9	Pass Pass Pass Pass
HbA1c Advanced	20 – 140 mmol/mol	19.51 mmol/mol	144.49 mmol/mol	Pass	Slope: 1.0 ± 0.05 Intercept: ≤ ± 5.5 mmol/L R: ≥ 0.990 N: ≥ 9	Pass Pass Pass Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Method Comparison

Method comparison and bias estimation experiments were designed using CLSI Guideline EP09-A3; "*Measurement Procedure Comparison and Bias Estimation using Patient Samples; Approved Guideline*." The patient correlation studies were performed using a standardized test method in an NGSP Secondary Reference Laboratory (SRL) using a test system (method X - HA8180V HPLC) with an analytical measuring range of 4-15% HbA1c (NGSP) and the proposed new Beckman Coulter HbA1c test system (method Y – HbA1c Advanced, 1 lot) with a proposed measuring range of 4-15 % HbA1c (NGSP) on a DxC 700 AU analyzer. Over a 120 (duplicates) of venous human frozen whole blood specimens (K2 EDTA anticoagulant type) with HbA1c concentrations were tested using on the DxC 700 AU Analyzer.

Table 13: Sample Distribution

Hemoglobin A1c Level	No. of Samples (SRL)	% Samples tested (SRL)	No. of Samples tested (Beckman)	% Samples tested (Beckman)
≤5%	6	4.35	6	4.35
5 – 6%	18	13.04	22	15.94
6 – 6.5%	32	23.19	32	23.19
6.5 – 7%	35	25.36	35	25.36
7 – 8%	25	18.12	23	16.67
8 – 9%	12	8.7	10	7.25
> 9%	10	7.25	10	7.25
Total Samples	138	100%	138	100%

Weighted Deming's and Passing-Bablok regression analysis was performed for the HbA1c Advancedmethod versus an NGSP SRL standardized method, results are summarized below in tables 14 and 15.

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Table 14: Summary of Method Comparison for HbA1c Advanced results and specifications (Weighted Deming analysis) NGSP Units.

Sample Range:	Specifications	Results (95%CI Low; HIgh)	Pass / Fail
Method X: 4.7 - 14.2 % HbA1c Method Y: 4.6 – 14.3 % HbA1c	Slope: 1.0 ± 0.05	0.990 (0.978; 1.002)	Pass
	Intercept: ≤ ± 0.5% HbA1c	0.010 %HbA1c (-0.070; 0.089) %HbA1c	Pass
	R: ≥ 0.975	0.998	Pass
	N: ≥ 120	138	Pass

Table 15: Summary of Method Comparison for HbA1c Advanced results and specifications (Passing-Bablok analysis) NGSP Units.

Sample Range:	Specifications	Results (95% CI Low; High)	Pass / Fail
Method X: 4.7 - 14.2 % HbA1c Method Y: 4.6 – 14.3 % HbA1c	Slope: 1.0 ± 0.5	0.980 (0.964;0.992)	Pass
	Intercept: ≤ ± 0.5 %HbA1c	0.090 %HbA1c (-0.006; 0.187) % HbA1c	Pass
	R: ≥ 0.975	0.998	Pass
	N: ≥ 120	138	Pass

Total Error

Total error was evaluated using the results of the bias estimation (%Bias) from single measurements conducted of the new device compared to results of the standardised test method (method comparison) and precision estimates from the precision study. Total Error (TE) at four concentrations (5.0%, 6.5%, 8.0%, and 12.0%) was calculated as follows: "%TE = |(%Bias)| + 1.96*%CV*(1+%Bias/100)". The results are presented in Table 5.

Table 16: Total Error Estimation

%HbA1c Decision Level	% Bias	%CV	%TE	Acceptance Criteria: ≤6%
5.0	-0.80	1.78	4.3	Pass
6.5	-0.85	1.69	4.2	Pass
8.0	-0.88	1.74	4.3	Pass
12.0	-0.92	1.22	3.3	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Analytical Specificity

Interference (Analytical Specificity) studies were designed based on CLSI Guideline EP07 Third Edition: *"Interference Testing in Clinical Chemistry; Approved Guideline"* and used to assess common or known substances which could interfere with the HbA1c Advanced assay.

Endogenous Interference

The interfering substances analyzed were tested at two % HbA1c concentrations; approximately 6.5% HbA1c (low level human venous whole blood K2 EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood K2 EDTA sample) using one lot of reagent on one DxC700 AU analyzer. Low and high pools were prepared by interdiluting human whole blood samples.

The whole blood samples were tested at a minimum of 5 levels for each interferent (Conjugated Bilirubin, Unconjugated Bilirubin, Lipemia, Ascorbic Acid, RF, Total Protein and Glucose) with 10 replicates tested per level on the DxC700 AU Analyzer to determine the magnitude of the interference.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results in Table 1 show no significant interference up to the stated concentrations.

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Table 17: Specifications and Summary of Endogenous Interference data

Potential Interfering Substance	Interference pool details	Interferent Level
Conjugated Bilirubin	Whole Blood Pools spiked with Conjugated Bilirubin Stock Solution	60 mg/dL
Unconjugated Bilirubin	Whole Blood Pools spiked with unconjugated Bilirubin Stock Solution	60 mg/dL
Lipemia	Whole Blood Pools spiked with 20% w/v Intralipid	500 mg/dL
Ascorbic Acid	Whole Blood Pools spiked with Ascorbate	300 mg/dL
RF	Whole Blood Pools spiked with RF positive plasma	1000 IU/ml
Total Protein	Whole Blood Pools spiked with Human Serum Albumin	21 g/dL
Glucose	Whole Blood Pools spiked with Anhydrous Glucose	2000 mg/dL

Drug Interference

Potential drug interfering substances were analyzed to determine their effect on HbA1c Advanced reagent . All drug interferences were tested at two % HbA1c concentrations, approximately 6.5% HbA1c (low level human venous whole blood EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood EDTA sample). Testing was completed using one lot of reagent on DxC 700 AU Analyzer.

Low and high pools were prepared by inter-diluting human whole blood samples. The two whole blood sample pools were spiked with each potential interfering drug to create test samples. Ten replicates of each test and reference sample (sample containing no potential interferent) were tested on the DxC 700 AU to determine the magnitude of the interference. Each drug was tested to at least 5 times the highest drug concentration under therapeutic treatment.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results outlined below showed no significant interference up to the stated concentrations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 18: Specifications and Summary of Drug Interference data

Potential Interfering Substance	Interference pool details	Interferent Level
Glyburide	Whole Blood Pools spiked with Glyburide Stock Solution	0.12 mg/dL
Salicyclic Acid	Whole Blood Pools spiked with Salicyclic Acid Stock Solution	4.76 mg/dL
Sitagliptin	Whole Blood Pools spiked with Sitagliptin Phosphate stock solution	0.2 mg/dL
Rosiglitazone	Whole Blood Pools spiked with Rosiglitazone maleate stock solution	0.33 mg/dL
Metformin	Whole Blood Pools spiked with Metformin Hydrochloride stock solution	5 mg/dL
Cyclosporine	Whole Blood Pools spiked with Cyclosporine stock solution	0.5 mg/dL
Heparin	Whole Blood Pools spiked with Sodium Heparin stock solution	5500 IU/L
Calcium Dobesilate	Whole Blood Pools spiked with Calcium Dobsilate stock solution	20 mg/dL
Metronidazole	Whole Blood Pools spiked with Metronidazole stock solution	200 mg/dL
Levodopa	Whole Blood Pools spiked with Levodopa Stock solution	20 mg/dL
Acetylsalicyclic acid	Whole Blood spiked with Acetysalicyclic acid Stock Solution	1000 mg/dL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Acarbose	Whole blood spiked with Ascarbose Stock Solution	0.05 mg/dL
Acetaminophen	Whole blood spiked with Acetaminophen Stock Solution	26 mg/dL
Acetylcystein	Whole blood spiked with Acetylcystein Stock Solution	166 mg/dL
Ampicillin-Na	Whole blood spiked with Ampicillin-Na Stock Solution	1000 mg/dL
Cefoxitin	Whole blood spiked with Cefoxin Stock Solution	2500 mg/dL
Doxycyclin	Whole blood spiked with Doxycyclin Stock Solution	50 mg/dL
Ibuprofen	Whole blood spiked with Ibuprofen Stock Solution	50 mg/dL
Methyldopa	Whole blood spiked with Methyldopa Stock Solution	20 mg/dL
Phenylbutazone	Whole blood spiked with Phenylbutazone Stock Solution	53.5 mg/dL
Rifampicin	Whole blood spiked with Rifampicin Stock Solution	8 mg/dL
Theophylline	Whole blood spiked with Theophylline Stock Solution	10 mg/dL

Hemoglobin Derivative and Cross Reactants

Hemoglobin derivatives and potential interfering cross reactants were tested at two % HbA1c concentrations; approximately 6.5% HbA1c (low level human venous whole blood K2 EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood K2 EDTA sample) using one lot of reagent on one DxC700 AU analyzer. Low and high pools were prepared by interdiluting human whole blood samples.

Hemoglobin derivatives and potentially interfering cross reactants were tested at a minimum of 5 levels for: Labile Hemoglobin, Acetylated Hemoglobin, Carbamylated Hemoglobin, Glycated Albumin, HbA0 and HbA1a+b with 10 replicates tested per level on the DxC 700 AU analyzer to determine the magnitude of any interference effect.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results in Table 19 showed no significant interference up to the stated concentrations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 19: Specification and Summary of Hemoglobin Derivative and Cross Reactant Interferences

Potential Interfering Substance	Interference Pool details	Interferent Level
Labile Hemoglobin	Whole Blood Pools spiked with Glucose Stock Solution	2000 mg/dL
Acetylated Hemoglobin	Whole Blood Pools spiked with Acetylsalicylic acid Stock Solution	0.5 mg/mL
Carbamylated Hemoglobin	Whole Blood Pools spiked with Potassium Cyanate Stock Solution	1.5 mg/mL
Glycated Albumin	Whole Blood Pools spiked with Human Glycated Albumin Stock Solution	5mg/mL
HbA0	Whole Blood Pools spiked with HbA0 Stock Solution	12 mg/mL
HbA1a + 1b	Whole Blood Pools spiked with HbA1a +1b Stock Solution	0.16 mg/mL

Hemoglobin Variants

A hemoglobin variant study was performed to determine the presence of significant hemoglobin variant interference with major hemoglobin variants in the HbA1c Advanced assay. Results from singlicate measurements of samples were compared to results from a reference method, demonstrated to be free from hemoglobin interference; Trinity Biotech Hb9210 and Ultra2, Menarini HA8181V and TOSOH G8.

A minimum of 20 samples were tested for each variant (HbC, HbD, HbE, HbF, HbS and HbA2) on the DxC 700 AU Analyzer.

The following tables outline the number of samples of each variant, the range of % variant concentrations, %HbA1c concentrations and the relative % bias at 6.5% and 9.0% HbA1c.

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Table 20: Hemoglobin Variant Sample Ranges

Hemoglobin Variant	Number of Samples	Range in %Variant Concentration	Range in %HbA1c Concentration
HbC	28	28.5 - 38.2	4.8 - 14.7
HbD	23	31.1 – 42.0	5.0 - 10.6
HbE	24	20.1 - 36.1	5.4 - 10.8
HbF	22	3.2 – 34.0	4.9 - 12.8
HbS	29	31.0 – 42.0	5.0 - 12.7
HbA2	28	3.3 - 6.2	5.4 - 7.5

Table 21: Relative Bias Summary

Hb Variant	Relative % bias (Range of % bias) observed relative to Reference method	
	HbA1c~6.5% HbA1c	HbA1c~9.0% HbA1c
HbC	-2.57 (-4.30% to -1.80%)	-3.19 (-6.48% to 0.41%)
HbD	-0.77 (-4.81% to 2.99%)	-1.22 (-6.30% to -0.22%)
HbE	-1.12 (-9.16% to 2.48%)	0.47 (-1.76% to 4.21%)
HbS	-1.18 (-2.17% to 3.04%)	-1.04 (-3.33% to 4.41%)
HbA2	0.48 (-1.92% to 5.60%)	2.49 (-0.98% to 3.60%)
HbF	Specimens containing high amounts of HbF (> 7%) may yield lower than expected HbA1c Values	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Anticoagulants

The data supports the use of the following blood collection tubes with the HbA1c Advanced reagent .

- K2 EDTA
- K3 EDTA
- Sodium Heparin
- Lithium Heparin

Expected Values/Reference Interval

Beckman Coulter used evidence recommended by the American Diabetes Association Standards of (ADA), which may be used as an aid in the diagnosis of diabetes mellitus:

Table 1: HbA1c ranges recommended by the ADA as an aid in the diagnosis of diabetes mellitus[1,2,3]

HbA1c Advanced		Suggested Diagnosis
NGSP %	IFCC mmol/mol	
≥ 6.5	≥48	Diabetic
5.7 – 6.4	39 - 47	Pre-Diabetic
< 5.7	<39	Non-Diabetic

Conclusion

The information and data in this 510(k) document demonstrate that the HbA1c Advanced reagent on the DxC700 AU Analyzer is an accurate, reliable, precise test that correlates well with current cleared methods and NGSP standardized testing for the quantitation of HbA1c.
The contents of this submission demonstrates that the HbA1c Advanced Reagent is substantially equivalent to the Biorad D-100™ HbA1c and D-100™HbA1c Calibrator Pack. It is therefore safe and effective for its intended use. The submitted information in this pre-market notification is complete and supports a substantial equivalence decision.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=yRF7AbnlWwrwzaO-Pztaf-txiK2oet3WDKgKov1OS28&s=wAghdHyHHHZGPy_-Q_4k2ktEOWKu1W2eNtbeNyCIQ3E&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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U.S. FOOD & DRUG ADMINISTRATION

January 16, 2019

Beckman Coulter Ireland Inc.
Catriona Hourigan, Regulatory Affairs Specialist
Lismeehan
O' Callaghan's Mills
Co. Clare
Ireland
V94 PP63

Re: k182651
Trade/Device Name: HbA1c Advanced
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c test system
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: September 20, 2018
Received: September 24, 2018

Dear Catriona Hourigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182651

Device Name
HbA1c Advanced

Indications for Use *(Describe)*
The HbA1c (Hemoglobin A1c) Advanced assay on the Beckman Coulter DxC700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

HbA1c Advanced

1.0 Submitted By:

Catriona Hourigan
Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.,
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email: chourigan@beckman.com

2.0 Date Submitted:

15th January 2019

3.0 Device Name(s):

Proprietary Name: HbA1c Advanced
K182651

4.0 Predicate Device:

Table 1: Predicate Details

Candidate(s)	Predicate	Manufacturer	Docket Number
HbA1c Advanced	D-100™ HbA1c, D-100™HbA1c Calibrator Pack	Bio-Rad Laboratories, Inc;	K151321

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5.0 Recommended Reagent Classification:

Name: Hemoglobin A1c Test System
Regulation: 862.1373
Class: II
Panel: Clinical Chemistry
Product Code: PDJ

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Name: Assay Glycosylated Hemoglobin
Regulation: 864.7470
Class: II
Panel: Hematology
Product Code: LCP

6.0 Description:

The HbA1c Advanced reagent kit is in a liquid format and is ready to use. It contains four reagents HbA1c R1 and HbA1c R2, Total Hemoglobin R1 and Hemolyzing reagent R1. The HbA1c calibrator is supplied with the reagent, in a liquid, ready to use format and contains 5 x 2mL calibrator levels. The sample hemolysis is automated on the DxC700 AU Clinical Chemistry analyzer. Sample handling is performed as follows: 200 µL of hemolyzing reagent is aspirated from the Hemolyzing Reagent R1and dispensed into a cuvette. Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. 2 µL of whole blood sample is then aspirated from the patient sample and added to the hemolyzing reagent in the cuvette. This hemolyzed whole blood is then added to the THb assay cuvette and HbA1c assay cuvette as per the assay parameters.

