DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SEBIA, INC.
KAREN ANDERSON
DIRECTOR OF TECHNICAL AND QUALITY ASSURANCE
1705 CORPORATE DRIVE, SUITE 400
NORCROSS GA 30093

February 17, 2017

Re: K162281
Trade/Device Name: CAPI 3 Hb A1c
MULTI-SYSTEM Hb A1c CAPILLARY Controls (2)
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JJX
Dated: August 8, 2016
Received: August 15, 2016

Dear Karen Anderson:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CAPI 3 Hb A1c

Indications for Use *(Describe)*
The CAPI 3 Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in venous whole human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 3 TERA instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. This test is not for screening or diagnosis of diabetes. The CAPI 3 Hb A1c kit is designed for Professional 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.

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

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The burden time for this collection of information is estimated to average 79 hours 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
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MULTI-SYSTEM Hb A1c CAPILLARY CONTROLS (2)

Indications for Use *(Describe)*
The Multi-system Hb A1c CAPILLARY Controls (2) are designed for the migration control and quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures:
- CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument,
- CAPI 3 Hb A1c performed with the CAPILLARYS 3 TERA automated instrument and,
- MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument.

The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

For In Vitro Use.

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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510K SUMMARY (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Sebia, Inc.
Address	1705 Corporate Drive Suite 400 Norcross, Georgia 30093, USA
Contact	Karen Anderson, Dir of Technical and QA Phone: 1-800-835-6497 Fax: 770-446-8511 Email: karen.anderson@sebia-usa.com Aigars Brants, Ph.D, Scientific Affairs Officer Phone 1-800-835-6497 Fax 770-446-8511 Email: aigars.brants@sebia-usa.com
Date Prepared	July 25, 2016 / Revised February 14, 2017
Manufacturing	Sebia Parc Technologique Léonard de Vinci Rue Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex FRANCE Phone: (33) 1 69 89 80 80 Fax: (33) 1 69 89 78 78
Product Name	CAPI 3 Hb A1c (PN 2515), MULTI-SYSTEM Hb A1c CAPILLARY Controls (2) (PN 4768) using CAPILLARYS 3 TERA instrument (PN 1246)
Common Name	Whole blood hemoglobin A1c (HbA1c) by capillary electrophoresis
Product Regulation No.	21 CFR Part 864.7470,862.1660
Product Codes	LCP, JJX
Device classification	Class II , Class I (general controls)
Establishment Registration No.	8023024

Predicate Device Name	Predicate Device 510(k) number
CAPILLARYS Hb A1c kit	K122101
Hb A1c CAPILLARY Controls	K122101 and K133344
CAPILLARYS 2 FLEX-PIERCING instrument	K122101

1. DEVICE DESCRIPTION

The capillary electrophoresis provides complete automation with fast separation and good resolution. This electrokinetic separation technique is carried out in a silica glass tube (i.e., capillary) with internal diameter lower than 100 µm filled with a buffer composed of electrolytes.

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation occurs according to the electrolyte pH and electroosmotic flow.

The CAPILLARYS 3 TERA instrument has silica capillaries functioning in parallel allowing 12 simultaneous analyses of HbA1c quantification in a whole blood sample. A sample dilution with hemolysing solution is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the hemoglobins is made at the cathodic end of the capillary at 415 nm, which is the absorbance wave length specific to hemoglobins. Before each run, the capillaries are washed with a wash solution and prepared for the next analysis with buffer.

Direct detection provides accurate relative quantification of individual hemoglobin A1c fraction. In addition, the high resolution of CAPI 3 Hb A1c procedure allows the quantification of HbA1c even in the presence of labile HbA1c, carbamylated and acetylated hemoglobins, and major hemoglobin variants.

By using an alkaline pH buffer, normal and abnormal (or variant) hemoglobins are detected in the following order, from cathode to anode: A2/C, E, S/D, F, A0, other Hb (including minor Hb A1) and then A1c.

Reagents:

CAPI 3 Hb A1c KIT

ITEMS	PN 2515
Buffer (ready to use)	2 vials, 700 mL each
Hemolysing solution (ready to use)	1 vial, 700 mL
Filters	4 filters

Additional reagents not included in the CAPI 3 Hb A1c KIT

ITEMS	PN	COMPONENTS
CAPICLEAN CAPILLARYS 3	2060	1 vial, 25 mL
CAPILLARYS 3 WASH SOLUTION	2062	1 vial, 75mL
CAPI 3 DISPOSABLES KIT	2580	10 packs of 14 reagent cups 5 bins for used reagent cups
TEST TUBES	9214	200 of 100mm-tubes
CAPI 3 BINS FOR USED REAGENT CUPS	2581	5 units
TUBES AND CAPS FOR CONTROLS	9202 9205	20 units 500 units

2. INDICATIONS FOR USE

CAPI 3 Hb A1c kit:

The CAPI 3 Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in venous whole blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 3 TERA instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. This test is not for screening or diagnosis of diabetes. The CAPI 3 Hb A1c kit is designed for Professional Use Only.

