

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

A. 510(k) Number:

k122101

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood hemoglobin A1c (HbA1c)

D. Type of Test:

Capillary Electrophoresis

E. Applicant:

Sebia Inc.

F. Proprietary and Established Names:

CAPILLARYS Hb A1c kit

Hb A1c CAPILLARY Calibrators

Hb A1c CAPILLARY Controls

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCP	II	21 CFR 864.7470	Hematology (81)
JIS	II	21 CFR 862.1150	Chemistry (75)
JJX	Class I, reserved	21 CFR 862.1660	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for use below

2. Indication(s) for use:

The **CAPILLARYS Hb A1c kit** is designed for separation and quantification of the HbA1c glycosylated fraction of hemoglobin in human whole 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 HbA1c kit is designed for Professional Use Only.

The **Hb A1c CAPILLARY Calibrators** are designed for the calibration and migration control of human glycosylated hemoglobin A1c quantification with SEBIA CAPILLARYS HbA1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Calibrators are designed for Professional Use Only.

The **Hb A1c CAPILLARY Controls** are designed for the quality control of human glycosylated hemoglobin A1c quantification with CAPILLARYS Hb A1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The Hb A1c CAPILLARY Controls are designed for Professional Use Only.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

CAPILLARYS 2 FLEX-PIERCING instrument

I. Device Description:

The CAPILLARYS Hb A1c kit, control and calibrators are to be used with the CAPILLARYS 2 FLEX- Piercing system.

The components are summarized as follows:

- CAPILLARYS Hb A1c kit contains a ready to use buffer (2 vials, 700 ml each), a ready to use hemolysing solution (1 vial, 700 ml), Wash solution (1 vial, 75 ml), Green Dilution segments (1 pack of 90) and Filters (4 filters per kit)
- Hb A1c CAPILLARY Calibrators consist of a HbA1c CAPILLARYS Calibrator 1 (green cap) and a HbA1c CAPILLARYS Calibrator 2 (red cap), 1 vial of each, 600 µL each and bar code labels for each level of calibrator.

- Hb A1c CAPILLARY Controls consist of HbA1c CAPILLARYS Control 1 (white cap) and HbA1c CAPILLARYS Control 2 (black cap), 1 vial of each, 600 µL each. White and Grey Dilution segments (4 each) and Barcode labels for each level of control.

J. Substantial Equivalence Information:

1. Predicate device name(s):

TOSOH G8 Automated Glycohemoglobin Analyzer HLC-723G8

TOSOH A1C Calibrator Set

TOSOH Hemoglobin A1c Controls

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

k071132, k021484

3. Comparison with predicate:

Similarities and Differences: Reagent		
Item	New Device CAPILLARYS Hb A1c kit	Predicate Device TOSOH G8 Automated Glycohemoglobin Analyzer HLC-723G8 k071132
Intended Use/Indications for Use	The CAPILLARYS Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human whole 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 HbA1c kit is designed for Professional Use Only.	The Tosoh G8 Automated Glycohemoglobin Analyzer HLC-723G8 is intended for In Vitro diagnostic Use for the measurement of hemoglobin A1c (HbA1c) in whole blood specimens.
Method	Free solution capillary electrophoresis	Ion-exchange high performance liquid chromatography (HPLC)
Sample Type	Whole blood	Whole blood

Similarities and Differences: Reagent		
Item	New Device CAPILLARYS Hb A1c kit	Predicate Device TOSOH G8 Automated Glycohemoglobin Analyzer HLC-723G8 k071132
Measuring Range	4.0-14.7% HbA1c	4.0-16.9% HbA1c
Collection tubes	K3EDTA anticoagulant	EDTA anticoagulant
Absorbance wave length	410 and 510 nm	415 nm

Similarities and Differences: Calibrators		
Item	New Device Hb A1c CAPILLARY Calibrators	Predicate TOSOH A1c Calibrator Set k071132
Intended Use/Indications for Use	The HbA1c CAPILLARY Calibrators are designed for the calibration and migration control of human glycosylated hemoglobin A1c quantification with SEBIA CAPILLARYS HbA1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The HbA1c CAPILLARY Calibrators are designed for Professional Use Only.	The A1c Calibrator Set is a reference agent designed for calibrating the Tosoh Automated Glycohemoglobin Analyzer
Format	2 levels	Same
Storage Temperature	3 years at -30°C/-18°C (-22°F/0°F). When reconstituted the in use storage stability is 1 week at 2-8°C (36-46°F), 6 months at -22°C / -18°C (-8°F/0°F). Do not freeze and that more than 3 times	Unopened: between -30°C and -18°C until expiration date printed on vial. Opened and reconstituted: -18°C and -22°C for 6 months. Do not freeze and thaw more than 3 times.