The concentrations of both HbA1c and Total Hemoglobin are determined. The HbA1c/Total Hemoglobin ratio is expressed either as mmol/mol (IFCC) or %HbA1c (DCCT/NGSP).

Total Hemoglobin Reagent is used to measure total hemoglobin concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent is used to measure hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

The calibrator is manufactured from human material; therefore should be handled as though capable of transmitting infectious disease. Each donor used in the preparation of this material was tested by the United States Food and Drug Administration (FDA), approved method and found to be negative for the presence of the antibodies for HIV-1/2, HCV, Hepatitis B surface antigen and was determined to not be repeatedly reactive.

Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis B virus

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or other infectious agents are absent from biological materials, this product should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control and Prevention/National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories.

7.0 Intended Use:

HBA1c Advanced

The HbA1c Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For In vitro diagnostic use only.

8.0 Comparison to the Predicate(s):

Table 2: Similarities between the Predicate Device and the Proposed Device:

Test System	HbA1c Predicate	Proposed New System
Proprietary and Established Names	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	HbA1c Advanced
Similarities		
Intended use	The D-100™ HbA1c test is intended for the quantitative determination of hemoglobin A1c (IFCC mmol/mol and NGSP %) in human whole blood using ion-exchange high performance liquid chromatography (HPLC) on the D-100 Hemoglobin testing system. Hemoglobin A1c measurements are used as an aid in the diagnosis of diabetes mellitus, as an aid to identify patients who may be at risk for developing diabetes mellitus, and for the monitoring of long-term	The HbA1c (Hemoglobin A1c) Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

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	blood glucose control in individuals with diabetes mellitus. Calibrators: The D-100^{Tm} HbA1c Calibrator pack is for the calibration of the D-100 Hemoglobin Testing System used for the quantitative determination of hemoglobin A1c (HbA1c) in human whole blood.	
Reporting Units	HbA1c results are provided to the customers using two different units: NGSP equivalent units (%) and IFCC equivalent units (mmol/mol).	Same
Sample Types	Whole blood K2-EDTA K3-EDTA Lithium Heparin Sodium Heparin	Whole blood K2-EDTA K3-EDTA Li-Heparin Na-Heparin
Reagent Stability	**Unopened** 2° - 8^{0}C until expiration date	**Unopened** 2° - 8^{0}C until expiration date
Reference Range	Literature reference: Diabetic ≥6.5 NGSP %, ≥48 IFCC mmol/mol; Pre-Diabetic 5.7 – 6.4 NGSP%, IFCC 39 – 47 mmol/mol;: Non--Diabetic<5.7 NGSP%, <39 IFCC mmol/mol	Same
Traceability	Traceable to the Diabetes Control and Complications trial (DCCT) reference	Same

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	method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	
Sensitivity	Not stated	Not stated
Specificity (Interference - Hb Variants)	Significant interference was defined as ≥ 7% change in HbA1c value in the presence of the hemoglobin variant relative to control. HbC, HbD, HbE, HbS HbA2, HbF	No Significant interference (NSI) is recovery within 7% of the reference value from Hb variants C, S, D, E, A2. Hemoglobin F interference shall be displayed as a disclaimer on package insert.
Specificity (Interferences - Endogenous)	NSI is observed from the following endogenous substances up to the stated concentrations (Significant interference is defined as ≥7% change in HbA1c value of the mean test value relative to mean of the reference samples): • Conjugated Bilirubin: NSI up to 60 mg/dL • Unconjugated Bilirubin: NSI up 60 mg/dL • Glucose: NSI up 2000 mg/dL • Total Protein: NSI up to 21 g/dL	The criteria for NSI is recovery within 7% of the initial value (sample containing no interferent). Similar for: • Conjugated Bilirubin: NSI up to 60 mg/dL • Unconjugated Bilirubin: NSI up to 60 mg/dL • Glucose: NSI up to 2000 mg/dL • Total Protein: NSI up to 21 g/dL
Specificity (Interference - Hb Derivatives and Cross Reactants)	Significant interference defined as % recovery of ±7% change in % HbA1c value from the control • Acetylated Hb: up to 50 mg/dL	NSI is recovery within 7% of the initial value (sample containing no interferent). • Acetylated Hb: NSI up to 0.5 mg/mL

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Specificity (Interference - Drug)	Significant interference was defined as a ≥7% change in %HbA1c value from the control. Acetylcysteine: 166 mg/dL Ampicillin-Na: 1000 mg/dL Acetylsalicylic Acid: 1000 mg/dL Ascorbic Acid: 300 mg/dL Cefoxitin: 2500 mg/dL Levodopa: 20 mg/dL Methyldopa: 20 mg/dL Metronidazole: 200 mg/dL Doxycyclin: 50 mg/dL Cyclosporine: 5 mg/L Theophylline: 100 mg/L Ibuprofen: 500 mg/L Theophyline: 100mg/L	The criteria for no significant interference (NSI) is recovery within 7% of the initial value (Sample containing no interferent): Acetylcystein:166 mg/dL Ampicillin-Na: 1000 mg/dL Acetylsalicylic Acid: 1000 mg/dL Ascorbic Acid: 300 mg/dL Cefoxitin: 2500 mg/dL Levodopa: 20 mg/dL Methyldopa: 20 mg/dL Metronidazole: 200 mg/dL Doxycyclin: 50 mg/dL Cyclosporine: 0.5 mg/dL Theophylline: 10 mg/dL Ibuprofen: 50 mg/dL
Total Allowable Error	≤6%	≤6%

Table 3: Differences between the Predicate Device and the Proposed Device:

Feature	Predicate	Proposed New System
Proprietary and Established Names	D-100™ HbA1c, D-100™ HbA1c Calibrator Pack	HbA1c Advanced
Instrument Platform	D-100™ Hemoglobin Testing System	DxC 700 AU Clinical Chemistry Analyzer
Control	Commercially available Bio-Rad Lyphocheck Diabetes control materials	2 Levels of control material
Operating Principle	Ion-exchange Quantitative high performance liquid chromatography (HPLC)	Quantitative turbidimetric inhibition immunoassay

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Sample Types	Capillary blood Acceptable anticoagulants are Potassium Oxalate/ Sodium Fluoride Sodium Citrate	Not Applicable for HbA1c Advanced
Analytical Range (Linearity)	HbA1c: 3.5 to 20% HbA1c (NGSP) 15 - 195 mmol/mol (IFCC)	HbA1c: 4.0 – 15% HbA1c (NGSP) 20 – 140 mmol/mol (IFCC)
Specificity (Interferences - Endogenous)	Significant interference defined as a ±7% change in % HbA1c value from the control • Lipemia (Intralipid): NSI up to 6000 mg/dL • Rheumatoid Factor: NSI up to 750 IU/mL	NSI is recovery within 7% of the initial value (sample containing no interferent). Lipemia: NSI up to 500 mg/dL Rheumatoid Factor (RF): NSI up to 1000 IU/mL
Specificity (Interference - Hb Derivatives and Cross Reactants)	Significant interference defined as % recovery of ±7% change in % HbA1c value from the control • Carbamylated Hb: up to 5% • Labile Hb: up to 1200 mg/dL of glucose does not interfere with this assay	NSI is recovery within 7% of the initial value (sample containing no interferent). • Carbamylated Hb: NSI up to 1.5 mg/mL • Labile Hb; NSI up to 2000 mg/dL • Glycated Albumin: NSI up to 5 mg/mL • HbA0: NSI up to 12 mg/mL

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		• HbA1a+b: NSI up to 0.16 mg/mL
Drug Interference	Significant interference was defined as a ±7% change in %HbA1c value from the control. • Acetaminophen: 200 mg/L • Heparin: 5000 U/L • Rifampicin: 64 mg/L • Phenzylbutazone – 400 mg/L	NSI is recovery within 7% of the initial value (sample containing no interferent): • Acetaminophen: 26 mg/dL • Heparin: 5500 IU/L • Rifampicin: 8 mg/dL • Phenzylbutazone: 53.5 mg/dL • Glyburide: 0.12 mg/dL • Salicyclic Acid: 4.76 mg/dL • Sitagliptin: 0.2 mg/dL • Rosiglitazone: 0.33 mg/dL • Metformin: 5 mg/dL • Calcium Dobsilate: 20mg/dL • Acarbose: 0.05 mg/dL
Specificity (Interference - Hb Variants)	Significant interference was defined as ≥ 7% change in HbA1c value in the presence of the hemoglobin variant relative to control. HbF concentrations up to 30% do not interfere with the test.	No Significant interference is recovery within 7% of the reference value (value assigned in Secondary Reference Laboratory). Samples containing ≥7% HbF may result in lower than expected HbA1c results

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9.0 Performance Characteristics – Analytical Performance:

Precision

Precision of the HbA1c Advanced reagent on the DxC 700 AU was evaluated based on CLSI guideline EP05-A3: *"Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Third Edition".* Studies were carried out on 3 lots of HbA1c Advanced by testing four levels of HbA1c K2 EDTA human venous whole blood patient samples at HbA1c concentrations of approximately 5.0%, 6.5%, 8.0%, 12% and 14%. The experimental design used duplicate sample analysis, twice daily, over the course of twenty working days (n=2) in random order. NGSP results are shown in Tables 4 – 7. IFCC results are shown in Tables 8 – 11.

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Table 4: DxC 700 AU: Instrument 1: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.06	0.88	0.04	Pass	0.80	0.04	0.64	0.03	0.92	0.05	1.63	0.08	Pass
Human Whole Blood 2	6.72	1.01	0.07	Pass	0.60	0.04	0.65	0.04	0.93	0.06	1.64	0.11	Pass
Human Whole Blood 3	8.06	0.77	0.06	Pass	0.47	0.04	0.73	0.06	1.06	0.09	1.57	0.13	Pass
Human Whole Blood 4	11.70	0.79	0.09	Pass	0.48	0.06	0.84	0.10	0.19	0.02	1.26	0.15	Pass
Spiked Human Whole Blood	14.02	0.74	0.10	Pass	0.49	0.07	0.72	0.10	0.32	0.04	1.19	0.17	Pass
Whole Blood Control 1	5.32	1.19	0.06	Pass	0.84	0.04	0.66	0.03	1.34	0.07	2.08	0.11	Pass
Whole Blood Control 2	9.88	0.77	0.08	Pass	0.48	0.05	0.65	0.06	1.07	0.11	1.54	0.15	Pass

Table 5: DxC 700 AU Instrument 2: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.03	1.15	0.06	Pass	0.37	0.02	0.57	0.03	1.02	0.05	1.68	0.08	Pass
Human Whole Blood 2	6.69	1.14	0.08	Pass	0.20	0.01	0.50	0.03	0.83	0.06	1.51	0.10	Pass
Human Whole Blood 3	8.05	0.86	0.07	Pass	0.48	0.04	0.49	0.04	0.70	0.06	1.31	0.11	Pass
Human Whole Blood 4	11.69	0.71	0.08	Pass	0.33	0.04	0.61	0.07	0.56	0.07	1.14	0.13	Pass
Spiked Human Whole Blood	14.04	0.75	0.11	Pass	0.58	0.08	0.34	0.05	0.69	0.10	1.22	0.17	Pass
Whole Blood Control 1	5.28	1.23	0.06	Pass	0.41	0.02	0.75	0.04	1.32	0.07	1.99	0.11	Pass
Whole Blood Control 2	9.88	0.77	0.08	Pass	0.42	0.04	0.54	0.05	0.95	0.09	1.40	0.14	Pass

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Table 6: DxC 700 AU Instrument 3: NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.03	0.83	0.04	Pass	0.45	0.02	0.70	0.04	1.02	0.05	1.55	0.08	Pass
Human Whole Blood 2	6.66	0.82	0.06	Pass	0.31	0.02	0.48	0.03	1.31	0.09	1.65	0.11	Pass
Human whole Blood 3	7.98	0.73	0.06	Pass	0.58	0.05	0.47	0.04	1.68	0.14	1.98	0.16	Pass
Human Whole Blood 4	11.68	0.71	0.08	Pass	0.21	0.03	0.67	0.08	0.54	0.06	1.14	0.13	Pass
Spiked Human Whole Blood	13.99	0.66	0.09	Pass	0.44	0.06	0.56	0.08	0.66	0.09	1.18	0.17	Pass
Whole Blood Control 1	5.25	0.93	0.05	Pass	0.97	0.05	0.60	0.03	1.37	0.07	2.01	0.11	Pass
Whole Blood Control 2	9.72	0.65	0.06	Pass	0.36	0.03	0.65	0.06	1.45	0.14	1.75	0.17	Pass

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Table 7: Instruments Combined (Instrument 1, 2, 3): NGSP units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean % HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision		Specification
		% CV	SD	CV ≤1.5% or SD ≤0.1% HbA1c	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2% or SD ≤0.13% HbA1c
Human Whole Blood 1	5.07	0.96	0.05	Pass	0.57	0.03	0.64	0.03	0.99	0.05	0.74	0.04	1.78	0.09	Pass
Human Whole Blood 2	6.72	1.00	0.07	Pass	0.41	0.03	0.55	0.04	1.05	0.07	0.56	0.04	1.69	0.11	Pass
Human Whole Blood 3	8.07	0.79	0.06	Pass	0.51	0.04	0.58	0.05	1.22	0.10	0.57	0.05	1.74	0.14	Pass
Human Whole Blood 4	11.71	0.74	0.09	Pass	0.36	0.04	0.71	0.08	0.46	0.05	0.32	0.04	1.22	0.14	Pass
Spiked Human Whole Blood	14.03	0.72	0.10	Pass	0.51	0.07	0.56	0.08	0.58	0.08	0.12	0.02	1.20	0.17	Pass
Whole Blood Control 1	5.29	1.12	0.06	Pass	0.78	0.04	0.67	0.04	1.34	0.07	0.50	0.03	2.09	0.11	Pass
Whole Blood Control 2	9.84	0.73	0.07	Pass	0.43	0.04	0.61	0.06	1.17	0.12	0.70	0.07	1.72	0.17	Pass