For *In Vitro* Diagnostic Use.

MULTI-SYSTEM Hb A1c CAPILLARY CONTROLS (2):

The Multi-system Hb A1c CAPILLARY Controls (2) are designed for the migration control and quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures:

- CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument,
- CAPI 3 Hb A1c performed with the CAPILLARYS 3 TERA automated instrument and, - MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument. The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

For *In Vitro* Use.

3. TECHNOLOGICAL CHARACTERISTICS

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in free solution which is the most common form of capillary electrophoresis. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow.

The CAPILLARYS 3 TERA instrument has silica capillaries functioning in parallel allowing 12 simultaneous analyses of Hb A1c quantification in a whole blood sample. A sample dilution with hemolysing solution is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the hemoglobins is made at the cathodic end of the capillary at 415 nm, which is the absorbance wave length specific to hemoglobins. Before each run, the capillaries are washed with a wash solution and prepared for the next analysis with buffer.

Direct detection provides accurate relative quantification of individual hemoglobin A1c fraction. In addition, the high resolution of CAPI 3 Hb A1c procedure allows the quantification of HbA1c, and particularly, even in the presence of labile HbA1c, carbamylated and acetylated hemoglobins, and major hemoglobin variants.

By using an alkaline pH buffer, normal and abnormal (or variant) hemoglobins are detected in the following order, from cathode to anode: A2/C, E, S/D, F, A0, other Hb (including minor Hb A1) and then A1c.

SUBSTANTIAL EQUIVALENCE INFORMATION:

Predicate Device Name	Predicate Device 510(k) number
CAPILLARYS Hb A1c	K122101
Hb A1c CAPILLARY Controls	K122101 and K133344

The technological characteristics of the CAPI 3 Hb A1c procedure using the CAPILLARYS 3 TERA instrument (candidate device) utilizes the same principles of capillary electrophoresis in an alkaline buffer reading at a wavelength of 415 nm as the CAPILLARYS Hb A1c procedure (predicate device).

Table A.
Similarities and differences between the predicate device (CAPILLARYS Hb A1c) and the candidate device (CAPI 3 Hb A1c). Both are members of the Sebia CAPILLARYS family of instruments.

Table A	SEBIA CAPILLARYS Hb A1c (K) 122101	SEBIA CAPI 3 Hb A1c
Intended Use	The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 2 FLEX-PIERCING instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus. The CAPILLARYS Hb A1c kit is designed for Professional Use Only. For *In Vitro* Diagnostic Use.	The CAPI 3 Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in venous whole blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 3 TERA instrument. Measurement of hemoglobin A1c is effective in monitoring long-term glycemic control in individuals with diabetes mellitus.This test is not for screening or diagnosis of diabetes. The CAPI 3 Hb A1c kit is designed for Professional Use Only. For *In Vitro* Diagnostic Use.
Separation system	Free solution capillary electrophoresis (FSCE): hemoglobin separation on an alkaline buffer (pH 9.4) according to their charge, to the electrolyte pH and electroosmotic flow. Fast separation and good resolution. Electrophoregrams show separated fractions according to their charge.	Same
Reagent	CAPILLARYS Hb A1c Kit (PN 2015) :	CAPI 3 Hb A1c Kit (PN 2515) :
Composition	Buffer (ready to use) : 2 vials, 700 mL each Hemolysing solution (ready to use) : 1 vial, 700 mL Wash solution (stock solution) : 1 vial, 75 mL Dilution segments : 1 pack of 90 Filters : 4 filters	Buffer (ready to use) : 2 vials, 700 mL each Hemolysing solution (ready to use) : 1 vial, 700 mL Filters : 4 filters
Shelf life (*)	Buffer : 3 years at 2 – 8 °C Hemolysing solution : 3 years at 2 – 30 °C	Same
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING instrument, PN 1227	SEBIA CAPILLARYS 3 TERA instrument, PN 1246
Analysis throughput	40 analyses / hour	62 analyses / hour
Interface	PC interface	PC interface + touch screen
Temperature Control	By Peltier device	Same

