510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k181915

B. Purpose for Submission:

New device

C. Measurand:

Glycosylated hemoglobin (HbA1c)

D. Type of Test:

Quantitative Immunoassay

E. Applicant:

iXensor Co., LTD.

F. Proprietary and Established Names:

PixoTest POCT System - PixoTest POCT Analyzer and PixoTest A1c Test Kit

G. Regulatory Information:

Classification Name	Regulation Section	Device Class	Product Code	Panel
Assay, Glycosylated Hemoglobin	21 CFR 864.7470	II	LCP	Hematology (81)
Analyzer, Chemistry (Photometric, Discrete), For Clinical Use	21CFR 862.2160	I	JJE	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The PixoTest POCT System, consisting of PixoTest POCT Analyzer and PixoTest A1c Test Kit, is used for the quantitative measurement of glycated hemoglobin (%HbA1c) in venous whole blood samples. It is an in-vitro diagnostic system intended to monitor long term glycemic control in individuals previously diagnosed with diabetes mellitus.

   The PixoTest POCT System is intended for clinical laboratory and Point-of-Care Professional use. It is not intended for use in the diagnosis of or screening for diabetes and is not intended for use on neonates.

3. Special conditions for use statement(s):

   - For prescription use only.
   - This test should not be used in monitoring daily glucose control and should not be used to replace daily home testing of urine and blood glucose levels.
   - This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss.
   - For professional use in clinical laboratory and point-of-care settings.
   - This test is not intended for use in the diagnosis of or screening for diabetes.
   - This test is not intended for use on neonates.
   - For in-vitro diagnostic use only.
   - If the total hemoglobin result is outside the range of 7-23g/dL, the test result could be inaccurate.
   - Collect venous whole blood using K2-EDTA, lithium heparin, sodium heparin or sodium fluoride tubes only. Do not use tubes with any other anticoagulants.
   - Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the PixoTest POCT System show that there is no significant interference for samples containing Hemoglobin C (≤ 36%), Hemoglobin D (≤ 41%), Hemoglobin E (≤ 28%), Hemoglobin S (≤ 40%), Hemoglobin F (≤ 19%), and Hemoglobin A2 (≤ 6.5%).

4. Special instrument requirements:

   PixoTest POCT Analyzer

I. Device Description:

The iXensor PixoTest POCT System consists of the following components:

1) PixoTest POCT Analyzer, including
   - PixoHealth POCT A1c App
   - USB Charger
   - USB Type C Charge Cable
   - PixoTest POCT Calibration Card

- Instructions for Use

2) PixoTest POCT A1c Test Kit, including
   - PixoTest A1c Test Strips
   - Spoits (to acquire 5µl blood sample by capillary action and to mix blood and buffer together) with Latex-Tablets (containing blue dyed latex micro particles conjugated to specific antibodies for detection of HbA1c)
   - Buffer Solution Tubes
   - Instructions for Use

J. Substantial Equivalence Information:

1. Predicate device name(s):

   SD A1cCare System and SD A1cCare Spoit Type Test Kit

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

   k140827

3. Comparison with predicate:

Similarities & Differences		
Item	Device PixoTest POCT System (k181915)	Predicate SD A1cCare System (k140827)
Indications for Use	Quantitative determination of percent hemoglobin A1c to monitor long term glycemic control in individuals previously diagnosed with diabetes.	Same
Test Principle	Immunoassay	Same
Intended Use Environment	Clinical laboratories and point-of-care settings	Same
Measuring Range	4.0-15.0%	Same
Sample Type	Venous whole blood (anticoagulated with K2-EDTA, sodium heparin, lithium heparin, or sodium fluoride)	Fingerstick capillary or venous whole blood (anticoagulated with K2-EDTA, sodium heparin, lithium heparin, or sodium fluoride)
Sample Volume	5 µL	Same
Sample Pretreatment tools	Spoit, buffer tube	Same