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Table 8: DxC 700 AU Instrument 1: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.84	1.51	0.48	Pass	1.43	0.46	1.08	0.34	1.60	0.51	2.84	0.90	Pass
Human Whole Blood 2	49.92	1.49	0.75	Pass	0.90	0.45	0.97	0.48	1.36	0.68	2.41	1.21	Pass
Human Whole Blood 3	64.65	1.06	0.68	Pass	0.61	0.40	1.01	0.65	1.43	0.93	2.14	1.38	Pass
Human Whole Blood 4	104.38	1.31	1.37	Pass	0.00	0.00	1.03	1.07	0.23	0.24	1.68	1.76	Pass
Spiked Human Whole Blood	129.76	0.87	1.13	Pass	0.57	0.74	0.86	1.11	0.37	0.49	1.40	1.82	Pass
Whole Blood Control 1	34.65	2.01	0.70	Pass	1.28	0.44	1.18	0.41	2.22	0.77	3.46	1.20	Pass
Whole Blood Control 2	84.53	0.98	0.83	Pass	0.61	0.51	0.82	0.69	1.36	1.15	1.96	1.66	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 9: DxC 700 AU Instrument 2: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.51	2.01	0.63	Pass	1.19	0.37	0.77	0.24	1.81	0.57	3.05	0.96	Pass
Human Whole Blood 2	49.59	1.63	0.81	Pass	0.42	0.21	0.74	0.37	1.18	0.59	2.18	1.08	Pass
Human Whole Blood 3	64.48	1.18	0.76	Pass	0.66	0.43	0.67	0.43	0.96	0.62	1.79	1.15	Pass
Human Whole Blood 4	104.29	0.88	0.91	Pass	0.38	0.40	0.75	0.78	0.70	0.73	1.40	1.46	Pass
Spiked Human Whole Blood	129.92	0.88	1.15	Pass	0.66	0.85	0.43	0.56	0.82	1.06	1.44	1.87	Pass
Whole Blood Control 1	34.24	2.09	0.72	Pass	0.74	0.25	1.23	0.42	2.23	0.76	3.38	1.16	Pass
Whole Blood Control 2	84.52	0.98	0.83	Pass	0.54	0.46	0.69	0.58	1.22	1.03	1.80	1.52	Pass

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Table 10: DxC 700 AU Instrument 3: IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concentration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Total Precision		Specifications
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.46	1.41	0.46	Pass	1.18	0.38	1.31	0.42	1.78	0.58	2.88	0.93	Pass
Human Whole Blood 2	49.27	1.21	0.61	Pass	0.46	0.23	0.70	0.35	1.93	0.97	2.42	1.22	Pass
Human Whole Blood 3	63.68	1.00	0.65	Pass	0.79	0.52	0.63	0.41	2.29	1.49	2.69	1.75	Pass
Human Whole Blood 4	104.18	0.87	0.92	Pass	0.25	0.26	0.81	0.85	0.66	0.70	1.39	1.46	Pass
Spiked Human Whole Blood	129.37	0.79	1.02	Pass	0.52	0.67	0.66	0.86	0.87	1.01	1.39	1.81	Pass
Whole Blood Control 1	33.83	1.58	0.54	Pass	1.61	0.55	1.02	0.35	2.32	0.79	3.40	1.16	Pass
Whole Blood Control 2	82.77	0.83	0.69	Pass	0.46	0.38	0.83	0.69	1.86	1.55	2.24	1.87	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 10: Instruments Combined (Instrument 1, 2, 3): IFCC units: Summary of 20 Day Precision Performance

Sample/ Control details	Mean (mmol/mol) HbA1c Concen-tration	Repeatability (Within-run)		Specification	Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision		Specification
		% CV	SD	CV ≤2.3% or SD ≤1.1 mmol/mol	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	CV ≤2.9% or SD ≤1.4 mmol/mol
Human Whole Blood 1	31.91	1.66	0.53	Pass	1.27	0.41	1.08	0.34	1.73	0.55	1.31	0.42	3.20	1.02	Pass
Human Whole Blood 2	49.95	1.45	0.72	Pass	0.63	0.31	0.81	0.41	1.53	0.76	0.82	0.41	2.49	1.24	Pass
Human Whole Blood 3	64.75	1.08	0.70	Pass	0.69	0.45	0.79	0.51	1.66	1.07	0.77	0.50	2.37	1.53	Pass
Human Whole Blood 4	104.51	1.04	1.09	Pass	0.23	0.24	0.87	0.91	0.57	0.60	0.40	0.42	1.54	1.61	Pass
Spiked Human Whole Blood	129.84	0.85	1.10	Pass	0.58	0.76	0.67	0.87	0.69	0.89	0.14	0.19	1.42	1.84	Pass
Whole Blood Control 1	34.32	1.91	0.66	Pass	1.26	0.43	1.15	0.39	2.26	0.78	0.87	0.30	3.52	1.21	Pass
Whole Blood Control 2	84.10	0.93	0.78	Pass	0.54	0.46	0.78	0.66	1.50	1.26	0.90	0.76	2.20	1.85	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Linearity:

Dynamic Range/ Analytical Measuring Range studies were designed using CLSI Guideline EP06-A: *"Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"*. High and low pools were prepared as per Table 1. A linearity series was prepared by inter-diluting the high and low pools to achieve a % HbA1c concentration spanning the required analytical range. The samples were mixed together in varying ratios.

Data was analyzed using Polynomial regression analysis (for first, second and third order polynomials) to determine the statistical significance of non-linearity. Where data generated was non-linear, the best fitting polynomial was applied to the data and difference between this best fitting, non-linear polynomial and the linear polynomial was calculated. Regression parameters for slope, intercept and R value were calculated.

The results of the study provides data to support the dynamic range/analytical measuring range claim for HbA1c Advanced reagent 4 – 15% (NGSP) HbA1c and 20 – 140 mmol/mol HbA1c (IFCC).

Table 12: Linearity Results Summary

Reagent	Acceptance Criteria	Results		Pass/ Fail	Acceptance Criteria	Pass/Fail
	Linear Range	Linear From	Linear To		Regression Parameters	
HbA1c Advanced	4-15% HbA1c	3.94% HbA1c	15.37% HbA1c	Pass	Slope: 1.0 ± 0.05 Intercept: ≤ ± 0.5 % HbA1c R: ≥ 0.990 N: ≥ 9	Pass Pass Pass Pass
HbA1c Advanced	20 – 140 mmol/mol	19.51 mmol/mol	144.49 mmol/mol	Pass	Slope: 1.0 ± 0.05 Intercept: ≤ ± 5.5 mmol/L R: ≥ 0.990 N: ≥ 9	Pass Pass Pass Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Method Comparison

Method comparison and bias estimation experiments were designed using CLSI Guideline EP09-A3; "*Measurement Procedure Comparison and Bias Estimation using Patient Samples; Approved Guideline*." The patient correlation studies were performed using a standardized test method in an NGSP Secondary Reference Laboratory (SRL) using a test system (method X - HA8180V HPLC) with an analytical measuring range of 4-15% HbA1c (NGSP) and the proposed new Beckman Coulter HbA1c test system (method Y – HbA1c Advanced, 1 lot) with a proposed measuring range of 4-15 % HbA1c (NGSP) on a DxC 700 AU analyzer. Over a 120 (duplicates) of venous human frozen whole blood specimens (K2 EDTA anticoagulant type) with HbA1c concentrations were tested using on the DxC 700 AU Analyzer.

Table 13: Sample Distribution

Hemoglobin A1c Level	No. of Samples (SRL)	% Samples tested (SRL)	No. of Samples tested (Beckman)	% Samples tested (Beckman)
≤5%	6	4.35	6	4.35
5 – 6%	18	13.04	22	15.94
6 – 6.5%	32	23.19	32	23.19
6.5 – 7%	35	25.36	35	25.36
7 – 8%	25	18.12	23	16.67
8 – 9%	12	8.7	10	7.25
> 9%	10	7.25	10	7.25
Total Samples	138	100%	138	100%

Weighted Deming's and Passing-Bablok regression analysis was performed for the HbA1c Advancedmethod versus an NGSP SRL standardized method, results are summarized below in tables 14 and 15.

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Table 14: Summary of Method Comparison for HbA1c Advanced results and specifications (Weighted Deming analysis) NGSP Units.

Sample Range:	Specifications	Results (95%CI Low; HIgh)	Pass / Fail
Method X: 4.7 - 14.2 % HbA1c Method Y: 4.6 – 14.3 % HbA1c	Slope: 1.0 ± 0.05	0.990 (0.978; 1.002)	Pass
	Intercept: ≤ ± 0.5% HbA1c	0.010 %HbA1c (-0.070; 0.089) %HbA1c	Pass
	R: ≥ 0.975	0.998	Pass
	N: ≥ 120	138	Pass

Table 15: Summary of Method Comparison for HbA1c Advanced results and specifications (Passing-Bablok analysis) NGSP Units.

Sample Range:	Specifications	Results (95% CI Low; High)	Pass / Fail
Method X: 4.7 - 14.2 % HbA1c Method Y: 4.6 – 14.3 % HbA1c	Slope: 1.0 ± 0.5	0.980 (0.964;0.992)	Pass
	Intercept: ≤ ± 0.5 %HbA1c	0.090 %HbA1c (-0.006; 0.187) % HbA1c	Pass
	R: ≥ 0.975	0.998	Pass
	N: ≥ 120	138	Pass

Total Error

Total error was evaluated using the results of the bias estimation (%Bias) from single measurements conducted of the new device compared to results of the standardised test method (method comparison) and precision estimates from the precision study. Total Error (TE) at four concentrations (5.0%, 6.5%, 8.0%, and 12.0%) was calculated as follows: "%TE = |(%Bias)| + 1.96*%CV*(1+%Bias/100)". The results are presented in Table 5.

Table 16: Total Error Estimation

%HbA1c Decision Level	% Bias	%CV	%TE	Acceptance Criteria: ≤6%
5.0	-0.80	1.78	4.3	Pass
6.5	-0.85	1.69	4.2	Pass
8.0	-0.88	1.74	4.3	Pass
12.0	-0.92	1.22	3.3	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Analytical Specificity

Interference (Analytical Specificity) studies were designed based on CLSI Guideline EP07 Third Edition: *"Interference Testing in Clinical Chemistry; Approved Guideline"* and used to assess common or known substances which could interfere with the HbA1c Advanced assay.

Endogenous Interference

The interfering substances analyzed were tested at two % HbA1c concentrations; approximately 6.5% HbA1c (low level human venous whole blood K2 EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood K2 EDTA sample) using one lot of reagent on one DxC700 AU analyzer. Low and high pools were prepared by interdiluting human whole blood samples.

The whole blood samples were tested at a minimum of 5 levels for each interferent (Conjugated Bilirubin, Unconjugated Bilirubin, Lipemia, Ascorbic Acid, RF, Total Protein and Glucose) with 10 replicates tested per level on the DxC700 AU Analyzer to determine the magnitude of the interference.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results in Table 1 show no significant interference up to the stated concentrations.

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Table 17: Specifications and Summary of Endogenous Interference data

Potential Interfering Substance	Interference pool details	Interferent Level
Conjugated Bilirubin	Whole Blood Pools spiked with Conjugated Bilirubin Stock Solution	60 mg/dL
Unconjugated Bilirubin	Whole Blood Pools spiked with unconjugated Bilirubin Stock Solution	60 mg/dL
Lipemia	Whole Blood Pools spiked with 20% w/v Intralipid	500 mg/dL
Ascorbic Acid	Whole Blood Pools spiked with Ascorbate	300 mg/dL
RF	Whole Blood Pools spiked with RF positive plasma	1000 IU/ml
Total Protein	Whole Blood Pools spiked with Human Serum Albumin	21 g/dL
Glucose	Whole Blood Pools spiked with Anhydrous Glucose	2000 mg/dL

Drug Interference

Potential drug interfering substances were analyzed to determine their effect on HbA1c Advanced reagent . All drug interferences were tested at two % HbA1c concentrations, approximately 6.5% HbA1c (low level human venous whole blood EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood EDTA sample). Testing was completed using one lot of reagent on DxC 700 AU Analyzer.

Low and high pools were prepared by inter-diluting human whole blood samples. The two whole blood sample pools were spiked with each potential interfering drug to create test samples. Ten replicates of each test and reference sample (sample containing no potential interferent) were tested on the DxC 700 AU to determine the magnitude of the interference. Each drug was tested to at least 5 times the highest drug concentration under therapeutic treatment.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results outlined below showed no significant interference up to the stated concentrations.

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Table 18: Specifications and Summary of Drug Interference data

Potential Interfering Substance	Interference pool details	Interferent Level
Glyburide	Whole Blood Pools spiked with Glyburide Stock Solution	0.12 mg/dL
Salicyclic Acid	Whole Blood Pools spiked with Salicyclic Acid Stock Solution	4.76 mg/dL
Sitagliptin	Whole Blood Pools spiked with Sitagliptin Phosphate stock solution	0.2 mg/dL
Rosiglitazone	Whole Blood Pools spiked with Rosiglitazone maleate stock solution	0.33 mg/dL
Metformin	Whole Blood Pools spiked with Metformin Hydrochloride stock solution	5 mg/dL
Cyclosporine	Whole Blood Pools spiked with Cyclosporine stock solution	0.5 mg/dL
Heparin	Whole Blood Pools spiked with Sodium Heparin stock solution	5500 IU/L
Calcium Dobesilate	Whole Blood Pools spiked with Calcium Dobsilate stock solution	20 mg/dL
Metronidazole	Whole Blood Pools spiked with Metronidazole stock solution	200 mg/dL
Levodopa	Whole Blood Pools spiked with Levodopa Stock solution	20 mg/dL
Acetylsalicyclic acid	Whole Blood spiked with Acetysalicyclic acid Stock Solution	1000 mg/dL

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Acarbose	Whole blood spiked with Ascarbose Stock Solution	0.05 mg/dL
Acetaminophen	Whole blood spiked with Acetaminophen Stock Solution	26 mg/dL
Acetylcystein	Whole blood spiked with Acetylcystein Stock Solution	166 mg/dL
Ampicillin-Na	Whole blood spiked with Ampicillin-Na Stock Solution	1000 mg/dL
Cefoxitin	Whole blood spiked with Cefoxin Stock Solution	2500 mg/dL
Doxycyclin	Whole blood spiked with Doxycyclin Stock Solution	50 mg/dL
Ibuprofen	Whole blood spiked with Ibuprofen Stock Solution	50 mg/dL
Methyldopa	Whole blood spiked with Methyldopa Stock Solution	20 mg/dL
Phenylbutazone	Whole blood spiked with Phenylbutazone Stock Solution	53.5 mg/dL
Rifampicin	Whole blood spiked with Rifampicin Stock Solution	8 mg/dL
Theophylline	Whole blood spiked with Theophylline Stock Solution	10 mg/dL

Hemoglobin Derivative and Cross Reactants

Hemoglobin derivatives and potential interfering cross reactants were tested at two % HbA1c concentrations; approximately 6.5% HbA1c (low level human venous whole blood K2 EDTA sample) and approximately 8.0% HbA1c (high level human venous whole blood K2 EDTA sample) using one lot of reagent on one DxC700 AU analyzer. Low and high pools were prepared by interdiluting human whole blood samples.

Hemoglobin derivatives and potentially interfering cross reactants were tested at a minimum of 5 levels for: Labile Hemoglobin, Acetylated Hemoglobin, Carbamylated Hemoglobin, Glycated Albumin, HbA0 and HbA1a+b with 10 replicates tested per level on the DxC 700 AU analyzer to determine the magnitude of any interference effect.

No Significant Interference is recovery within 7% of the initial value (sample containing no interferent). Results in Table 19 showed no significant interference up to the stated concentrations.