Detection system	Deuterium lamp	Deuterium lamp and LED
Software for data processing	SEBIA PHORESIS™ software	Same
Firmware	Included into the PHORESIS software	Included into the instrument
Number of separation units	8 parallel capillaries	12 parallel capillaries
Samples tubes	Uncapped tubes or capped tubes depending on the procedure	Same
Samples identification	Yes (Bar code reading on both sample racks and tubes)	Yes (Bar code reading on sample tubes and RFID labels on sample racks)
Reagent identification	No	Yes (RFID labels on reagent vials)
Introduction of the samples into the automatic system	Primary capacity of 88 tubes for HbA1c technique (i.e. 11 sample racks), uninterrupted throughput on sample racks. Each sample rack contains 8 sample tube.	Primary maximal capacity of 120 tubes (i.e. 15 sample racks), uninterrupted throughput on sample racks (8 positions available).
Reagent bay : main compartement	CAPILLARYS 2 FLEX-PIERCING: Contains one vial of water, wash solution, hemolyzing solution (for Hb and Hb A1c techniques) and buffer container.	Up to 4 analysis buffers or hemolysing solutions (identified by RFID labels); 1 waste container, 1 container for water, 1 container for the wash solution
Reagent bay : secondary compartment	NA	Up to 3 vials and 1 rack with immunotyping reagents (all RFID tagged) in temperature controlled environment (< 15 °C); 1 RFID labeled vial and three tubes (for maintenance solutions) at room temperature
Dimensions	L. 95 cm x H. 39 cm x D. 63 cm	L. 90 cm x H. 54 cm x D. 67 cm
Weight	50 kg	75 kg

(*) The reagent shelf life (buffer and hemolysing solution) has been extended (3 years instead of 2 years)

Table B. Similarities and differences between the candidate device (Multi-system Hb A1c CAPILLARY Controls (2)) and the predicate device (Hb A1c CAPILLARY Controls).

TABLE C	SEBIA Hb A1c CAPILLARY Controls K122101 and K133344	SEBIA Multi-system Hb A1c CAPILLARY Controls (2)
Intended Use	The Hb A1c CAPILLARY Controls are designed for the migration control and quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures : - CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument and, - MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument. The Hb A1c CAPILLARY Controls are designed for Professional Use Only. For In Vitro Use.	The Multi-system Hb A1c CAPILLARY Controls (2) are designed for the migration control and quality control of human glycated hemoglobin A1c quantification with SEBIA capillary electrophoresis procedures: - CAPILLARYS Hb A1c performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument, - CAPI 3 Hb A1c performed with the CAPILLARYS 3 TERA automated instrument and, - MINICAP Hb A1c performed with the MINICAP FLEX-PIERCING automated instrument. The Hb A1c CAPILLARY Controls are designed for Professional Use Only. For In Vitro Use.
Product Number	4774	4768
Format	Hb A1c CAPILLARY Control 1 : 1 vial Hb A1c CAPILLARY Control 2 : 1 vial	Same
Preparation	Reconstitute the lyophilized control vial with 0.6 mL of distilled or deionized water.	Reconstitute the lyophilized control vial with 0.75 mL of distilled or deionized water.
Storage temperature	Before reconstitution, store the lyophilized controls refrigerated (2 to 8 °C). They are stable until the expiration date indicated on the vial labels.	Same
Shelf life	3 years at 2 - 8 °C	Same
In use storage	CAPILLARYS Hb A1c : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and	CAPILLARYS Hb A1c : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and

TABLE B	SEBIA Hb A1c CAPILLARY Controls K122101 and K133344	SEBIA Multi-system Hb A1c CAPILLARY Controls (2)
	- 30 °C. Do not freeze and thaw the reconstituted controls more than 30 times. After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 30 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times. MINICAP Hb A1c : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 30 °C. Do not freeze and thaw the reconstituted controls more than 30 times.	- 30 °C. Do not freeze and thaw the reconstituted controls more than 30 times. After hemolysis with the CAPILLARYS 2 FLEX-PIERCING instrument, store the dilution segments with controls at 2 - 8 °C and use them within the day (for 8 hours maximum). They may be stored, without any delay, between - 18 °C and - 30 °C for 1 month maximum. Do not freeze and thaw a dilution segment with hemolyzed control more than three times. MINICAP Hb A1c : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 30 °C. Do not freeze and thaw the reconstituted controls more than 30 times. CAPI 3 Hb A1c : After reconstitution, store the controls at 2 - 8 °C in a closed conical tube for control blood and use them within the day (for 24 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 6 months maximum between - 18 °C and - 30 °C. Do not freeze and thaw the reconstituted controls more than 30 times.
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING SEBIA MINICAP FLEX-PIERCING	SEBIA CAPILLARYS 2 FLEX-PIERCING SEBIA MINICAP FLEX-PIERCING SEBIA CAPILLARYS 3 TERA

Performance Data:

a. Precision

The precision of the CAPI 3 Hb A1c procedure was evaluated in a study based on the Clinical Laboratory Standards Institute (CLSI - USA) EP5-A3 guideline "Evaluation of Precision of Quantitative Measurements Procedures; Approved Guideline – Third Edition".
The means, standard deviations (SD) and coefficients of variation (CV %) were calculated for $HbA1_c$ concentration (mmol/mol) and percentage (%) for each sample.