Similarities & Differences		
Item	Device PixoTest POCT System (k181915)	Predicate SD A1cCare System (k140827)
Hematocrit	25-65%	Same
Calibration	QR code with lot-specific calibration for associated test kits; calibration card for optical functional check	Code chip with lot-specific calibration for associated test kits; check strip for optical functional check
Quality Control	Bio-Rad Liquicheck Diabetes Control (Level 1, Level 2) available separately	SD HbA1c Control Set (Level 1, Level 2), SD HbA1c Control Level M
Storage Temperature	34-86°F (1-30°C)	Same
Maximum Altitude	3,000 m (9,843 feet)	2,000 m (6,560 feet)
Operating Temperature	59-90°F (15-32°C)	59-104°F (15-40°C)
Operating Humidity	10-90% relative humidity	Same
Shelf-Life of Test Strips	18 months	Same
Device Dimensions	181 x 111 x 53 (mm)	163 x 96 x 52 (mm)
Device Weight	314.3 g	500 g
Power supply	5000 mAh battery, non-removable, rechargeable	4x 1.5V AA Alkaline batteries or AC Adapter
Memory Capacity	>10000 tests results with date and time	900 tests results with date and time

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

ISO 14971:2007, Medical devices - Application of risk management to medical devices

ISO 15223-1:2016, Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements

L. Test Principle:

The PixoTest A1c Test kit uses an anti-HbA1c antibody which is specific for the first few amino acid residues of the glycated N-terminus of the ß-chain of hemoglobin A0. When whole blood is added to the buffer solution tube and mixed with the spoit, the erythrocytes are instantly lysed to release the glycated hemoglobin (hereafter, HbA1c). When sample mixture is loaded onto the sample port of the test panel, the mixture fluid migrates along the membrane of the test panel by capillary action, and the HbA1c is then immobilized onto the anti-HbA1c antibody coated line. The amount of the blue conjugates on the anti-HbA1c line reflects the amount of HbA1c in the sample. The intensity of hemoglobin color from the

desired area on the membrane of test panel is measured. Chemical and immune reaction that occurs on the test strip is measured by the optical system in PixoTest POCT Analyzer. This system measures both fractions and uses an algorithm to convert the result into the percentage HbA1c in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

An internal precision study was performed with K2-EDTA venous whole blood samples containing five levels of HbA1c. Samples were tested in duplicate for two runs per day over 20 days using 1 test kit lot per analyzer for a total of 3 test kit lots and 3 analyzers. The results are shown below:

HbA1c level (%)	Lot	N	Mean HbA1c (%)	Repeatability (Within-run)		Between run		Between day		Total	
				SD	CV	SD	CV	SD	CV	SD	CV
4.0 to 5.5	1	80	5.27	0.17	3.1%	0.01	0.3%	0.12	2.2%	0.16	3.1%
	2	80	5.17	0.15	2.8%	0.01	0.1%	0.11	2.0%	0.14	2.8%
	3	80	5.25	0.20	3.8%	0.01	0.3%	0.16	3.0%	0.20	3.8%
	Combined	240	5.23	0.17	3.2%	0.01	0.2%	0.13	2.4%	0.17	3.3%
5.5 to 6.5	1	80	5.99	0.23	3.7%	0.01	0.2%	0.16	2.7%	0.22	3.7%
	2	80	6.00	0.22	3.8%	0.01	0.2%	0.18	3.0%	0.22	3.7%
	3	80	5.98	0.23	3.9%	0.03	0.5%	0.18	3.0%	0.23	3.8%
	Combined	240	5.98	0.23	3.8%	0.02	0.3%	0.17	2.9%	0.22	3.7%
6.5 to 7.5	1	80	6.97	0.25	3.6%	0.03	0.4%	0.17	2.4%	0.25	3.5%
	2	80	6.86	0.25	3.6%	0.03	0.4%	0.16	2.3%	0.25	3.6%
	3	80	6.97	0.21	3.1%	0.01	0.2%	0.14	2.0%	0.21	3.0%
	Combined	240	6.93	0.24	3.4%	0.02	0.3%	0.16	2.2%	0.22	3.1%
7.5 to 8.5	1	80	7.83	0.25	3.2%	0.04	0.5%	0.14	1.7%	0.25	3.2%
	2	80	7.93	0.26	3.3%	0.01	0.2%	0.16	2.1%	0.26	3.3%
	3	80	7.86	0.24	3.0%	0.05	0.6%	0.15	1.9%	0.24	3.0%
	Combined	240	7.88	0.25	3.2%	0.03	0.4%	0.15	1.9%	0.24	3.1%
11 to 13	1	80	11.88	0.29	2.4%	0.01	0.1%	0.17	1.4%	0.28	2.4%
	2	80	11.97	0.27	2.3%	0.06	0.5%	0.18	1.5%	0.28	2.3%
	3	80	11.96	0.26	2.2%	0.03	0.2%	0.14	1.2%	0.26	2.2%
	Combined	240	11.94	0.27	2.3%	0.03	0.3%	0.16	1.4%	0.29	2.4%