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Table 19: Specification and Summary of Hemoglobin Derivative and Cross Reactant Interferences

Potential Interfering Substance	Interference Pool details	Interferent Level
Labile Hemoglobin	Whole Blood Pools spiked with Glucose Stock Solution	2000 mg/dL
Acetylated Hemoglobin	Whole Blood Pools spiked with Acetylsalicylic acid Stock Solution	0.5 mg/mL
Carbamylated Hemoglobin	Whole Blood Pools spiked with Potassium Cyanate Stock Solution	1.5 mg/mL
Glycated Albumin	Whole Blood Pools spiked with Human Glycated Albumin Stock Solution	5mg/mL
HbA0	Whole Blood Pools spiked with HbA0 Stock Solution	12 mg/mL
HbA1a + 1b	Whole Blood Pools spiked with HbA1a +1b Stock Solution	0.16 mg/mL

Hemoglobin Variants

A hemoglobin variant study was performed to determine the presence of significant hemoglobin variant interference with major hemoglobin variants in the HbA1c Advanced assay. Results from singlicate measurements of samples were compared to results from a reference method, demonstrated to be free from hemoglobin interference; Trinity Biotech Hb9210 and Ultra2, Menarini HA8181V and TOSOH G8.

A minimum of 20 samples were tested for each variant (HbC, HbD, HbE, HbF, HbS and HbA2) on the DxC 700 AU Analyzer.

The following tables outline the number of samples of each variant, the range of % variant concentrations, %HbA1c concentrations and the relative % bias at 6.5% and 9.0% HbA1c.

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Table 20: Hemoglobin Variant Sample Ranges

Hemoglobin Variant	Number of Samples	Range in %Variant Concentration	Range in %HbA1c Concentration
HbC	28	28.5 - 38.2	4.8 - 14.7
HbD	23	31.1 – 42.0	5.0 - 10.6
HbE	24	20.1 - 36.1	5.4 - 10.8
HbF	22	3.2 – 34.0	4.9 - 12.8
HbS	29	31.0 – 42.0	5.0 - 12.7
HbA2	28	3.3 - 6.2	5.4 - 7.5

Table 21: Relative Bias Summary

Hb Variant	Relative % bias (Range of % bias) observed relative to Reference method	
	HbA1c~6.5% HbA1c	HbA1c~9.0% HbA1c
HbC	-2.57 (-4.30% to -1.80%)	-3.19 (-6.48% to 0.41%)
HbD	-0.77 (-4.81% to 2.99%)	-1.22 (-6.30% to -0.22%)
HbE	-1.12 (-9.16% to 2.48%)	0.47 (-1.76% to 4.21%)
HbS	-1.18 (-2.17% to 3.04%)	-1.04 (-3.33% to 4.41%)
HbA2	0.48 (-1.92% to 5.60%)	2.49 (-0.98% to 3.60%)
HbF	Specimens containing high amounts of HbF (> 7%) may yield lower than expected HbA1c Values	

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Anticoagulants

The data supports the use of the following blood collection tubes with the HbA1c Advanced reagent .

- K2 EDTA
- K3 EDTA
- Sodium Heparin
- Lithium Heparin

Expected Values/Reference Interval

Beckman Coulter used evidence recommended by the American Diabetes Association Standards of (ADA), which may be used as an aid in the diagnosis of diabetes mellitus:

Table 1: HbA1c ranges recommended by the ADA as an aid in the diagnosis of diabetes mellitus[1,2,3]

HbA1c Advanced		Suggested Diagnosis
NGSP %	IFCC mmol/mol	
≥ 6.5	≥48	Diabetic
5.7 – 6.4	39 - 47	Pre-Diabetic
< 5.7	<39	Non-Diabetic

Conclusion

The information and data in this 510(k) document demonstrate that the HbA1c Advanced reagent on the DxC700 AU Analyzer is an accurate, reliable, precise test that correlates well with current cleared methods and NGSP standardized testing for the quantitation of HbA1c.
The contents of this submission demonstrates that the HbA1c Advanced Reagent is substantially equivalent to the Biorad D-100™ HbA1c and D-100™HbA1c Calibrator Pack. It is therefore safe and effective for its intended use. The submitted information in this pre-market notification is complete and supports a substantial equivalence decision.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k185651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

I look forward to working with you.

Thanks and Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

[cid:image004.jpg@01D4121F.6E3ACB20]<https://www.linkedin.com/company/beckman-coulter>[cid:image006.jpg@01D4121F.6E3ACB20]<https://www.youtube.com/user/beckmancoulter>

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Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

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rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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[cid:image003.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=https-3A__twitter.com_US-5FFDA&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=S0HXpvC31hdTr842eqtOx-plyrJARrdFgf__jTBrvdM&e=>
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HERE<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D531-26E-3D-26S-3DE&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=Rq_C0xWyNjnSXAf_GUEPapzsHz4QnwG5YLEFOCidsY4&e=> regarding the customer service you have received.

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(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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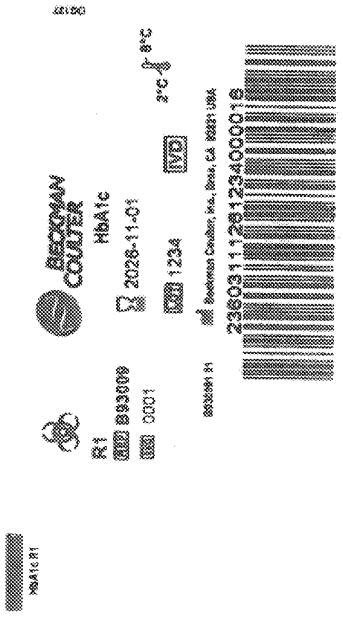

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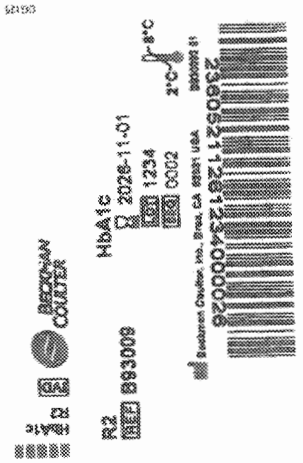

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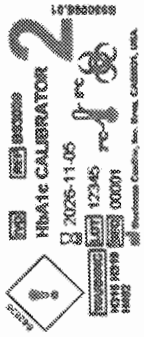

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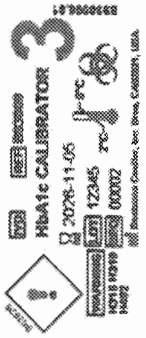

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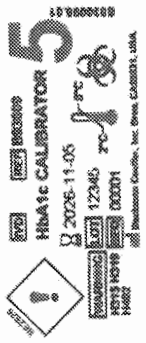

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Does not require EMC and electrical safety evaluation

– NOT APPLICABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification Truthful and Accuracy Statement

- As required by 21 CFR 807.87 (k) -

I certify that, in my capacity as Regulatory Affairs Specialist of Beckman Coulter Ireland Inc., I believe to the best of my knowledge, that all data and information submitted in the Pre-market notification are truthful and accurate and that no material fact has been omitted.

The above referenced statement is made in good faith. It should be emphasized, however, that this 510(k) was prepared in the ordinary course of business. The existence of clerical or other inadvertent errors is thus possible.

(b)(6)

Signature of Certifier

Catriona Hourigan
Typed Name

19 Sept 2018
Date

Pre-market notification
510(k) number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D4121F.6E3AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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November 1, 2018</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K182651, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Rosemary Lusk.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

(b)(4)

Warm regards,

Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>

Sent: Wednesday, January 16, 2019 11:28 AM

To: chourigan@beckman.com

Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Class III Summary and certification – NOT APPLICABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Beckman Coulter Ireland Inc.
Catriona Hourigan, Regulatory Affairs Specialist
Lismeehan
O' Callaghan's Mills
Co. Clare
Ireland
V94 PP63

Re: k182651
Trade/Device Name: HbA1c Advanced
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c test system
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: September 20, 2018
Received: September 24, 2018

Dear Catriona Hourigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

We have received your email. I will discuss this with my colleagues in development and will respond before the end of today.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Best regards,
Rosemary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

clclimage002.jpg@01D41 21F.6E3AC820	**Catriona Hourigan**
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

---

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

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Hi Rosemary,

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Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

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Thanks and Kind Regards

Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

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Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

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Importance: High

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Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJr1Q9TDlMqTXQ&e=>

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January 16, 2019</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

Thank you for the update. We appreciate that you will respond later today.

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Wednesday, December 12, 2018 8:58 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

Warm Regards

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the **(b)(4)** **(b)(4)** My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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BECKMAN COULTER

AU

Instructions For Use

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HbA1c Advanced
HbA1c

REF B93009 2 x 41.4 mL HbA1c R1
2 x 9.9 mL HbA1c R2
2 x 38.3 mL Total Hemoglobin R1
2 x 54.7 mL Hemolyzing Reagent R1
5 x 2 mL HbA1c Calibrator (Levels 2-6)

APPROVAL C NOT FOR PUBLICATION

For *In Vitro* Diagnostic Use

For Rx use only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The HbA1c (hemoglobin A1c) Advanced assay on the Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or %HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term blood glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

SUMMARY AND EXPLANATION

Diabetes mellitus is a condition characterized by hyperglycemia resulting from the body's inability to use blood glucose for energy. In Type 1 diabetes, the pancreas no longer makes insulin and therefore, blood glucose cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly[1,2]. The direct and indirect effects on the human vascular tree are the major source of morbidity and mortality in both type 1 and type 2 diabetes. Generally, the injurious effects of hyperglycemia are separated into macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy)[3].

HbA1c is the major species of glycohemoglobin found in human blood, and is formed by the non-enzymatic glycation of the free amino group at the N-terminal of the hemoglobin A0 β-chain[4]. HbA1c testing has been recommended for the diagnosis of Type 2 diabetes by the International Expert Committee (IEC), the American Diabetes Association (ADA), and the World Health Organization (WHO), which recommended a diagnostic threshold of ≥ 6.5% (≥ 48 mmoL/moL) HbA1c[5,6,7]. HbA1c testing has also been recommended for the identification of individuals at increased risk for developing diabetes (pre-diabetic). The ADA has defined the HbA1c range for pre-diabetes as 5.7% - 6.4% (39 – 46 mmoL/moL) HbA1c[2,5,8,9,10].

Detection and treatment of prediabetes may reduce or eliminate the risk of developing Type 2 diabetes and related complications[5].

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HbA1c determinations are useful for monitoring long-term blood glucose control in individuals with diabetes mellitus. Determination of HbA1c provides an important tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus. Therapy for diabetes requires the long term maintenance of a blood glucose level as close as possible to normal levels, minimizing the risk of long-term vascular consequences[11]. A single fasting blood glucose measurement is an indication of the patient's immediate past condition (hours), but may not represent the true status of blood glucose regulation[12,13].

The measurement of HbA1c every two to three months has been accepted as a measure of glycemic control in the care and treatment of patient with diabetes mellitus. Long term treatment of the disease emphasizes control of blood glucose levels in preventing the acute complications of ketosis and hyperglycemia. In addition, long term complications such as retinopathy, neuropathy and cardiovascular disease can be minimized if blood glucose levels are effectively controlled.

The HbA1c Advanced assay reflects the average blood glucose levels over the preceding 3 months (i.e. the average life span of a red blood cell) and therefore may be falsely low during any condition associated with the recent onset of hyperglycemia (including gestational diabetes) and/or decreased red blood cell survival[14,15,16,17]. Refer to Limitations section for additional information.

METHODOLOGY

The HbA1c Advanced assay (B93009) involves the use of three reagents: Total Hemoglobin (R1), HbA1c (R1 and R2), and Hemolyzing Reagent (R1). The DxC 700 AU Clinical Chemistry analyzer automatically performs the whole blood hemolysis using 200 µL of Hemolyzing reagent (R1) and 2 µL of whole blood in a cuvette.

Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. The hemolyzed whole blood is then added to both the Total Hemoglobin and HbA1c assay cuvettes according to their defined assay parameters.

Total Hemoglobin reagent (R1) is used to measure Total Hemoglobin (T-Hb) concentration by a colorimetric method. Change in absorbance is measured at 570/660 nm.

HbA1c reagent (R1 and R2) is used to measure hemoglobin A1c (A1c) concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies in the reagent combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm.

The concentrations of both T-Hb and A1c are determined, and are used in the calculation of the reported HbA1c (A1c/T-Hb ratio), which is expressed either as mmol/mol (IFCC) or % (DCCT/NGSP).

SPECIMEN

SPECIMEN STORAGE AND STABILITY

Reference[18,19]

Whole blood samples are stable for up to 8 hours when stored at 20°C to 25°C, 7 days when stored at 2°C to 8°C and up to 1 month when frozen at -20°C and -70°C. Frozen samples should be thawed only once.

Each laboratory should evaluate sample handling procedures to avoid variable results.

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

Additional handling conditions as designated by this laboratory:

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SPECIMEN COLLECTION AND PREPARATION

K_2-EDTA, K_3-EDTA, Li-Heparin or Na-Heparin whole blood (freshly drawn blood treated with EDTA is the preferred specimen). Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of the chemistry information sheet.

HbA1c Advanced should be programmed using "WHOLE BLOOD" as the sample type. Thoroughly mix the whole blood sample to ensure a uniform distribution of erythrocytes IMMEDIATELY before loading onto the analyzer. Settling of the erythrocytes may cause an elevated total hemoglobin result. Ensure there are no bubbles in the sample and remove any visible clots. Samples should not be centrifuged prior to analysis.

SAMPLE VOLUME

When using a primary sample tube for the whole blood sample, refer to the manufacturer's recommendations for minimum/maximum fill volume. When using a 2.5 mL sample cup (MU853200), the minimum volume for patient whole blood samples is 250µL.

Additional instructions for patient sample preparation as designated by this laboratory:

Additional type conditions as designated by this laboratory:

REAGENTS

CONTENTS

HbA1c Advanced Reagent

Reagent storage location in this laboratory:

WARNING AND PRECAUTIONS

Reference[20]

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL.

The calibrator is manufactured from human material; each donor used in the preparation of this material was tested by an FDA approved method for the presence of the antibody to HIV-1/2 and HCV as well as for hepatitis B surface antigen and was not repeatedly reactive. Because no test method can offer complete assurance that HIV-1/2, HCV, hepatitis

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B virus or other infectious agents are absent from biological materials, this product should be handled at the Biosafety Level 2 as recommended for any infectious human serum or blood specimen in the Centers for Disease Control and Prevention/National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories.*

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

HbA1c R1 Antibody Reagent		**HbA1c R2 Polyhapten Reagent**	
Anti-human HbA1c Antibody (sheep)	≥ 0.403 mg/mL	HbA1c Polyhapten	≥ 1.29 µg/mL
MES (2-morpholino-ethanesulphonic acid) Buffer	0.020 mol/L	MES (2-morpholino-ethanesulphonic acid) Buffer	0.004 mol/L
TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)	0.012 mol/L	TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)	0.002 mol/L
Non-reactive chemicals necessary for optimum system performance			

Total Hemoglobin Reagent	
Phosphate Buffer, pH 7.4	0.018 mol/L
Non-reactive chemicals necessary for optimum system performance	

Hemolyzing Reagent
0.9% Tetradecyltrimethylammonium bromide 26.5 mmol/L

The concentrations of the reactive ingredients of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 bottles. The reagent composition which is shown in this Instructions For Use is the final concentration of these ingredients in the reaction cuvette after the addition of the applicable components required for the reaction (R1, Sample, R2).