Similarities and Differences: Controls		
Item	New Device Hb A1c CAPILLARY Controls	Predicate TOSOH Hemoglobin A1C control k021484
Intended Use/Indications for Use	The HbA1C CAPILLARY Controls are designed for the quality control of human glycated hemoglobin A1c quantification with CAPILLARTYS HbA1c electrophoresis procedure performed with the CAPILLARYS 2 FLEX-PIERCING automated instrument for capillary electrophoresis. The HbA1c CAPILLARY Controls are designed for Professional Use Only.	The TOSOH Hemoglobin A1c Controls are intended for use as quality control materials to monitor the precision of laboratory testing procedures for HbA1c quantitation. The controls are designed for use with Tosoh Bioscience, Inc G7 and G8 analyzers.
Format	2 levels; 1 vial (0.6mL) per level	2 levels; 4 vials (0.25mL) per level
Storage Temperature	3 years at 2-8°C (36-46°F). When reconstituted the controls are stable for 1 day at 2-8°C (36-46°F), 6 months at -22°C/-18°C (-8°F/0°F). When hemolyzed the controls are stable for 1 month at -22°C/-18°C (-8°F/0°F). Do not freeze and thaw more than 3 times.	Hemoglobin A1c controls are stable until the last day of the expiration date shown on the vial when stored unopened at 2-8°C

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

CLSI Guideline, EP9-A2: *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second edition*

CLSI Guideline, EP6-A: *Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline*

CLSI Guideline, EP5-A2: *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline Second edition*

CLSI Guideline, EP7-A2: *Interference Testing in Clinical Chemistry; Approved Guideline-Second edition*

L. Test Principle:

The CAPILLARYS 2 FLEX Piercing HbA1c assay employs 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 also occurs according to the electrolyte pH and electroosmotic flow.

The assay has silica capillaries functioning in parallel allowing 8 simultaneous analyses for HbA1c quantification from a whole blood sample. A sample dilution with hemolyzing 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 wavelength specific to hemoglobins. Before each run, the capillaries are washed with a wash solution and prepared for the next analysis with buffer.

Direct detection provided accurate relative quantification of individual hemoglobin A1c fraction. In addition, the high resolution of CAPILLARYS HbA1c 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 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 HbA1) and then A1c.

At the end of analysis, relative quantification of individual HbA1c fraction is performed automatically. The HbA1c concentrations are standardized and indicated in %HbA1c (DCCT/NGSP) and in mmol/mol (IFCC) units.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision within the same capillary

Eight different blood samples were analyzed using the CAPILLARYS A1c procedure in 8 capillaries of the same CAPILLARYS 2 FLEX-PIERCING instrument. The analyzed blood samples included 3 samples with normal HbA1c levels (~5.1-5.5%) (samples 1,2 and 3), 1 sample with HbA1c level close to the cut-off value (6% HbA1c) (sample 4) and 4 samples with elevated HbA1c levels (~7.9, 8.4, 9.8 and 10.0%),(samples 5, 6, 7 and 8) . Each blood sample was analyzed on the same capillary, including 40 runs over 20 working days. Samples were analyzed in duplicate. The results are shown below:

Sample	N	Mean (%A1c)	Within-run (%CV)	Between-run (%CV)	Between-day (%CV)	Total (%CV)
Sample No.1	80	5.1	1.4	1.2	0.0	1.8
Sample No.2	80	5.5	1.3	0.5	0.0	1.3
Sample No.3	80	5.5	0.8	0.0	0.0	0.8
Sample No.4	80	6.0	0.7	0.0	0.4	0.8
Sample No.5	80	7.9	1.0	0.6	0.0	1.1
Sample No.6	80	8.4	1.1	0.0	0.0	1.1
Sample No.7	80	9.8	0.6	0.3	0.1	0.6
Sample No.8	80	10.0	0.9	0.0	0.3	1.0

Precision between capillaries from the same instrument

Eight different blood samples were analyzed using the CAPILLARYS HbA1c assay in 8 capillaries of the same CAPILLARYS 2 FLEX-PIERCING instrument. The analyzed blood samples included 3 samples with normal HbA1c levels (~5.1-5.5%) (samples 1, 2 and 3), 1 sample with a HbA1c value close to the cut-off value (6% HbA1c)(sample 4) and 4 samples with elevated HbA1c levels (~7.9, 8.4, 9.8 and 10.0%) (samples 5, 6, 7 and 8). Each sample was assayed on all capillaries from the same instrument to include 40 runs over 20 working days. Samples were analyzed in duplicate within each run. The results are shown below:

Sample	N	Mean (%A1c)	Within-run (%CV)	Between-run (%CV)	Between-day (%CV)	Total (%CV)
Sample No.1	80	5.0	1.8	0.5	0.2	1.9
Sample No.2	80	5.5	1.3	0.0	0.8	1.5
Sample No.3	80	5.5	1.9	0.0	0.0	1.9
Sample No.4	80	6.0	1.6	0.0	0.0	1.6
Sample No.5	80	8.0	1.3	0.5	0.0	1.3
Sample No.6	80	8.4	1.3	0.0	0.0	1.3
Sample No.7	80	9.9	1.3	0.0	0.0	1.3
Sample No.8	80	10.1	1.1	0.1	0.0	1.1

Precision between lots and instruments

Eight different blood samples were analyzed using the CAPILLARYS HbA1c assay in 8 capillaries of 3 different CAPILLARYS 2 FLEX-PIERCING instruments and with 3 lots of CAPILLARYS HbA1c kits. The analyzed blood samples included 3 samples with normal HbA1c levels (~5.0-5.5%)(samples 1, 2 and 3, 1 sample with HbA1c level close to the cut-off value (6%);(sample 4) and 4 samples with elevated HbA1c levels (~7.9-10.0% HbA1c) (samples 5,6,7 and 8). Each blood sample was analyzed on all capillaries from each instrument, including 60 runs over 24 days. Samples were analyzed in duplicate. The results are shown below:

Sample	Mean (%A1c)	Within-Run reproducibility		Total reproducibility	
		% CV min	% CV max	% CV min	% CV max
Sample No.1	5.0	1.0	2.4	1.1	2.6
Sample No.2	5.5	0.5	1.6	0.9	2.4
Sample No.3	5.5	0.9	1.4	0.9	1.5
Sample No.4	6.0	0.4	1.6	0.8	1.7
Sample No.5	7.9	0.4	1.7	0.8	1.7
Sample No.6	8.4	0.7	1.5	1.0	1.7
Sample No.7	9.8	0.4	1.5	0.8	1.6
Sample No.8	10.0	0.6	1.3	0.7	1.4

An additional precision study was performed in order to demonstrate the precision of the CAPILLARYS HbA1c assay on the CAPILLARYS 2 FLEX-PIERCING instrument for samples with elevated HbA1c levels. The analyzed blood samples included 4 samples with high HbA1c levels (~11.0, 12.0, 13.0 and 14.1%) Each blood sample was analyzed in duplicate using all capillaries from each of two instruments, and 2 lots of reagent. The results are shown below:

Sample	Mean (%A1c)	Within-Run reproducibility		Total reproducibility	
		% CV min	% CV max	% CV min	% CV max
Sample No.1	11.0	0.9	1.3	1.2	1.3
Sample No.2	12.0	1.2	1.3	1.2	1.3
Sample No.3	13.0	1.1	1.2	1.3	1.4
Sample No.4	14.1	1.0	1.0	1.1	1.1

b. Linearity/assay reportable range:

The linearity of the CAPILLARYS HbA1c procedure was evaluated based on CLSI EP6-A guideline “Evaluation of the Linearity Quantitative Measurement Procedures: A Statistical Approach”. Two blood samples, including a normal sample with HbA1c concentration at 4.0% and an elevated HbA1c level sample with HbA1c concentration at 14.7% were mixed within different proportions and the dilutions were electrophoresed with the CAPILLARYS HbA1c assay kit using the CAPILLARYS 2 FLEX-PIERCING instrument. Samples were analyzed in duplicate.

A polynomial regression analysis was performed and the sponsor determined that the 3rd order regression provided the best fit. However, the % difference between 1st order regression and the best fit 3rd order regression is less than 0.3%(A1c units) at all linearity levels tested as summarized in the table below.

Comparison of 1st Order and 3rd Order (best fit) regressions

Expected value (%)	1 st Order value (%)	3 rd Order Value (%)	1 st – 3 rd Difference (%)
14.7	15.0	14.8	0.2
14.1	13.9	13.9	0.1
12.8	12.9	12.9	0.1
11.9	11.8	11.9	0.1
10.9	10.7	10.8	0.1
9.8	9.6	9.7	0.1
8.4	8.5	8.6	0.1
7.5	7.4	7.4	0.0
6.4	6.4	6.3	0.1
5.4	5.3	5.2	0.1
4.0	4.2	4.1	0.1

The 1st order linear regression generated is:

$$Y = -0.108x + 15.027, r^2 = 0.997, r = 0.998$$

The sponsor claims a linearity range of 4.0 – 14.7% HbA1c

In addition, 2 blood samples, including a normal sample with HbA1c concentration at 5.4% HbA1c and an elevated HbA1c level sample with HbA1c concentration at 7.8% HbA1c were both serially diluted in hemolysing solution and electrophoresed with the CAPILLARYS HbA1c procedure. According to the sponsor, the tests were determined to be linear within the entire ranges studied from 1.4 to 31.0 g/dL total hemoglobin concentration of the samples.