Eight (8) different blood samples were run using the CAPI 3 Hb A1c procedure on 3 CAPILLARYS 3 instruments. The analyzed blood samples included 3 samples with normal

HbA_{1c} level (No. 1, 2 and 3), 1 sample with HbA_{1c} level close to the cut-off value (No. 4) and 4 samples with elevated HbA_{1c} level (No. 5, 6, 7 and 8).
Each sample was analyzed in duplicate on two capillaries per run, two runs per day over six days per lot of CAPI 3 Hb A1c kit, using three lots yielding a total of 432 results per sample over 18 days.

The Overall analysis is summarized in the following tables including within-capillary, between-capillary, between-run, between-day, between-lot, between-instrument and total reproducibility precision estimates (%CV) for the HbA_{1c} concentrations (in mmol/mol) and percentages.

		Within capillary		Between capillary		Between run		Between day		Between lot		Between instrument		Total reproducibility (*)	
	Mean (mmol/mol)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,5	1,6%	0,3	0,9%	0,0	0,0%	0,2	0,8%	0,3	1,0%	0,0	0,0%	0,7	2,3%
Blood No. 2	33	0,5	1,5%	0,4	1,2%	0,0	0,0%	0,3	0,8%	0,1	0,4%	0,2	0,5%	0,7	2,2%
Blood No. 3	35	0,5	1,5%	0,3	0,8%	0,0	0,0%	0,3	0,8%	0,0	0,0%	0,1	0,3%	0,7	1,9%
Blood No. 4	46	0,6	1,4%	0,2	0,5%	0,0	0,0%	0,2	0,5%	0,2	0,5%	0,1	0,1%	0,8	1,6%
Blood No. 5	67	0,4	0,7%	0,3	0,5%	0,0	0,0%	0,3	0,4%	0,0	0,0%	0,8	1,2%	1,0	1,5%
Blood No. 6	73	0,5	0,6%	0,3	0,5%	0,1	0,1%	0,3	0,4%	0,3	0,5%	0,0	0,0%	0,7	1,0%
Blood No. 7	85	0,6	0,7%	0,2	0,3%	0,0	0,0%	0,3	0,4%	0,1	0,1%	0,3	0,4%	0,8	0,9%
Blood No. 8	108	0,5	0,5%	0,5	0,5%	0,0	0,0%	0,5	0,5%	0,2	0,2%	0,2	0,2%	0,9	0,9%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day, between-lot and between-instrument.

		Within capillary		Between capillary		Between run		Between day		Between lot		Between instrument		Total reproducibility (*)	
	Mean (%)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,04	0,9%	0,02	0,5%	0,00	0,0%	0,02	0,4%	0,02	0,5%	0,00	0,0%	0,06	1,2%
Blood No. 2	5,1	0,05	0,9%	0,03	0,6%	0,00	0,0%	0,02	0,4%	0,01	0,1%	0,02	0,3%	0,06	1,3%
Blood No. 3	5,3	0,05	0,9%	0,03	0,6%	0,00	0,0%	0,03	0,5%	0,00	0,0%	0,01	0,2%	0,06	1,2%
Blood No. 4	6,4	0,06	0,9%	0,02	0,4%	0,00	0,0%	0,02	0,3%	0,02	0,3%	0,00	0,0%	0,07	1,1%
Blood No. 5	8,3	0,04	0,5%	0,04	0,4%	0,00	0,0%	0,02	0,2%	0,00	0,1%	0,07	0,9%	0,09	1,1%
Blood No. 6	8,9	0,05	0,5%	0,04	0,4%	0,00	0,0%	0,03	0,3%	0,03	0,4%	0,00	0,0%	0,07	0,8%
Blood No. 7	9,9	0,06	0,6%	0,03	0,3%	0,00	0,0%	0,03	0,3%	0,00	0,0%	0,03	0,3%	0,07	0,7%
Blood No. 8	12,0	0,05	0,4%	0,04	0,3%	0,00	0,0%	0,04	0,4%	0,04	0,3%	0,02	0,2%	0,09	0,7%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day, between-lot and between-instrument.