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GHS HAZARD CLASSIFICATION

HbA1c Calibrator (Levels 2 - 6)	WARNING	
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P337+P313	If eye irritation persists: Get medical advice/attention.
		Tetradecyltrimethylammonium bromide 1 - 2%
Hemolyzing Reagent	WARNING	
	H316	Causes mild skin irritation.
	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tetradecyltrimethylammonium bromide 0.1 - 1%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

0.9% Saline solution.

At least two levels of control material

Storage location of the saline solution in this laboratory:

EQUIPMENT AND MATERIALS

DxC 700 AU Beckman Coulter Analyzers.

Sample cups 2.5mL, REF MU853200

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Storage location of test tubes or sample cups in this laboratory:

REAGENT PREPARATION

Total Hemoglobin (R1), HbA1c (R1 and R2) and Hemolyzing Reagent (R1) are ready for use, and can be placed directly on board the analyzer.

REAGENT STORAGE AND STABILITY

1. The unopened reagents are stable, up to the stated expiration date when stored at 2 to 8°C.
2. Opened bottles of reagent are stable for 30 days when stored in the refrigerated compartment of the analyzer.
3. Do not freeze

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, gross turbidity, precipitate, or change in color in the HbA1c, Total Hemoglobin or Hemolyzing reagents may indicate degradation and warrant discontinuation of use.

Additional storage requirements as designated by this laboratory:

CALIBRATION

CALIBRATOR PREPARATION

1. For each individual level of calibrator, carefully remove the cap and stopper, avoiding any loss of lyophilized material. Ensure each level of calibrator is reconstituted individually to remove the possibility of cap and stopper mix up.
2. Add 2.00 mL of sterile deionized water at 15 to 25°C (room temperature) to the lyophilized material using a calibrated pipette or gravimetrically using an analytical balance. Ensure the deionized water being used for reconstitution is at room temperature for accurate aspiration and dispensing into the calibrator bottle. Failure to accurately measure 2.00 mL for each level of calibrator will lead to variability in test results.
3. Replace the cap and stopper.
4. Invert to ensure any material on the stopper is in solution. Dissolve the contents completely by gently mixing for 30 minutes. Vortex each bottle for 5 seconds at medium speed. Avoid foaming. Ensure that all lyophilized material is reconstituted.
5. Record the date the calibrator was reconstituted on the bottle label.

CALIBRATOR STORAGE AND STABILITY

Unopened, the calibrators should be stored at 2 to 8°C until the expiration date printed on the calibrator bottle.

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After reconstitution, calibrators are stable for up to 8 hours stored at 15°C to 25°C or up to 30 hours stored at 2°C to 8°C. Calibrators that are aliquoted immediately after reconstitution and stored at -20°C are stable for up to 60 days, as long as it has not exceeded the expiration date printed on the original calibrator bottle. Frozen calibrators should be thawed only once. After thawing, vortex each bottle for 5 seconds at medium speed[19]. Avoid foaming.

Calibration Stability

Recalibrate the assay every 15 days or when the following occur:

1. Change in reagent lot or significant shift in control values.
2. Major preventative maintenance was performed on the analyzer or a critical part was replaced.

   Following calibration, the resulting curve should be visually reviewed on the Beckman Coulter DxC 700 AU Analyzer for acceptability using the software options to access the Calibration Monitor.

   Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

CALIBRATION INFORMATION

Calibrators are included in the kit.

CALIBRATOR ASSIGNED VALUES

Refer to table below for information on calibrator levels. Refer to table of assigned values included in the kit.

NOTE: Calibrators are lot-specific and provided as a set for a specific lot of reagent. They should not be interchanged.

Calibration of Total Hemoglobin: Two Point Calibration

- Level 1 (0.9% Saline) (not supplied with kit)
- HbA1c Calibrator Level 3

Calibration of A1c: Multi-point Calibration

- HbA1c Calibrator Levels 2 to 6 only are used for the calibration of the A1c assay

Cup Sequence Order	Assay Name: A1c	Assay Name: T-Hb
1	Not Applicable	0.9% Saline
2	Calibrator 2	Not Applicable
3	Calibrator 3	Calibrator 3
4	Calibrator 4	Not Applicable
5	Calibrator 5	Not Applicable
6	Calibrator 6	Not Applicable

TRACEABILITY

Reference[21]

The HbA1c calibrator values are traceable to the IFCC HbA1c reference method via IFCC HbA1c reference material. The relationship between results from the NGSP network (DCCT aligned) and the IFCC network has been evaluated and a Master Equation has been developed for conversion of results from IFCC (mmol/mol) to NGSP (%) units.

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MASTER EQUATION

NGSP = (0.0915 x IFCC (mmol/mol)) + 2.15

IFCC Formula = (A1c / T-Hb) * 1000 = HbA1c (mmol/mol)

The definition of the relationship between the two networks links IFCC traceable results to clinically meaningful HbA1c results from the DCCT and the United Kingdom Prospective Diabetes Study (UKPDS). The Master Equation also provides these DCCT results with traceability to a higher order reference method.

Results

Results for calculated HbA1c may be reported from the DxC 700 AU analyzer in either IFCC (mmol/mol) or NGSP (%) units. To change reporting units, please contact your Beckman Coulter representative.

QUALITY CONTROL

At least 2 levels of control material should be analyzed. Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

Confirm that a volume of QC material sufficient for analysis plus the required dead volume is in the recommended 2.5 mL sample cup.

Location of controls used at this laboratory.

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

Refer to the Beckman Coulter DxC 700 AU Chemistry Analyzer Instrument Instructions For Use (IFU) and Reference Manual for analyzer-specific instructions.

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Note: The DxC 700 AU cannot process whole blood patient samples from the STAT table. Calibrators and controls in 2.5 mL sample cups (REF MU853200) only, may be loaded directly onto the STAT table.

REPORTING RESULTS

Data contained within this section is representative of performance on the Beckman Coulter DxC 700 AU Chemistry Analyzer. Data obtained in your laboratory may differ from these values.

REFERENCE INTERVALS

Reference[5,6,7,19,22,23]

The following HbA1c ranges recommended by the American Diabetes Association (ADA) may be used as an aid in the diagnosis of diabetes mellitus:

HbA1c Advanced		
NGSP %	**IFCC mmol/mol**	**Suggested Diagnosis:**
≥ 6.5	≥ 48	Diabetic
5.7 - 6.4	39 - 47	Pre-Diabetic
< 5.7	< 39	Non-Diabetic

The expected HbA1c range for non-diabetic adults is 4-6%[24]. This reference interval was taken from the literature. Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. Results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

ANALYTICAL MEASURING RANGE

The reportable range for the calculated HbA1c is 20 – 140 mmol/mol HbA1c (IFCC) and 4 – 15% HbA1c (NGSP). Note: a calculated HbA1c result may be outside the reportable range based on either the T-Hb or the A1c result being outside of their respective analytical ranges (refer to the Limitations section).

Expected reference ranges in this laboratory:

INTERVALS	SAMPLE TYPE	UNITS

Additional reporting information as designated by this laboratory:

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PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

Reference[19]

The following anticoagulants were assessed by Deming regression analysis with paired EDTA and heparin whole blood samples. Values of K2-EDTA whole blood (X), ranging from 4.9% HbA1c to 10% HbA1c, were compared with values for K3-EDTA whole blood, lithium heparin whole blood and sodium heparin whole blood (Y), yielding the following results:

ANTICOAGULANT	CONCENTRATION OF ANTICOAGULANT TESTED	DEMING REGRESSION ANALYSIS
K_3-EDTA	1.8 mg/mL	Y = 1.000X + 0.043 ; r = 0.997
Lithium Heparin	17 I.U./mL	Y = 1.004X + 0.013 ; r = 0.994
Sodium Heparin	17 I.U./mL	Y = 1.002X - 0.009 ; r = 0.997

LIMITATIONS

1. The result from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
2. This assay is designed only for the measurement of mmol/mol HbA1c (IFCC) and %HbA1c (NGSP). Individual results for T-Hb and A1c concentration should not be reported.
3. The analytical range for T-Hb is 3.7 - 17.0 mmol/L (5.97 - 27.4 g/dL). The analytical range for A1c is 0.19 mmol/L (0.3 g/dL) to the concentration of Calibrator 6[19]. When the result for T-Hb and/or A1c is outside the analytical range a “Tx” flag is generated. This could indicate that settling of the whole blood sample has occurred, which will be indicated by an “F” flag on the individual T-Hb or A1c results. In this instance this sample should be inverted to re-suspend the erythrocytes and analyzed immediately. If on repeat the “Tx” flag is repeated, the calculated HbA1c should not be reported.
4. This test should not replace glucose testing for patients with Type 1 diabetes, pediatric patients or pregnant women.
5. In cases of rapidly evolving Type 1 diabetes, the increase of HbA1c values might be delayed compared to the acute increase in glucose concentrations. In these conditions, diabetes mellitus must be diagnosed based on plasma glucose concentration and/or the typical clinical symptoms [6].
6. HbA1c should not be used to diagnose diabetes during pregnancy or to diagnose gestational diabetes. HbA1c reflects the average blood glucose levels over the preceding 3 months (the average life of a red blood cell), and therefore may be falsely low during pregnancy or any other condition associated with recent onset of hyperglycemia[6].
7. The HbA1c Advanced assay allows its use in patients with hemoglobin variants S, C, D and E traits. However, hemoglobinopathies might affect the red blood cell turnover or the in vivo glycation rates, and these patients may suffer from anemia and undergo transfusion. Therefore, results reported correctly by the assay may not reflect the same level of glycemic control as would be expected in patients with normal hemoglobin. In these cases, even analytically correct results do not reflect the same level of glycemic control that would be expected in patients with normal hemoglobin. Whenever, it is suspected that the presence of a Hb variant (eg HbSS, HbCC or HbSC) affects the correlation between the HbA1c value and glycemic control, HbA1c must not be used for the diagnosis of diabetes mellitus.
8. This test is not intended for analysis of samples collected from newborns. Glycated HbF is not detected by the assay as it does not contain the β-chain that characterizes HbA1c. However, HbF is measured in the T-Hb assay and as a consequence, specimens containing high amounts of HbF (>7%) may result in lower than expected

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mmol/mol HbA1c values (IFCC) and % HbA1c values (DCCT/NGSP)[25,26]. HbA1c results are invalid for patients with abnormal amounts of HbF including those with known Hereditary Persistence of Fetal Hemoglobin.

9. HbA1c should not be used to diagnose or monitor diabetes in patients with any conditions resulting in decreased erythrocyte survival, decrease in mean erythrocyte age or abnormal red blood cell turnover (e.g. hemolytic anemia, including hereditary spherocytosis, iron deficiency, thalassemias, malignancies, recovery from acute blood loss[27] and severe chronic hepatic and renal disease). Shortened red cell survival time will reduce the exposure of red cells to glucose, with a resultant decrease in HbA1c values. The altered red blood cell turnover interferes with the relationship between mean blood glucose and HbA1c values[6,28].
10. The HbA1c Advanced Assay requires the use of Contamination Prevention Parameters. Please refer to the latest version of the DxC 700 AU Reagent Contamination Prevention Parameters on the Beckman Coulter Website.

INTERFERENCES

Reference[19,27,29,30,31]

Drugs and Endogenous Substances

Results of studies conducted to evaluate the susceptibility of the method to interference from common or known drugs and endogenous substances that could interfere with the assay are listed below. The criteria for no significant interference is recovery within 7% of the initial value (sample containing no interferent).

No significant interference is observed from substances up to the following concentrations:

Acarbose	0.05 mg/dL
Acetaminophen	26 mg/dL
Acetylcystein	166 mg/dL
Acetylsalicylic Acid	1000 mg/dL
Ampicillin-Na	1000 mg/dL
Ascorbic Acid	300 mg/dL
Calcium Dobsilate	20 mg/dL
Cefoxitin	2500 mg/dL
Conjugated Bilirubin	60 mg/dL
Cyclosporine	0.5 mg/dL
Doxycyclin	50 mg/dL
Glucose	2000 mg/dL
Glyburide	0.12 mg/dL
Heparin	5500 IU/L
Ibuprofen	50 mg/dL
Levodopa	20 mg/dL
Lipemia	500 mg/dL
Metformin	5 mg/dL
Methyldopa	20 mg/dL
Metronidazole	200 mg/dL
Phenzylbutazone	53.5 mg/dL
Rheumatoid Factor	1000 IU/mL

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Rifampicin	8 mg/dL
Rosiglitazone maleate	0.33 mg/dL
Salicyclic Acid	4.76 mg/dL
Sitagliptin	0.2 mg/dL
Theophylline	10 mg/dL
Total Protein	21 g/dL
Unconjugated Bilirubin	60 mg/dL

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Hemoglobin Derivatives and Cross Reactants

Results of studies conducted to evaluate the susceptibility of the method to interference from common hemoglobin variants are listed below. The criteria for no significant interference is recovery within 7% of the initial value (sample containing no interferent).

No significant interference is observed from substances up to the following concentrations:

HbA0	12 mg/mL
HbA1a+b	0.16 mg/mL
Acetylated hemoglobin	0.5 mg/mL
Carbamylated hemoglobin	1.5 mg/mL
Glycated albumin	5 mg/mL
Labile HbA1c	2000 mg/dL

Hemoglobin Variants

Results of studies conducted to evaluate the susceptibility of the method to interference from common hemoglobin variants are listed below. The criteria for no significant interference is recovery within 7% of the reference value (value assigned in a Secondary Reference Laboratory).

HbC	38%
HbD	42%
HbE	36%
HbA2	6.2%
HbS	42%

No significant interference is observed from the following variants: HbC, HbD, HbE, HbS and HbA2.

The following representative data was generated using the HbA1c advanced assay on the DxC 700 AU:

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Hemoglobin Variant	No. of samples	% Variant	Range in % HbA1c Concentration	Relative % Bias (Range % Bias) 6.5% HbA1c	Relative % Bias (Range % Bias) 9.0% HbA1c
HbC	28	28.5 - 38.2	4.8 - 14.7	-2.57 (-4.30 to -1.80)	-3.19 (-6.48 to 0.41)
HbD	23	31.1 - 42.0	5.0 - 10.6	-0.77 (-4.81 to 2.99)	-1.22 (-6.30 to -0.22)
HbE	24	20.1 - 36.1	5.4 - 10.8	-1.12 (-9.16 to 2.48)	0.47 (-1.76 to 4.21)
HbS	29	31.0 - 42.0	5.0 - 12.7	-1.18 (-2.17 to 3.04)	-1.04 (-3.33 to 4.41)
HbA2	28	3.3 - 6.2	5.4 - 7.5	0.48 (-1.92 to 5.60)	2.49 (-0.98 to 3.60)

Note: Samples containing ≥7% HbF may result in lower than expected HbA1c results.

WARNING: The Hemoglobin A1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin. Refer to Limitations section.

Refer to references for further information on interfering substances.