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

Traceability: The CAPILLARYS HbA1c assay is certified with the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification expires in one year. See NGSP website for current certification at <http://www.ngsp.org>.

Value Assignment: Calibrator and control values are assigned by multiple measurements using multiple CAPILLARYS 2 FLEX-PIERCING instruments and IFCC traceable calibrators.

Stability: The stability protocols and acceptance criteria were reviewed and determined to be adequate.

The expiration date of the different components of the CAPILLARYS HbA1c kit are indicated as follows:

Kit component	Shelf-Life	On Board Stability
CAPILLARYS HbA1c buffer:	2 years at 2-8°C (36-46°F)	20 days at 15-30°C (59-86°F)
CAPILLARYS HbA1c hemolysing solution:	2 years at 2-30°C (36-86°F)	2 months at 37°C (99°F)
CAPILLARYS/MINICAP wash solution:	3 years at 2-30°C (36-86°F)	3 months at 37°C (99°F)

The shelf life of the freeze dried Hb A1c CAPILLARY Calibrators is 3 years at -30°C/-18°C (-22°F/0°F). When reconstituted the in use storage stability is 1 week at 2-8°C (36-46°F), 6 months at -22°C / -18°C (-8°F/0°F). The labeling states that the Hb A1c CAPILLARY Calibrators should not be frozen and thawed more than 3 times.

The shelf life of the Hb A1c CAPILLARYS controls are 3 years at 2-8°C (36-46°F). When reconstituted the controls are stable for 1 day at 2-8°C (36-46°F), 6 months at -22°C/-18°C (-8°F/0°F). When hemolyzed the controls are stable for 1 month at -22°C/-18°C (-8°F/0°F). The labeling states that the HbA1c CAPILLARYS controls should not be frozen and thawed more than 3 times.

d. Detection limit:

The Limit of Blank (LoB) and Limit of Detection (LoD) were determined by assaying a zero sample (blank) and five low HbA1c samples according to CLSI guideline EP17-A . The results are as follows:

LoB= 0.3%, LoD = 1.2%

The claimed measuring range, 4.0- 14.7%, is based on linearity. See 1b. above

e. Analytical specificity:

i.) Studies were performed to assess common or known substances that could interfere with the CAPILLARYS HbA1c assay kit. The interfering substances were evaluated in whole blood K3EDTA samples that contained three different concentrations of A1c (~5.3%, ~7.0% and ~10.3%). Samples containing various concentrations of potential interferents were tested and the results compared to those obtained from control samples containing no potential interfering substances. The sponsor's definition of non-significant interference is $\geq 0.3\%$ HbA1c between the tested and the control samples.

The results are as follows:

Potential interfering substance	Concentration at which no significant interference ($\leq 0.3\%$) was observed
Bilirubin	≤ 25.6 mg/dL
Triglycerides	≤ 1120 mg/dL
Rheumatoid Factor	≤ 2178 IU/mL

Urea	≤291 mg/dL
Ascorbic Acid	≤ 60 mg/dL
Glybenclamide	≤3 mg/dL

ii.) To study interference from Carbamylated hemoglobin, three K3EDTA whole blood patient samples with A1c concentrations at ~5.1%, ~7.0% and ~10.1% were split into two aliquots. One aliquot, at each A1c level, was spiked with 1mmol/L of Potassium Cyanate and incubated for 3 hours at 37°C. Another aliquot, at each A1c level, was incubated for 3 hours at 37°C. Samples were then analyzed on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit, Samples were analyzed in triplicate. The sponsor's definition of non-significant interference is ≤ 0.3 HbA1c% between the tested and the control samples.

The sponsor concluded that Carbamylated hemoglobin does not interfere with this assay.

iii.) To study interference from labile hemoglobin, three K3EDTA whole blood patient samples with A1c concentrations at ~5.3%, ~7.7% and ~11.3% were split into two aliquots. One aliquot, at each A1c level, was spiked with glucose (100 mmol/mol; glucose concentration= 1800 mg/dL) and incubated for 90 minutes at 37°C. Another aliquot, at each A1c level, was incubated for 90 minutes at 37°C. Samples were then analyzed on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit. Samples were tested in triplicate. The sponsor's definition of non-significant interference is ≤ 0.3 HbA1c%.