The Instrument by Instrument analysis is summarized in the following tables:

- including within-capillary, between-capillary, between-run, between-day, between-lot and total reproducibility precision estimates (%CV) for the HbA1c concentrations (in mmol/mol) and percentages for each instrument.
- including the within-laboratory precision estimates (%CV) for the HbA1c concentrations (in mmol/mol) and percentages for each lot on each instrument.

Instrument No. 1

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (mmol/mol)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,5	1,7%	0,3	1,0%	0,0	0,0%	0,2	0,7%	0,2	0,7%	0,6	2,2%
Blood No. 2	33	0,5	1,6%	0,5	1,4%	0,0	0,0%	0,2	0,7%	0,2	0,5%	0,7	2,3%
Blood No. 3	35	0,5	1,5%	0,3	1,0%	0,0	0,0%	0,2	0,7%	0,0	0,0%	0,7	1,9%
Blood No. 4	46	0,6	1,4%	0,3	0,6%	0,0	0,0%	0,4	0,9%	0,2	0,4%	0,8	1,8%
Blood No. 5	67	0,5	0,7%	0,1	0,2%	0,2	0,3%	0,2	0,4%	0,1	0,1%	0,6	0,9%
Blood No. 6	73	0,5	0,7%	0,3	0,4%	0,0	0,0%	0,4	0,5%	0,3	0,4%	0,7	1,0%
Blood No. 7	85	0,5	0,6%	0,2	0,2%	0,2	0,3%	0,5	0,6%	0,0	0,0%	0,7	0,9%
Blood No. 8	108	0,5	0,4%	0,5	0,5%	0,0	0,0%	0,6	0,5%	0,0	0,0%	0,9	0,9%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (mmol/mol)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,6	2,0%	0,7	2,4%	0,6	2,1%
Blood No. 2	33	0,6	1,8%	0,8	2,4%	0,8	2,5%
Blood No. 3	35	0,7	1,9%	0,7	1,9%	0,7	1,9%
Blood No. 4	46	0,9	2,0%	0,7	1,6%	0,8	1,8%
Blood No. 5	67	0,6	0,9%	0,6	0,9%	0,6	1,0%
Blood No. 6	73	0,7	0,9%	0,9	1,2%	0,4	0,6%
Blood No. 7	85	0,6	0,7%	0,7	0,9%	0,9	1,1%
Blood No. 8	108	0,7	0,6%	1,0	0,9%	1,2	1,1%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (%)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,05	1,0%	0,03	0,5%	0,00	0,0%	0,02	0,3%	0,02	0,4%	0,06	1,2%
Blood No. 2	5,1	0,05	1,0%	0,03	0,5%	0,00	0,0%	0,02	0,5%	0,00	0,0%	0,06	1,2%
Blood No. 3	5,3	0,05	0,9%	0,04	0,7%	0,00	0,0%	0,02	0,5%	0,00	0,0%	0,06	1,2%
Blood No. 4	6,4	0,06	1,0%	0,03	0,4%	0,00	0,0%	0,02	0,2%	0,02	0,4%	0,07	1,1%
Blood No. 5	8,3	0,04	0,5%	0,03	0,4%	0,00	0,0%	0,00	0,0%	0,01	0,1%	0,05	0,6%
Blood No. 6	8,9	0,05	0,6%	0,03	0,4%	0,00	0,0%	0,04	0,4%	0,03	0,3%	0,08	0,9%
Blood No. 7	9,9	0,04	0,4%	0,03	0,3%	0,01	0,1%	0,04	0,4%	0,00	0,0%	0,07	0,7%
Blood No. 8	12,0	0,05	0,4%	0,04	0,4%	0,00	0,0%	0,05	0,4%	0,02	0,2%	0,08	0,7%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (%)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,06	1,2%	0,06	1,2%	0,05	1,1%
Blood No. 2	5,1	0,05	0,9%	0,07	1,4%	0,06	1,2%
Blood No. 3	5,3	0,06	1,1%	0,06	1,2%	0,07	1,3%
Blood No. 4	6,4	0,08	1,3%	0,06	1,0%	0,06	1,0%
Blood No. 5	8,3	0,05	0,6%	0,07	0,9%	0,05	0,7%
Blood No. 6	8,9	0,07	0,8%	0,08	0,9%	0,06	0,7%
Blood No. 7	9,9	0,06	0,6%	0,06	0,6%	0,08	0,8%
Blood No. 8	12,0	0,06	0,5%	0,09	0,7%	0,09	0,7%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