Laboratory specific procedure notes:

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PERFORMANCE CHARACTERISTICS

METHODS COMPARISON

Reference[32]

A correlation study was performed using guidance document CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Human K2 EDTA whole blood specimen results from the HbA1c Advanced (B93009) assay on the DxC 700 AU were compared with those from an NGSP secondary reference laboratory method. Results of Deming regression in %HbA1c units were as follows:

Slope = 0.99	Intercept = 0.01 %HbA1c	r = 0.998	n = 138	Sample range = 4.7 – 14.2% HbA1c

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Using the results of the bias estimation (%bias) in the method comparison study and total precision estimates in the precision study, Total Error (TE) at four HbA1c concentrations was calculated as follows: %TE = |%Bias| + 1.96*%CV*(1+%Bias/100)[33]

% HbA1c	% Bias	% CV	% TE
5.00	-0.80	1.78	4.3
6.50	-0.85	1.69	4.2
8.00	-0.88	1.74	4.3
12.00	-0.92	1.22	3.3

PRECISION

Reference[34]

Estimates of imprecision, based on CLSI recommendations, are consistent with typical performance. Testing was conducted using 3 lots of the HbA1c Advanced kit and 3 DxC 700 AU analyzers, analyzed over 20 days. Comparative performance data for the DxC 700 AU Chemistry Analyzers evaluated using the CLSI approved guideline EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures appears in the table below. Each laboratory should characterize their own instrument performance for comparison purposes.

DxC 700 AU Chemistry Analyzer - % HbA1c (NGSP) units

HbA1c Advanced, B93009	Mean % HbA1c	Repeatability (Within-run)		Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	5.07	0.96	0.05	0.57	0.03	0.64	0.03	0.99	0.05	0.74	0.04	1.78	0.09
Human Whole Blood 2	6.72	1.00	0.07	0.41	0.03	0.55	0.04	1.05	0.07	0.56	0.04	1.69	0.11
Human Whole Blood 3	8.07	0.79	0.06	0.51	0.04	0.58	0.05	1.22	0.10	0.57	0.05	1.74	0.14
Human Whole Blood 4	11.71	0.74	0.09	0.36	0.04	0.71	0.08	0.46	0.05	0.32	0.04	1.22	0.14
Spiked Human Whole Blood	14.03	0.72	0.10	0.51	0.07	0.56	0.08	0.58	0.08	0.12	0.02	1.20	0.17
Whole Blood Control 1	5.29	1.12	0.06	0.78	0.04	0.67	0.04	1.34	0.07	0.50	0.03	2.09	0.11
Whole Blood Control 2	9.84	0.73	0.07	0.43	0.04	0.61	0.06	1.17	0.12	0.70	0.07	1.72	0.17

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DxC 700 AU Chemistry Analyzer - mmol/moL HbA1c (IFCC) units

HbA1c Advanced, B93009	Mean HbA1c mmol/moL	Repeatability (Within-run)		Between-Run		Between-Day		Between-Lot		Between Instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	31.91	1.66	0.53	1.27	0.41	1.08	0.34	1.73	0.55	1.31	0.42	3.20	1.02
Human Whole Blood 2	49.95	1.45	0.72	0.63	0.31	0.81	0.41	1.53	0.76	0.82	0.41	2.49	1.24
Human Whole Blood 3	64.75	1.08	0.70	0.69	0.45	0.79	0.51	1.66	1.07	0.77	0.50	2.37	1.53
Human Whole Blood 4	104.51	1.04	1.09	0.23	0.24	0.87	0.91	0.57	0.60	0.40	0.42	1.54	1.61
Spiked Human Whole Blood	129.84	0.85	1.10	0.58	0.76	0.67	0.87	0.69	0.89	0.14	0.19	1.42	1.84
Whole Blood Control 1	34.32	1.91	0.66	1.26	0.43	1.15	0.39	2.26	0.78	0.87	0.30	3.52	1.21
Whole Blood Control 2	84.10	0.93	0.78	0.54	0.46	0.78	0.66	1.50	1.26	0.90	0.76	2.20	1.85

ADDITIONAL INFORMATION

DxC 700 AU has a standard format for abbreviated Test Name for each reagent application. Refer to the table below for the abbreviated Test Name assigned to each application for this assay.

Test Name	Description
A1c	HbA1c
T-Hb	Total Hemoglobin
Denat	Hemolysate

Setting Sheet Footnotes
User defined

It is recommended to set Critical Limits where an audible alarm and a pl or ph flag for results outside the Analytical Measuring Range (AMR) for HbA1c% or HbA1c mmol/mol is required.

Ψ Unit for T-Hb and A1c components is shown in mmol/L. To change unit to g/dL, contact your local Beckman Coulter Representative.

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Ω HbA1c Calibrators are included in the kit and are lot specific. The concentrations (Conc.) will vary by lot number. Values set for working in mmol/l or g/dL as defined in CONFIGURATION PARAMETERS > SPECIFIC TEST PARAMETERS >TEST VOLUME AND METHODS > HBA1C>UNIT.

* Concentration of HbA1c Advanced Calibrator Level 6.

For the T-Hb Level 1 (zero) calibrator, saline should be used.

The calculation used for HbA1c% or HbA1c mmol/mol is hardcoded into the software and is not visible or editable in the Calculated Test tab.

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Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182651

Device Name
HbA1c Advanced

Indications for Use *(Describe)*
The HbA1c (Hemoglobin A1c) Advanced assay on the Beckman Coulter DxC700 AU Clinical Chemistry Analyzer, is intended for the quantitative determination of mmol/mol HbA1c (IFCC) or % HbA1c (DCCT/NGSP) concentration in human venous whole blood. The determination of HbA1c is used as an aid in the diagnosis of diabetes mellitus, for the monitoring of long-term glucose control in individuals with diabetes mellitus and identifying patients who may be at risk for developing diabetes mellitus. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Dear Catriona,

(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, December 13, 2018 11:16 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 18:27
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
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Subject: RE: k182651 HbA1c Advanced Additional information request

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Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the **(b)(4) Deficiencies** My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

clclimage002.jpg@01D41 21F.6E3AC820	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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manual signature that is included in any attachment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

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Subject: RE: k182651 HbA1c Advanced Additional information request

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Warm Regards

Catriona

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Sent: Thursday 6 December 2018 12:51

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Subject: RE: k182651 HbA1c Advanced Additional information request

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

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Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

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Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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Excellent customer service is important to us. Please take a moment to provide feedback HERE<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D531-26E-3D-26S-3DE&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=Rq_C0xWyNjnSXAf_GUEPapzsHz4QnwG5YLEFOCidsY4&e=> regarding the customer service you have received.

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Beckman Coulter Ireland Inc.,
Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

20 September 2018

U.S. Food and Drug Administration,
Center for Devices and Radiological Health,
Document Control Center - WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002.

Re: 510(k) Notification [21 CFR 807.90(e)] for HbA1c Advanced

Dear Director,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended (the Act), Beckman Coulter Ireland Inc. proposes to introduce into interstate commerce for commercial distribution a device intended for human use and hereby report to the Food and Drug Administration as required by law. This 510(k) report is being submitted at least ninety days prior to the date upon which we propose to begin introduction of the device herein described. There have been no prior submissions for this device. Beckman Coulter has submitted a Pre-Submission for this 510(k) - Reference No. Q170940. Please provide CLIA categorization.

1. Submission Type: Traditional 510(k)

2. Basis: New Reagent and Calibrator

3. Device Name: Common Name: HbA1c Advanced
Trade Name: HbA1c Advanced

4. Submitter: Beckman Coulter Ireland Inc.
Contact: Catriona Hourigan
Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.,
Lismeehan,
O' Callaghan's Mills,
Co. Clare,
Ireland.
V94 PP63

Phone: +353-65-6831417
FAX: +353-65-6831122

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

Email: chourigan@beckman.com

5. Recommended Reagent Classification: Name: Hemoglobin A1c Test System
Regulation: 862.1373
Class: II
Panel: Clinical Chemistry
Product Code: PDJ

Name: Assay Glycosylated Hemoglobin
Regulation: 864.7470
Class: II
Panel: Hematology
Product Code: LCP

Recommended Calibrator Classification: Name: Calibrator, Secondary
Regulation: 862.1150
Class: II
Panel: Clinical Chemistry
Product Code: JIT

Beckman Coulter has provided two electronic copies "eCopies" of this submission.

Beckman Coulter has included the Table of Contents in the cover letter.

We believe the foregoing information and referenced enclosures are sufficient for CDRH to make a substantial equivalence determination for this device. However, should additional information be required, it will be furnished upon request to the contact person listed above.

Sincerely,

(b)(6)

Catriona Hourigan
Beckman Coulter Ireland Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

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Registered Office: Lismeehan, O'Callaghan's Mills, Co. Clare.
Directors: Piers Devereux, Paul Henry, Orlaith A. Lawler
Incorporated in Republic of Ireland with limited liability. Co. Reg. No. 501471.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Beckman Coulter Ireland Inc.,
Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Tel. +353-65-6831100.
Fax. +353-65-6831122.

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Fax. +353-65-6831122.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

HbA1c Advanced

(b)(4) Draft

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Draft

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hi Rosemary,

Thank you so much for the quick responses also.

(b)(4)

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 13 December 2018 17:11
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, December 13, 2018 11:16 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Sent: Wednesday 12 December 2018 18:27
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 12, 2018 11:33 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,
Rosemary

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From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Best regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D41 21F 6E3ACB20	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Dear Catriona,

Best wishes for the New Year! We do not anticipate any delay in the review of k182651 as it is MDUFA funded. I will be sending it for division review this week and will let you know if we have additional questions.

Kind regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, January 07, 2019 9:06 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

Happy New to you, I hope you had a good holiday.
I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

I hope this email finds you well.

Thanks & Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 20 December 2018 18:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, December 20, 2018 12:17 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.
We look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 19:33
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

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(b)(4)

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(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 19, 2018 11:03 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 19 December 2018 15:35
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,
Thank you for your holiday schedule update. (b)(4)

(b)(4)

Best regards,
Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, December 17, 2018 12:33 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and I'm writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re – open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards
Catriona

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Monday 17 December 2018 15:26
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 18:27

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 12, 2018 11:33 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 12 December 2018 13:17

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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(b)(4)

Best regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

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Catriona Hourigan

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

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Dear Catriona,

We have received your response and will continue our review of k182651. Thank you for providing the additional information so quickly. We will let you know if we have any questions.

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Monday, December 10, 2018 12:13 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.

I look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 6 December 2018 12:51

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>>

Subject: RE: k182651 HbA1c Advanced Additional information request

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.govSubject<mailto:k185651@docs.fda.govSubject>: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[cid:image004.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.youtube.com_user_USFoodandDrugAdmin&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=MhVE9pPRkqTMadsUUybKEbapFJeV1rZLPwPqZ83sUJ4&e=>
[cid:image005.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.flickr.com_photos_fdaphotos_&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=oepR2tEHXKGuYYrTiLEutrYlF--e0-9c5AQnn4jwKxk&e=>
[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJrlQ9TDlMqTXQ&e=>

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Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary

Sent: Monday, November 19, 2018 11:49 AM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>

Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, November 19, 2018 11:27 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

[cid:image004.jpg@01D4121F.6E3ACB20]<https://www.linkedin.com/company/beckman-coulter>[cid:image006.jpg@01D4121F.6E3ACB20]<https://www.youtube.com/user/beckmancoulter>

Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Friday 16 November 2018 16:18

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Cc: k185651@docs.fda.gov<mailto:k185651@docs.fda.gov>

Subject: k182651 HbA1c Advanced Additional information request

Importance: High

Dear Catriona Hourigan,

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

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[cid:image006.jpg@01D1C57E.DFA022A0] <https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fda.gov_AboutFDA_ContactFDA_StayInformed_RSSFeeds_default.htm&d=DwMFAg&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=gQhbBAxf_Ts4oeZ7Co8JgdDck8m-w5gFySOetiNMdJ8&s=opRiOOWFOVXZoaPDBdGKl8xZIG_9SlJr1Q9TDlMqTXQ&e=>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary,

(b)(4)

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Monday 14 January 2019 19:06

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Subject: RE: K182651 additional information request

Importance: High

Dear Catriona,

K182651 is under division review and we have the following requests for additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Kind regards,

Rosemary

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From: Lusk, Rosemary

Sent: Monday, January 07, 2019 2:17 PM

To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Best wishes for the New Year! We do not anticipate any delay in the review of k182651 as it is MDUFA funded. I will be sending it for division review this week and will let you know if we have additional questions.

Kind regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, January 07, 2019 9:06 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

Happy New to you, I hope you had a good holiday.

I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

I hope this email finds you well.

Thanks & Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 20 December 2018 18:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Thursday, December 20, 2018 12:17 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 19:33

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 19, 2018 11:03 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FO-3D500-26D-3D530-26B-3D535-26E-3D-26S-3DE&d=DwMGaQ&c=9mghv0deYPYDGP-W745IEdQLV1kHpn4XJRvR6xMRXtA&r=WAWXCvJJkWa_koPeMVAmrcBdS4lESBuv6dLaeD2DCr8&m=yRF7AbnlWwrwzaO-Pztaf-txiK2oet3WDKgKov1OS28&s=wAghdHyHHHZGPy_-Q_4k2ktEOWKu1W2eNtbeNyCIQ3E&e=>

From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Dear Catriona,

Best wishes for the New Year! We do not anticipate any delay in the review of k182651 as it is MDUFA funded. I will be sending it for division review this week and will let you know if we have additional questions.

Kind regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Monday, January 07, 2019 9:06 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

Happy New to you, I hope you had a good holiday.

I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

I hope this email finds you well.

Thanks & Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 20 December 2018 18:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Many thanks for the revised documents and additional information. K182651 will be sent for management review tomorrow. I will be on leave 24 Dec and return 7 Jan. I will be checking email daily and will let you if anything urgent is needed. Please let me know if you have any questions.

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Thursday, December 20, 2018 12:17 PM

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Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 19:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

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(b)(4)

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 19, 2018 11:03 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

Thank you for your holiday schedule update. (b)(4)

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

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I look forward to hearing from you.

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Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

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FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Dear Catriona,

(b)(4)

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Wednesday, December 12, 2018 11:33 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see our responses below.

We look forward to hearing from you.

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Wednesday 12 December 2018 13:17
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona,

We have reviewed the information provided for k182651 and we have the following additional questions.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Sent: Monday, December 10, 2018 12:13 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

Please see below our responses and attached all supporting documentation.

Please advise if you need any further information.
I look forward to hearing from you.

Warm Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Thursday 6 December 2018 12:51
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,

The review of k182651 for the HbA1c Advanced is in progress and we are requesting additional information.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lusk, Rosemary
Sent: Monday, November 19, 2018 11:49 AM
To: 'Hourigan, Catriona' <CHOURIGAN@beckman.com>
Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

Dear Catriona,
Thank you for your quick response. Our review team is meeting today and the information provided is very helpful. The file number in my previous email had a typo in it, but it is corrected in this email.

Best regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Monday, November 19, 2018 11:27 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: k185651@docs.fda.gov**Subject:** RE: k182651 HbA1c Advanced Additional information request

Hi Rosemary,

I am writing in response to your query on the (b)(4) My response is in the attached document.

I look forward to working with you.