The sponsor concluded that labile A1c does not interfere with this assay.

iii.) To study interference from acetylated hemoglobin, two whole blood K3 EDTA samples with A1c concentrations at ~4.9% and ~ 8.3% were split into two aliquots. One aliquot, at each A1c level, was used as the control sample and the other aliquot was spiked with acetylated hemoglobin (180 mg/dL conc.) and incubated for 6 hours at 37°C. All aliquots were tested on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit. Samples were tested in triplicate. The sponsor's definition of non-significant interference is ≤ 0.3 HbA1c%.

The sponsor concluded that acetylated hemoglobin up to 180 mg/dL does not interfere with this assay.

iv.) To study interference from acetylsalicylic acid, two whole blood K3EDTA samples with A1c concentrations at ~4.9% and ~8.3% were split into two aliquots. One aliquot, at each A1c level, was used as the control sample and the other aliquot was incubated at 37°C for 6 hours with acetylsalicylic acid (180 mg/dL). The control samples which did not contain acetylsalicylic acid were incubated at 37°C for 6 hours. All aliquots were tested on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit. Samples were tested in triplicate. The sponsor's definition of non-significant interference is ≤ 0.3 HbA1c%.

The sponsor concluded that acetylsalicylic acid up to 180 mg/dL does not interfere with this assay.

v) A hemoglobin variant interference study was carried out using samples known to contain Hemoglobin variants S, E, D and C. These variant samples were tested on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit. The sponsor's definition of non-significant interference is $\pm 10\%$ difference between the candidate method and the comparative method.

The testing results show there is no significant interference for HbS ($\leq 40\%$), HbE ($\leq 32\%$), HbD ($\leq 42\%$) and HbC ($\leq 44\%$).

The sponsor includes the following limitation in their labeling: "due to the number of variants, the presence of another hemoglobin variant may be observed in the HbA1c migration zone; in the case of a shoulder on HbA1c, no result will be reported by the software.

vi) An additional variant interference study was carried out to study the variant interference from Hemoglobin F. Two whole blood samples with HbA1c concentrations of $\sim 5.5\%$ and $\sim 8.3\%$ contained varying concentrations of HbF and were tested on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1c assay kit.

The testing results show there is no significant interference for HbF $\leq 15\%$ therefore the sponsor has included the following limitation in their labeling: Samples that contain high amounts of HbF ($>15\%$), usually found in some people with thalassemia, infants, and in some pregnant women, may yield a lower than expected HbA1c result with this assay.

f. Assay cut-off:

Not-applicable

2. Comparison studies:

a. Method comparison with predicate device:

282 whole blood K2EDTA samples (119 normal and 163 with elevated HbA1c) with HbA1c ranging from 4.6% to 16.4% HbA1c were analyzed in singlicate using the CAPILLARYS HbA1c assay kit on the CAPILLARYS 2 FLEX-PIERCING instrument (candidate device) and the Tosoh G8 Automated Glycohemoglobin Analyzer HPLC 723 G8. Method comparison studies were performed according to CLSI EP9-A2 guideline. The linear regression correlation was calculated as follows:

HbA1c	Correlation Coefficient	y-intercept	Slope	HbA1c range
Percentage (%)	0.996	0.438	0.913	4.6 – 16.4

b. Matrix comparison:

A total of 26 random matched sample pairs (K2 EDTA and K3 EDTA) were tested on the CAPILLARYS 2 FLEX-PIERCING instrument using the CAPILLARYS HbA1s assay kit. The linear regression is presented in the table below:

Fraction	Number of Samples	Correlation Coefficient	y-intercept	Slope	Sample range
HbAc1%	26	0.998	0.139	0.984	4.7-10.6

An additional matrix comparison study was performed to include samples in the higher range of the assay. A total of 44 random matched sample pairs (K2EDTA and K3EDTA) were tested on the CAPILLARYS 2 FLEX PIERCING instrument using the CAPILLARYS HbA1c assay kit. The linear regression is presented in the table below :

Fraction	Number of Samples	Correlation Coefficient	y-intercept	Slope	Sample range
HbAc1%	44	0.999	0.013	1.001	4.7-14.2

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):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Reference Range¹

	NGSP	IFCC
Increased risk for diabetes	≥6.5%	≥48mmol/mol

¹American Diabetes Association. Standards of medical care in diabetes-2012. Diabetes Care. 2012 Jan;35 Suppl 1:S11-63

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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