Instrument No. 2

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (mmol/mol)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,5	1,6%	0,1	0,5%	0,0	0,0%	0,3	0,9%	0,4	1,4%	0,7	2,4%
Blood No. 2	33	0,5	1,4%	0,3	0,9%	0,0	0,0%	0,2	0,7%	0,2	0,7%	0,6	1,9%
Blood No. 3	35	0,5	1,3%	0,1	0,3%	0,0	0,0%	0,2	0,6%	0,0	0,0%	0,5	1,5%
Blood No. 4	46	0,7	1,6%	0,0	0,0%	0,2	0,4%	0,0	0,0%	0,2	0,4%	0,8	1,7%
Blood No. 5	67	0,4	0,6%	0,4	0,6%	0,0	0,0%	0,2	0,4%	0,0	0,0%	0,6	0,9%
Blood No. 6	73	0,4	0,6%	0,4	0,5%	0,0	0,0%	0,3	0,5%	0,3	0,5%	0,8	1,0%
Blood No. 7	85	0,7	0,8%	0,1	0,1%	0,0	0,0%	0,3	0,4%	0,0	0,0%	0,8	0,9%
Blood No. 8	108	0,0	0,0%	0,0	0,0%	0,0	0,0%	0,0	0,0%	0,0	0,0%	0,1	0,1%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (mmol/mol)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,6	1,9%	0,7	2,3%	0,5	1,9%
Blood No. 2	33	0,5	1,6%	0,6	1,9%	0,6	1,9%
Blood No. 3	35	0,3	0,9%	0,5	1,5%	0,7	1,9%
Blood No. 4	46	0,7	1,6%	0,8	1,8%	0,8	1,7%
Blood No. 5	67	0,7	1,1%	0,6	0,9%	0,5	0,8%
Blood No. 6	73	0,8	1,1%	0,6	0,8%	0,7	1,0%
Blood No. 7	85	0,6	0,7%	0,7	0,9%	0,9	1,1%
Blood No. 8	108	0,9	0,8%	1,1	1,1%	0,9	0,8%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (%)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,04	0,9%	0,01	0,2%	0,00	0,0%	0,02	0,5%	0,03	0,7%	0,06	1,3%
Blood No. 2	5,1	0,05	0,9%	0,03	0,6%	0,00	0,0%	0,02	0,4%	0,02	0,3%	0,06	1,2%
Blood No. 3	5,3	0,04	0,7%	0,03	0,6%	0,00	0,0%	0,03	0,5%	0,01	0,3%	0,06	1,1%
Blood No. 4	6,4	0,06	1,0%	0,00	0,0%	0,01	0,2%	0,02	0,4%	0,02	0,4%	0,07	1,1%
Blood No. 5	8,3	0,04	0,5%	0,05	0,6%	0,00	0,0%	0,02	0,2%	0,00	0,0%	0,07	0,8%
Blood No. 6	8,9	0,04	0,5%	0,05	0,5%	0,00	0,0%	0,02	0,2%	0,04	0,4%	0,08	0,8%
Blood No. 7	9,9	0,06	0,6%	0,03	0,3%	0,00	0,0%	0,03	0,3%	0,00	0,0%	0,07	0,7%
Blood No. 8	12,0	0,05	0,5%	0,03	0,3%	0,01	0,1%	0,04	0,3%	0,03	0,2%	0,08	0,7%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (%)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,06	1,2%	0,06	1,2%	0,04	0,9%
Blood No. 2	5,1	0,06	1,2%	0,06	1,2%	0,05	1,0%
Blood No. 3	5,3	0,05	1,0%	0,06	1,0%	0,07	1,2%
Blood No. 4	6,4	0,07	1,1%	0,08	1,2%	0,07	1,1%
Blood No. 5	8,3	0,07	0,9%	0,06	0,7%	0,06	0,7%
Blood No. 6	8,9	0,07	0,8%	0,07	0,8%	0,06	0,7%
Blood No. 7	9,9	0,06	0,6%	0,07	0,7%	0,08	0,8%
Blood No. 8	12,0	0,07	0,6%	0,09	0,8%	0,07	0,6%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