Thanks and Kind Regards
Catriona

cid:image002.jpg@01D4121F.6E3ACB20	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 16 November 2018 16:18
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k185651@docs.fda.gov
Subject: k182651 HbA1c Advanced Additional information request
Importance: High

Dear Catriona Hourigan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

Very Respectfully,

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

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Cc: 'k182651@docs.fda.gov' <k182651@docs.fda.gov>
Subject: RE: k182651 HbA1c Advanced Additional information request

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Catriona

cid:image002.jpg@01D41 21F.6E3AC820	**Catriona Hourigan**	
	REGULATORY AFFAIRS SPECIALIST Office: 353.65.683.1417 CHourigan@beckman.com www.beckmancoulter.com Lismeehan, O'Callaghan's Mills, Co Clare, Ireland	

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Tel: (240) 402-5029
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cid:image001.png@01D1C57E.DFA022A0

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%HbA1c (NGSP): HbA1c Advanced, B93009 - Whole Blood Application on the DxC 700 AU

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing

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Hi Rosemary,

Happy New to you, I hope you had a good holiday.

I am writing to enquire if the notification on the FDA website will delay the review of 510(K) K182651.

I hope this email finds you well.

Thanks & Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Thursday 20 December 2018 18:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com>

Cc: k182651@docs.fda.gov

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best wishes to you and your team for a happy holiday season. It has been a remarkable pleasure working with you.

Warm regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Thursday, December 20, 2018 12:17 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

If you need any further information, please let us know.

We look forward to hearing from you.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Warm Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 19:33

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4)

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(b)(4)

Best regards,

Rosemary

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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Wednesday, December 19, 2018 11:03 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

(b)(4)

Thanks and Kind Regards

Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]

Sent: Wednesday 19 December 2018 15:35

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Subject: RE: K182651 review will proceed via interactive review

Dear Catriona,

(b)(4)

Best regards,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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From: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Sent: Monday, December 17, 2018 12:33 PM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov<mailto:Rosemary.Lusk@fda.hhs.gov>>

Cc: k182651@docs.fda.gov<mailto:k182651@docs.fda.gov>

Subject: RE: K182651 review will proceed via interactive review

Hi Rosemary,

I received the below notification and Iâ€™m writing to inform you of our Christmas holidays. Our site will close at the end of the day on Friday the 21st December and will re â€" open on Wednesday the 2nd January 2019 (I will have access to my emails). If you require any additional information or supporting documentation, please let me know.

I look forward to hearing from you.

Thanks and Warm Regards

Catriona

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Monday 17 December 2018 15:26

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Catriona,

Thank you for your kind words. Your responsiveness to our questions and requests contributed to a successful review. Our team hopes to work with you again.

Warm regards,

Rosemary

Rosemary M. Lusk M.S., MT(ASCP)

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Division of Chemistry and Toxicology Devices

U.S. Food and Drug Administration

Tel: (240) 402-5029

rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>

[cid:image001.png@01D1C57E.DFA022A0]<http://www.fda.gov/>

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From: Hourigan, Catriona <CHOURIGAN@beckman.com>

Sent: Thursday, January 17, 2019 10:51 AM

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Subject: RE: K182651 Review Complete

Hi Rosemary,

On behalf of all the team here in Beckman Coulter Coulter Ireland Inc; we are delighted to receive the letter of substantial equivalence for HbA1c Advanced.

Thank you for a very efficient review and it has been a pleasure to work with you.

Thanks & Kind Regards

Catriona

[cid:image002.jpg@01D4121F.6E3ACB20]<https://www.beckmancoulter.com/wsrportal/wsr/index.htm>

Catriona Hourigan

[cid:image004.jpg@01D4121F.6E3ACB20]<https://www.linkedin.com/company/beckman-coulter>[cid:image006.jpg@01D4121F.6E3ACB20]<https://www.youtube.com/user/beckmancoulter>

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Regulatory Affairs Specialist

Office: 353.65.683.1417

CHourigan@beckman.com<mailto:CHourigan@beckman.com>
www.beckmancoulter.com<http://www.beckmancoulter.com/>

Lismeehan, Oâ€™Callaghanâ€™s Mills, Co Clare, Ireland

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]

Sent: Wednesday 16 January 2019 16:28

To: Hourigan, Catriona <CHOURIGAN@beckman.com<mailto:CHOURIGAN@beckman.com>>

Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov<mailto:rosemary.lusk@fda.hhs.gov>>

Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary,

Firstly apologies for not responding sooner.

Thank you for letting me know.

Regards
Catriona

From: Lusk, Rosemary [mailto:Rosemary.Lusk@fda.hhs.gov]
Sent: Friday 25 January 2019 21:19
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: k182651@docs.fda.gov
Subject: CLIA categorization for k182651

Dear Catriona,

(b)(4)

Warm regards,
Rosemary

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https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Sent: Wednesday, January 16, 2019 11:28 AM
To: chourigan@beckman.com
Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Landree, Leslie
Subject: RE: K182651 review will proceed via interactive review
Date: Monday, January 07, 2019 11:33:00 AM
Attachments: image002.png

Thanks, will do.

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Landree, Leslie
Sent: Monday, January 07, 2019 11:08 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: FW: K182651 review will proceed via interactive review

Hi Rosemary –

Welcome back and Happy New Year!

How it this review coming? I will need your completed SE package by this Wednesday (1/9) at the latest so that we can get it to Kellie this Friday (3 business days before the due date, Wednesday 1/16).

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Sent: Monday, December 17, 2018 10:26 AM
To: chourigan@beckman.com
Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Lessard, Juliane
Cc: Landree, Leslie
Subject: RE: k182651 (b)(5)
Date: Thursday, December 13, 2018 3:12:00 PM
Attachments: image001.png
image007.png
image008.png
image011.png

Thanks Juliane!

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lessard, Juliane
Sent: Thursday, December 13, 2018 3:11 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

have received by clicking here.

From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:04 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Hi Leslie and Juliane,

(b)(5)

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Thanks,

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lessard, Juliane
Sent: Thursday, December 13, 2018 1:12 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Hi Rosemary,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 Documents for PS review

HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 (b)(5)
Date: Friday, December 14, 2018 7:46:00 AM
Attachments: image008.png
image019.png
image025.png
image026.png
image027.png

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Landree, Leslie
Sent: Thursday, December 13, 2018 3:43 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 **(b)(4) Deficiencies**

(b)(5)

Thanks!
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:13 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

Thanks Juliane!

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lessard, Juliane
Sent: Thursday, December 13, 2018 3:11 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Subject: RE: k182651 **(b)(5)**

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:04 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

Hi Leslie and Juliane,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Thanks,

Rosemary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Lessard, Juliane
Sent: Thursday, December 13, 2018 1:12 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Hi Rosemary,

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 (b)(5)

HI Juliane,
The k182651 Documents are attached for your review

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Landree, Leslie
Subject: RE: k182651 (b)(5)
Date: Friday, December 14, 2018 1:51:00 PM
Attachments: k182651.LeadMemo.PI.pdf
image002.png
image013.png

Hi Leslie,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Landree, Leslie
Sent: Friday, December 14, 2018 12:19 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 update

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Friday, December 14, 2018 10:11 AM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 update

Hi Kellie,

(b)(5)

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Kelm, Kellie
Sent: Friday, December 14, 2018 9:41 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 update

Rosemary and Leslie – are you still planning to PI this file?

Thanks,
Kellie

Kellie B. Kelm, Ph.D
Deputy Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
Tel: 301-796-6145

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

MEMORANDUM TO FILE

Date: December 14, 2018
From: Rosemary Lusk, Lead Reviewer
(CDRH/OIR/DCTD)

To: The Record of k182651

Subject: Recommendation "PI" (proceed interactively)

Sponsor: Beckman Coulter Ireland Inc.

Device: HbA1c Advanced assay

(b)(5)

Rosemary Lusk -S
Digitally signed by Rosemary Lusk -S
Date: 2018.12.14 13:45:05 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Kelm, Kellie; Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:48:00 PM
Attachments: k182651 (b)(5)
image001.png
k182651 (b)(5)
k182651
k182651
k182651

Hi Kellie,
The current documents are attached. Please let me know if you have any questions.

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Kelm, Kellie
Sent: Monday, January 14, 2019 12:32 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Hi,

(b)(5)

Thanks,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

(b)(5)

Thanks,
Kellie

From: Landree, Leslie
Sent: Friday, January 11, 2019 4:25 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

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From: Lusk, Rosemary
Sent: Wednesday, January 09, 2019 2:16 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

Hi,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Beckman Coulter Ireland Inc.
Catriona Hourigan
Regulatory Affairs Specialist
Lismeehan
O' Callaghan's Mills, IE V94 PP63 Co. Clare

Re: K182651
Trade/Device Name: HbA1c Advanced
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c test system
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: September 20, 2018
Received: September 24, 2018

Dear Catriona Hourigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LETTER SHOULD BE DATED BEFORE SIGNING, AND MUST BE SIGNED OUT OF CTS ON THE DATE INDICATED ON THE LETTER.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(4) Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

510(k) Summary

(b)(4) Draft

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

(b)(5)

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From: Lusk, Rosemary
To: Landree, Leslie
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:49:00 PM
Attachments: image002.png
image013.png

Done, thanks Leslie.

Rosemary

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From: Landree, Leslie
Sent: Monday, January 14, 2019 12:44 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Kelm, Kellie
Sent: Monday, January 14, 2019 12:32 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Hi,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

(b)(5)

Thanks,
Kellie

From: Landree, Leslie
Sent: Friday, January 11, 2019 4:25 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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Center for Devices and Radiological Health
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leslie.landree@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Wednesday, January 09, 2019 2:16 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

Hi,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

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From: Lusk, Rosemary
To: Kelm, Kellie; Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 3:10:00 PM
Attachments: image001.png

Thanks Kellie,

(b)(5)

Rosemary

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From: Kelm, Kellie
Sent: Monday, January 14, 2019 3:06 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Thanks,
Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

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From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
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To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.

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From: Lusk, Rosemary
To: Kelm, Kellie; Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:28:00 PM
Attachments: k182651.DM.TC.01.14.19.docx
image007.png

Hi,

(b)(5)

Thanks,
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From: Kelm, Kellie
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To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
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Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
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From: Lusk, Rosemary
To: Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 (b)(5)
Date: Thursday, December 06, 2018 7:56:00 AM
Attachments: k182651 (b)(5)
image002.png
image015.png
image016.png

Hi Leslie,

(b)(5)

Thanks,
Rosemary

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From: Landree, Leslie
Sent: Tuesday, December 04, 2018 4:10 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 (b)(5)

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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leslie.landree@fda.hhs.gov

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From: Lessard, Juliane
Sent: Friday, November 30, 2018 10:51 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 (b)(5)

Hi Rosemary,

(b)(5)

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(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

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Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

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From: Lusk, Rosemary
To: Kelm, Kellie; Landree, Leslie
Subject: RE: k182651 update
Date: Friday, December 14, 2018 10:11:00 AM
Attachments: image007.png

Hi Kellie,

(b)(5)

Rosemary

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From: Kelm, Kellie
Sent: Friday, December 14, 2018 9:41 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 update

(b)(5)

Thanks,
Kellie

Kellie B. Kelm, Ph.D
Deputy Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
Tel: 301-796-6145

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Landree, Leslie
Subject: k182651 Beckman HbA1c Advanced-(b)(5)
Date: Thursday, November 01, 2018 3:06:00 PM

Hi Leslie,
k182651 Beckman HbA1c Advanced- **(b)(5)**
(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lusk, Rosemary
To: Lessard, Juliane
Subject: k182651 Documents for PS review
Date: Wednesday, December 12, 2018 5:10:00 PM
Attachments: k182651.Labeling.FINAL.pdf
k182651.IFU.FINAL.pdf
k182651.510Summary.FINAL.pdf
k182651.DM.TC.docx

HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

(b)(4) Draft

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510(k) Summary

HbA1c Advanced

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From: Lusk, Rosemary
To: Landree, Leslie
Cc: Lessard, Juliane
Subject: k182651 HbA1c Advanced
Date: Wednesday, January 09, 2019 2:16:00 PM
Attachments: k182651.DM.TC.docx

Hi,
The DM is attached for review. The SE letter, IFU, Labeling, 510k Summary and Internal email pdf are in DocMan.
Thanks,
Rosemary

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5) FDA Reviewer Notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Subject: FW: K182651 review will proceed via interactive review
Date: Monday, January 07, 2019 11:08:24 AM
Attachments: image002.png

Hi Rosemary –

Welcome back and Happy New Year!

How it this review coming? I will need your completed SE package by this Wednesday (1/9) at the latest so that we can get it to Kellie this Friday (3 business days before the due date, Wednesday 1/16).
Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Sent: Monday, December 17, 2018 10:26 AM
To: chourigan@beckman.com
Cc: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: K182651 review will proceed via interactive review

December 17, 2018

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K182651 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lessard, Juliane
To: Lusk, Rosemary
Cc: Landree, Leslie
Subject: RE: k182651 (b)(5)
Date: Thursday, December 13, 2018 3:11:02 PM
Attachments: image001.png
image007.png
image008.png
image009.png

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:04 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Hi Leslie and Juliane,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

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Thanks,

Rosemary

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From: Lessard, Juliane
Sent: Thursday, December 13, 2018 1:12 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 Documents for PS review

Hi Rosemary,

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
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Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 Documents for PS review

HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Cc: Lessard, Juliane
Subject: RE: k182651 (b)(5)
Date: Thursday, December 13, 2018 3:43:01 PM
Attachments: image001.png
image027.png
image028.png
image029.png
image002.png

(b)(5)

Thanks!
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
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From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:13 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Thanks Juliane!

Rosemary

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From: Lessard, Juliane
Sent: Thursday, December 13, 2018 3:11 PM

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

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U.S. FOOD & DRUG ADMINISTRATION

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From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:04 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

Hi Leslie and Juliane,

(b)(5)

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(b)(5)

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Rosemary

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From: Lessard, Juliane
Sent: Thursday, December 13, 2018 1:12 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 Documents for PS review

Hi Rosemary,

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
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Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

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From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 Documents for PS review

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lessard, Juliane
To: Lusk, Rosemary; Landree, Leslie
Subject: RE: k182651 (b)(5)
Date: Friday, December 14, 2018 7:55:15 AM
Attachments: image001.png
image007.png
image013.png
image014.png
image015.png

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

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U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Friday, December 14, 2018 7:47 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

Hi Leslie and Juliane,

(b)(5)

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(b)(5)

Rosemary

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From: Landree, Leslie
Sent: Thursday, December 13, 2018 3:43 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 (b)(5)

(b)(5)

Thanks!
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

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U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

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From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:13 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

Thanks Juliane!

Rosemary

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From: Lessard, Juliane
Sent: Thursday, December 13, 2018 3:11 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

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U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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From: Lusk, Rosemary
Sent: Thursday, December 13, 2018 3:04 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 **(b)(5)**

Hi Leslie and Juliane,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Thanks,

Rosemary

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From: Lessard, Juliane
Sent: Thursday, December 13, 2018 1:12 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 Documents for PS review

Hi Rosemary,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received by clicking here.

From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 Documents for PS review

HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Subject: RE: k182651 CTS ready -PI recommendation
Date: Friday, December 14, 2018 1:54:28 PM
Attachments: image008.png
image015.png
image002.png

Thanks Rosemary!

Enjoy your weekend

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Friday, December 14, 2018 1:52 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 CTS ready -PI recommendation

Hi Leslie,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Landree, Leslie
Sent: Friday, December 14, 2018 12:19 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 update

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Friday, December 14, 2018 10:11 AM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 update

Hi Kellie,

(b)(5)

Rosemary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

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From: Kelm, Kellie
Sent: Friday, December 14, 2018 9:41 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 update

Rosemary and Leslie – are you still planning to PI this file?

Thanks,
Kellie

Kellie B. Kelm, Ph.D
Deputy Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
Tel: 301-796-6145

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lessard, Juliane
To: Lusk, Rosemary
Cc: Landree, Leslie
Subject: RE: k182651 Documents for PS review
Date: Thursday, December 13, 2018 1:12:19 PM
Attachments: k182651 (b)(5)
k182651
image001.png

Hi Rosemary,

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

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From: Lusk, Rosemary
Sent: Wednesday, December 12, 2018 5:11 PM
To: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 Documents for PS review

HI Juliane,
The k182651 Documents are attached for your review

Thanks,
Rosemary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

(b)(5) FDA drafts

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To: Lusk, Rosemary
Cc: Lessard, Juliane; Kelm, Kellie
Subject: RE: k182651 HbA1c Advanced
Date: Friday, January 11, 2019 4:24:38 PM
Attachments: k182651 (b)(5)
k182651
k182651
image013.png

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

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Thanks,

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Rosemary

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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

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510(k) Summary

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From: Kelm, Kellie
To: Landree, Leslie; Lusk, Rosemary
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced
Date: Saturday, January 12, 2019 8:19:20 AM
Attachments: image013.png

(b)(5)

From: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Date: January 11, 2019 at 4:24:39 PM EST
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>, Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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Hi,

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Subject: RE: k182651 HbA1c Advanced
Date: Sunday, January 13, 2019 7:38:41 PM
Attachments: image002.png

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Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

Sent: Wednesday, January 09, 2019 2:16 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

Hi,

(b)(5)

Thanks,
Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Kelm, Kellie
To: Landree, Leslie; Lusk, Rosemary
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced
Date: Monday, January 14, 2019 11:58:45 AM
Attachments: image001.png

(b)(5)

Thanks,
Kellie

From: Landree, Leslie
Sent: Friday, January 11, 2019 4:25 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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Sent: Wednesday, January 09, 2019 2:16 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced
Date: Wednesday, January 09, 2019 4:17:16 PM
Attachments: image007.png

Thanks Rosemary

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
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U.S. Food and Drug Administration
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From: Lusk, Rosemary
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To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

Hi,

(b)(5)

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Kelm, Kellie; Lusk, Rosemary
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:43:48 PM
Attachments: image019.png
image007.png

(b)(5)

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Kelm, Kellie
Sent: Monday, January 14, 2019 12:32 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Hi,

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Thanks,
Rosemary

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From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

(b)(5)

Thanks,
Kellie

From: Landree, Leslie
Sent: Friday, January 11, 2019 4:25 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Lusk, Rosemary
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To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

Hi,

(b)(5)

Thanks,
Rosemary

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:55:00 PM
Attachments: image019.png
image025.png
image002.png

Thanks!

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (**click here**).

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:50 PM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Done, thanks Leslie.

Rosemary

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Landree, Leslie
Sent: Monday, January 14, 2019 12:44 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Leslie Landree, Ph.D.
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leslie.landree@fda.hhs.gov

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From: Kelm, Kellie
Sent: Monday, January 14, 2019 12:32 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

(b)(5)

Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

Hi,

(b)(5)

Thanks,
Rosemary

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the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=500&D=530&B=535&E=&S=E

From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

(b)(5)

Thanks,
Kellie

From: Landree, Leslie
Sent: Friday, January 11, 2019 4:25 PM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

Please let me know if you have any questions.

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
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From: Kelm, Kellie
To: Lusk, Rosemary; Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 3:06:23 PM
Attachments: image001.png

(b)(5)

Thanks,
Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced Update

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(b)(5)

Thanks,
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From: Kelm, Kellie
Sent: Monday, January 14, 2019 11:59 AM
To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>; Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

(b)(5)

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Sent: Friday, January 11, 2019 4:25 PM
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Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>; Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>
Subject: RE: k182651 HbA1c Advanced

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(b)(5)

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Diabetes Team Leader, Division of Chemistry and Toxicology Devices

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To: Landree, Leslie <Leslie.Landree@fda.hhs.gov>

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Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
Subject: k182651 HbA1c Advanced

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(b)(5)

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From: Kelm, Kellie
To: Lusk, Rosemary; Landree, Leslie
Cc: Lessard, Juliane
Subject: RE: k182651 HbA1c Advanced Update
Date: Monday, January 14, 2019 12:32:23 PM
Attachments: image001.png

(b)(5)

Kellie

From: Lusk, Rosemary
Sent: Monday, January 14, 2019 12:29 PM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Cc: Lessard, Juliane <Juliane.Lessard@fda.hhs.gov>
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Subject: RE: k182651 HbA1c Advanced

Hi Rosemary –

(b)(5)

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Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Cc: Kelm, Kellie; Lessard, Juliane
Subject: RE: k182651 update
Date: Friday, December 14, 2018 12:19:29 PM
Attachments: image019.png
image007.png

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

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From: Lusk, Rosemary
Sent: Friday, December 14, 2018 10:11 AM
To: Kelm, Kellie <Kellie.Kelm@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: RE: k182651 update

Hi Kellie,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Rosemary

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From: Kelm, Kellie
Sent: Friday, December 14, 2018 9:41 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>; Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 update

(b)(5)

Thanks,
Kellie

Kellie B. Kelm, Ph.D
Deputy Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
Tel: 301-796-6145

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Lessard, Juliane
To: Lusk, Rosemary
Cc: Landree, Leslie
Subject: k182651 Intralipid
Date: Friday, November 30, 2018 10:50:59 AM
Attachments: image001.png
image007.png

Hi Rosemary,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Landree, Leslie
To: Lusk, Rosemary
Cc: Lessard, Juliane
Subject: k182651 PI or SE by 12/17?
Date: Tuesday, December 04, 2018 4:09:56 PM
Attachments: image001.png
image008.png
image014.png

Hi Rosemary –

(b)(5)

Thank you,
Leslie

Leslie Landree, Ph.D.
Diabetes Team Leader, Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6147
leslie.landree@fda.hhs.gov

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From: Lessard, Juliane
Sent: Friday, November 30, 2018 10:51 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Cc: Landree, Leslie <Leslie.Landree@fda.hhs.gov>
Subject: k182651 Intralipid

Hi Rosemary,

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Thanks,
Juliane

Juliane C. Lessard, Ph.D.
Scientific Reviewer
Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. Food and Drug Administration
Tel: 240-402-6126
juliane.lessard@fda.hhs.gov

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Records processed under FOIA Request 2023-1587; Released by CDRH on 04-04-2024

From: Kelm, Kellie
To: Lusk, Rosemary; Landree, Leslie
Subject: k182651 update
Date: Friday, December 14, 2018 9:41:05 AM
Attachments: image001.png

Rosemary and Leslie – are you still planning to PI this file?

Thanks,
Kellie

Kellie B. Kelm, Ph.D
Deputy Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
Tel: 301-796-6145

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K182651 Date Received by DCC: Oct 18, 2018

Lead Reviewer: Rosemary Lusk

Branch: DDDB Division: DCTD Center/Office: CDRH/OIR

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4) Is the submission for a combination product that contains as a constituent part an approved drug that is under exclusive marketing rights? (503(g)(5)) If "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.		X	
Comments:			
5) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
6) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
7) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."		X	
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data	X				
a) Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators.*			X		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	X				
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	X				
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison.			X		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
B. Device Description					
11) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding device description that is applicable to the subject device.	X				
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
12) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
13) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
14) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
C. Substantial Equivalence Discussion					
15) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
16) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
18) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
19) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
20) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.	X				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	X				
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			X		
F. Shelf Life					
26) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
27) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.			X		
28) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			X		
Submission states that there: (one of the below must be checked)					
H. Software					
Submission states that the device: (one of the below must be checked)					
	Does contain software/firmware				
X	Does not contain software/firmware				
	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Software/firmware information not needed for this device (e.g., surgical suture, condom)				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
	Does require electrical safety evaluation				
X	Does not require electrical safety evaluation				
	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
	Electrical safety information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
	Does require EMC evaluation				
X	Does not require EMC evaluation				
	Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	EMC information not needed for this device (e.g., surgical suture, condom)				
	EMC information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
X	is an in vitro diagnostic device.				
	is not an in vitro diagnostic device.				
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					
40) Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
a) Precision/reproducibility		X			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	X				
c) Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	X				
d) Analytical specificity	X				
41) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				

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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Is an Addendum attached?: ( ) Yes (•) No Click paperclip icon on the left panel if Addendum is attached.

Digital Signature Concurrence Table

Reviewer Sign-Off	Rosemary Lusk -S Digitally signed by Rosemary Lusk -S Date: 2018.11.01 14:56:48 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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Dear Catriona,

Thank you for your kind words. Your responsiveness to our questions and requests contributed to a successful review. Our team hopes to work with you again.

Warm regards,
Rosemary

Rosemary M. Lusk M.S., MT(ASCP)
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices
U.S. Food and Drug Administration
Tel: (240) 402-5029
rosemary.lusk@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

Excellent customer service is important to us. Please take a moment to provide feedback HERE regarding the customer service you have received.

From: Hourigan, Catriona <CHOURIGAN@beckman.com>
Sent: Thursday, January 17, 2019 10:51 AM
To: Lusk, Rosemary <Rosemary.Lusk@fda.hhs.gov>
Subject: RE: K182651 Review Complete

Hi Rosemary,

On behalf of all the team here in Beckman Coulter Coulter Ireland Inc; we are delighted to receive the letter of substantial equivalence for HbA1c Advanced.

Thank you for a very efficient review and it has been a pleasure to work with you.

Thanks & Kind Regards
Catriona

cid:image002.jpg@01D4:31F6E3A0.820

Catriona Hourigan

REGULATORY AFFAIRS SPECIALIST
Office: 353.65.683.1417
CHourigan@beckman.com www.beckmancoulter.com
Lismeehan, O'Callaghan's Mills, Co Clare, Ireland

From: Rosemary Lusk [mailto:rosemary.lusk@fda.hhs.gov]
Sent: Wednesday 16 January 2019 16:28
To: Hourigan, Catriona <CHOURIGAN@beckman.com>
Cc: Rosemary Lusk <rosemary.lusk@fda.hhs.gov>
Subject: K182651 Review Complete

January 16, 2019

We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Rosemary Lusk.

*** This is a system-generated email notification ***

Please be advised that this email may contain confidential information. If you are not the intended recipient, please notify us by email by replying to the sender and delete this message. The sender disclaims that the content of this email constitutes an offer to enter into, or the acceptance of, any agreement; provided that the foregoing does not invalidate the binding effect of any digital or other electronic reproduction of a manual signature that is included in any attachment.

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From: Massey, Cherryace * [Cherryace.Massey@fda.hhs.gov]
Sent: 9/24/2018 10:17:26 PM
To: chourigan@beckman.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K182651 User Fee Notification
Attachments: User%20Fee%20Hold%20Letter.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

User Fee Hold Letter

9/24/2018

Catriona Hourigan, Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.
Lismeehan
O' Callaghan's Mills, Co. Clare V94 PP63
IRELAND

Dear Catriona Hourigan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K182651
Received: 9/24/2018
Applicant: Beckman Coulter Ireland Inc.
Device: HbA1c Advanced

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), and the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain types of submissions. This submission cannot be accepted for review until the user fee is paid in full.

You have received this letter because we have not received your payment in full. Additional information on user fees, including how and where to submit your user fee payment and how to generate a User Fee Cover Sheet, may be found on our webpage entitled, "User Fees" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm540444.htm.

In addition, please fax a completed copy of the User Fee Cover Sheet that includes the specific submission number above and the Payment Identification Number for this submission to our CDRH Document Control Center at (301) 847-8113.

You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to pay by check, make the check out to the Food and Drug Administration and reference the payment identification number, include a copy of the User Fee Cover sheet with the check, and mail them to one of the addresses listed below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733

By Private Courier (e.g., Fed Ex, UPS)
U.S. Bank
Attn: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4821

When we have been notified that your full user fee payment has been received, review of the submission will resume as of that date. Alternatively, you may request withdrawal of your submission.

If payment has not been received within 30 days, your submission will be deleted from our system.

If you have any questions concerning this letter, please contact 510(k) Staff at (301) 796-5640 or by email at 510K_Program@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

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Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2019. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BECKMAN COULTER INC BECKMAN COULTER, INC. 200 S KRAEMER BLVD BREA CA 92821 US US	Marguerita Sweeney 2.1 E-MAIL ADDRESS msweeney@beckman.com 2.2 TELEPHONE NUMBER (include Area code) 00353-683 1495 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0600	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)	12-Sep-2018

Form FDA 3601 (08/16)

"Close Window" Print Cover sheet

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June 02, 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Pre-Submission for a 510(k) – HbA1c Advanced reagent

Beckman Coulter is submitting a Pre-Submission for your review. Enclosed are two copies (one original paper copy and one electronic "e-copy") of the pre-submission for the HbA1c Advanced reagent 510(k) submission. **The enclosed eCopy is an exact duplicate of the paper copy being submitted.**

The following information is submitted for your consideration:

1. Submission Type: Pre-Submission

2. Reason: Clarification on Testing Requirements and Proposed Predicate

3. Device Name: Product Name: Hemoglobin A1c Test System
   Trade Name: HbA1c Advanced

4. Submitter: Beckman Coulter Ireland Inc.
   Contact:

Eimear Carr
Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.,
Lismeehan,
O' Callaghan's Mills,
Co. Clare,
Ireland.
Telephone: +353 683 1483
Email: ecarr@beckman.com

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Secondary Contact:

Marguerita Sweeney
Regulatory Affairs Manager
Beckman Coulter Ireland Inc.,
Lismeehan,
O' Callaghan's Mills,
Co. Clare,
Ireland.
Telephone: +353 683 1495
Email: MSweeney@beckman.com

5. Recommended Reagent Classification:

Name: Hemoglobin A1c Test System
Regulation: 862.1373
Class: II
Panel: Clinical Chemistry
Product Code: PDJ

Recommended Calibrator Classification:

Name: Calibrator, Secondary
Regulation: 862.1150
Class: II
Panel: Clinical Chemistry
Product Code: JIT

(b)(4)

Sincerely,

_____
Eimear Carr

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 2.0 - Device Description

(b)(4)

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Section 3.0 - Proposed FDA Classification for HbA1c Advanced Reagent

(b)(4)

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Section 5.0 - Predicate Review

(b)(4)

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Section 6.0 - Proposed Study Design

(b)(4)

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18.1 Precision / Reproducibility

(b)(4)

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(b)(4) Testing

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18.2 Dynamic Range/ Analytical Measuring Range (Linearity)

(b)(4)

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18.3 Method Comparison

(b)(4)

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18.4 Anticoagulants

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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18.6 Interferences (Analytical Specificity)

(b)(4)

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18.8 Limit of Detection

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U.S. FOOD & DRUG
ADMINISTRATION

January 16, 2019

Beckman Coulter Ireland Inc.
Catriona Hourigan, Regulatory Affairs Specialist
Lismeehan
O' Callaghan's Mills
Co. Clare
Ireland
V94 PP63

Re: k182651
Trade/Device Name: HbA1c Advanced
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c test system
Regulatory Class: Class II
Product Code: PDJ, LCP
Dated: September 20, 2018
Received: September 24, 2018

Dear Catriona Hourigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
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Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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