Instrument No. 3

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (mmol/mol)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,5	1,6%	0,3	1,2%	0,0	0,0%	0,2	0,8%	0,1	0,5%	0,6	2,2%
Blood No. 2	33	0,5	1,4%	0,4	1,3%	0,0	0,0%	0,3	0,9%	0,0	0,0%	0,7	2,1%
Blood No. 3	35	0,6	1,7%	0,3	0,9%	0,0	0,0%	0,4	1,1%	0,0	0,0%	0,8	2,2%
Blood No. 4	46	0,5	1,1%	0,3	0,7%	0,0	0,0%	0,2	0,3%	0,3	0,6%	0,7	1,5%
Blood No. 5	67	0,4	0,6%	0,4	0,6%	0,0	0,0%	0,3	0,4%	0,0	0,0%	0,6	1,0%
Blood No. 6	73	0,5	0,6%	0,3	0,4%	0,2	0,2%	0,2	0,3%	0,4	0,6%	0,7	1,0%
Blood No. 7	85	0,6	0,7%	0,3	0,4%	0,0	0,0%	0,0	0,0%	0,3	0,3%	0,7	0,8%
Blood No. 8	108	0,5	0,5%	0,5	0,5%	0,0	0,0%	0,3	0,3%	0,4	0,4%	0,9	0,8%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (mmol/mol)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	29	0,5	1,8%	0,7	2,4%	0,6	2,1%
Blood No. 2	33	0,6	1,7%	0,8	2,3%	0,7	2,3%
Blood No. 3	35	0,6	1,8%	1,0	2,8%	0,6	1,8%
Blood No. 4	46	0,6	1,3%	0,7	1,4%	0,7	1,6%
Blood No. 5	67	0,6	0,9%	0,7	1,0%	0,6	0,9%
Blood No. 6	73	0,6	0,8%	0,7	0,9%	0,6	0,8%
Blood No. 7	85	0,5	0,5%	0,9	1,1%	0,5	0,6%
Blood No. 8	108	0,7	0,7%	1,0	0,9%	0,7	0,6%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

		Within capillary		Between capillary		Between run		Between day		Between lot		Total reproducibility (*)	
	Mean (%)	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,04	0,9%	0,03	0,6%	0,00	0,0%	0,02	0,4%	0,01	0,2%	0,06	1,2%
Blood No. 2	5,1	0,04	0,9%	0,04	0,8%	0,00	0,0%	0,02	0,5%	0,00	0,0%	0,07	1,3%
Blood No. 3	5,3	0,05	1,0%	0,02	0,3%	0,00	0,0%	0,03	0,5%	0,00	0,0%	0,06	1,2%
Blood No. 4	6,4	0,05	0,8%	0,04	0,6%	0,00	0,0%	0,02	0,4%	0,02	0,3%	0,07	1,0%
Blood No. 5	8,3	0,04	0,5%	0,02	0,3%	0,00	0,0%	0,03	0,3%	0,00	0,0%	0,06	0,7%
Blood No. 6	8,9	0,04	0,5%	0,03	0,3%	0,00	0,0%	0,03	0,3%	0,04	0,4%	0,07	0,8%
Blood No. 7	9,9	0,06	0,6%	0,03	0,3%	0,00	0,0%	0,00	0,0%	0,02	0,2%	0,07	0,7%
Blood No. 8	12,0	0,05	0,4%	0,04	0,3%	0,01	0,0%	0,04	0,3%	0,05	0,4%	0,09	0,7%

(*) Total reproducibility includes : within-capillary, between-capillary, between-run, between-day and between-lot.

	Mean (%)	Within-laboratory (*)					
		Lot No. 1		Lot No. 2		Lot No. 3	
		SD	CV	SD	CV	SD	CV
Blood No. 1	4,8	0,05	1,1%	0,07	1,4%	0,05	1,1%
Blood No. 2	5,1	0,05	1,0%	0,08	1,5%	0,07	1,3%
Blood No. 3	5,3	0,06	1,1%	0,09	1,7%	0,05	1,0%
Blood No. 4	6,4	0,06	0,9%	0,07	1,1%	0,07	1,1%
Blood No. 5	8,3	0,05	0,7%	0,06	0,7%	0,06	0,7%
Blood No. 6	8,9	0,06	0,7%	0,07	0,8%	0,05	0,6%
Blood No. 7	9,9	0,05	0,5%	0,08	0,8%	0,07	0,7%
Blood No. 8	12,0	0,07	0,6%	0,08	0,7%	0,07	0,6%

(*) Within laboratory reproducibility includes : within-capillary, between-capillary, between-run and between-day.

b. Linearity

Mixture of 2 different blood samples:

2 characteristic blood samples, including a normal sample and an elevated HbA_{1c} level sample were mixed within different proportions and the mixtures were electrophoresed with the CAPI 3 Hb A1c procedure. For each mixture, samples were analyzed in triplicate.

The tests were determined to be linear within the entire range studied for HbA_{1c} hemoglobin fraction. The stated measuring range is 21 mmol/mol to 138 mmol/mol HbA_{1c} (4.0 % to 14.7 % HbA_{1c}).

Dilution of 4 different blood samples in hemolysing solution:

4 different characteristic blood samples, including 1 normal sample with HbA1c concentration at 21 mmol/mol (4.1 % HbA1c), 1 sample with HbA1c level close to the cut-off value with HbA1c concentration at 47 mmol/mol (6.4 % HbA1c) and 2 elevated HbA1c level samples with HbA1c concentrations at 82 mmol/mol (9.6 % HbA1c) and at 134 mmol/mol (14.4 % HbA1c), were all serially diluted in hemolysing solution and electrophoresed with the CAPI 3 Hb A1c procedure. The tests were determined to be linear within the entire ranges studied from 2.9 to 30.5 g/dL total hemoglobin and HbA1c fraction concentration and percentage were not affected by the hemoglobin concentration of the samples.

c. Accuracy – Internal correlation

The levels of HbA_{1c} were measured in 100 blood samples, including samples with normal and elevated HbA_{1c} levels, both by electrophoretic separations obtained with the CAPI 3 Hb A1c procedure on the CAPILLARYS 3 TERA instrument and a commercially available capillary electrophoresis technique for HbA_{1c} quantification that is NGSP standardized. The measured values of HbA1c concentrations and percentages from both procedures were analyzed by a linear regression statistical procedure. The results of linear regression analysis are tabulated below (y = CAPI 3 Hb A1c):

HbA_{1c}	**Correlation coefficient**	**y-Intercept**	**Slope**	**Range of values CAPI 3 Hb A1c**
Concentration (mmol/mol)	0.998	- 0.238	1.000	22 - 132
Percentage (%)	0.998	- 0.024	1.000	4.1 – 14.2

d. Accuracy - External correlations

In study No. 1, the levels of HbA_{1c} were measured in 175 blood samples, including samples with normal and elevated HbA_{1c} levels, both by electrophoretic separations obtained with CAPI 3 Hb A1c procedure with the CAPILLARYS 3 TERA instrument and a commercially available capillary electrophoresis technique for HbA_{1c} quantification that is NGSP standardized.

The measured values of HbA1c concentrations and percentages from both procedures were analyzed by a linear regression statistical procedure. The results of linear regression analysis are tabulated below (y = CAPI 3 Hb A1c):

HbA_{1c}	**Correlation coefficient**	**y-Intercept**	**Slope**	**Range of values CAPI 3 Hb A1c**
Concentration (mmol/mol)	0.998	0.249	0.993	23 - 138
Percentage (%)	0.997	0.045	0.992	4.3 – 14.7

In study No. 2, the levels of HbA_{1c} were measured in 117 blood samples, including samples with normal and elevated HbA_{1c} levels, both by electrophoretic separations obtained with CAPI 3 Hb A1c procedure with the CAPILLARYS 3 TERA instrument and a commercially available capillary electrophoresis technique for HbA_{1c} quantification that is NGSP standardized.

The measured values of HbA1c concentrations and percentages from both procedures were analyzed by a linear regression statistical procedure. The results of linear regression analysis are tabulated below (y = CAPI 3 Hb A1c):

HbA_{1c}	**Correlation coefficient**	**y-Intercept**	**Slope**	**Range of values CAPI 3 Hb A1c**
Concentration (mmol/mol)	0.998	1.417	0.970	22 - 127
Percentage (%)	0.998	0.205	0.968	4.2 – 13.7

Internal and External studies combined of 392 whole blood samples (normal and elevated HbA1c levels) spanning a HbA1c measuring range of 4.1 – 14.7 % with the CAPI 3 Hb A1c procedure using the CAPILLARYS 3 TERA instrument.

Interferences

No interference with the CAPI 3 Hb A1c procedure was detected due to the blood sample's high concentration of the following interfering factors tested at levels equal to the concentrations listed below:

Interfering Factor	Concentration
Triglycerides	3.85 g/dL (43.97mM)
Bilirubin	35.9 mg/dL (614 mM)
Ascorbic Acid	60 mg/dL (3.41 mM)
Urea	277 mg/dL (46.1 mM)
Rheumatoid factor	2178 IU/mL
Glybenclamide	3 mg/dL
Total Protein	149.5 g/L
Glucose	1000 mg/dL (55 mM)
Acetylsalicylic acid	1000 mg/dL (55.56 mM)
Acetaminophen	20 mg/dL (1325 µM)
Ibuprofen	50 mg/dL (2427 µM)
Metformin	5 mg/dL (387 µM)
Acetylated hemoglobin	≤ 2.1 %
Carbamylated hemoglobin	≤ 5.6 %
Labile HbA1c	≤ 12.7 %
Hb A2	Up to 11.3%
Hb F	Up to 23 %
Hb S	≤ 40.4%
Hb C	≤ 36.9%
Hb D	≤ 44.2%
Hb E	≤ 26.6%

3. Conclusion:

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