An external reproducibility study was performed at three point-of-care sites with three intended use operators per site over five days. K2-EDTA venous whole blood samples containing five levels of HbA1c were tested over three runs in triplicate per run per

day using 3 test kit lots and 3 analyzers. Within-run, between run, between day, between site, and between operator variability were assessed. The total precision CVs were ≤ 2.9% at 5.3% HbA1c, ≤ 3.3% at 6.2% HbA1c, ≤ 3.7% at 6.8% HbA1c, ≤ 3.1% at 7.8% HbA1c, and ≤ 2.6% at 12.0% HbA1c.

b. Linearity/assay reportable range:

A total of 13 K2-EDTA venous whole blood samples with HbA1c concentrations covering the assay measuring range (at approximately 3.9, 4.8, 5.8, 6.5, 7.7, 8.2, 9.7, 10.7, 11.4, 12.3, 13.8, 14.8, 15.5%) were analyzed in ten replicates per sample on one PixoTest POCT System using 3 lots of PixoTest POCT A1c Test Kits. The mean of these replicates was compared to the expected values obtained from TOSOH G7 analyzer (k011434). A representative linear regression equation from one lot is shown below:

$y = 0.99x + 0.13$, $r = 0.99$

The study supports the sponsor's claimed linearity range of 4.0 - 15.0% HbA1c.

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

Traceability:
The PixoTest POCT System is traceable to the International Federation of Clinical Chemistry (IFCC) reference material.

Test strip stability:
The PixoTest POCT Test Kit has a shelf-life of 18 months when stored at 34-86°F (1-30°C) and 10-90% relative humidity. Shelf-life protocols and acceptance criteria were previously reviewed in k140827 and found acceptable.

d. Detection limit:

The claimed HbA1c measuring range of 4.0%-15.0% for the PixoTest POCT System is based on linearity. See M.1.b. above.

e. Analytical specificity:

Endogenous and exogenous interference
Endogenous and exogenous substances were spiked at two levels into each of two K2-EDTA venous whole blood samples (containing approximately 5.5% or 9.6% HbA1c). Test samples measured on the PixoTest POCT System were compared to K2-EDTA venous whole blood control samples (containing no potential interferent) measured on the PixoTest POCT System. Test and control samples were tested in replicates of five. The sponsor defined non-significant interference as ≤ ± 6% change in the HbA1c measurements from the control value. The following substances demonstrated no significant interference at the concentrations described below:

Substance	Highest concentration without significant interference
Albumin	6000 mg/dL
Unconjugated bilirubin	20 mg/dL
Glycated Albumin	770 mg/dL
Lipemia/Intralipid	3300 mg/dL
Rheumatoid Factor	600 IU/mL
Total protein	12000 mg/dL
Urea	260 mg/dL
Aspirin (acetylsalicylic acid)	65 mg/dL
Ascorbic acid	10 mg/dL
Acetaminophen	30 mg/dL
Acetylcysteine	170 mg/dL
Ampicillin	5.3 mg/dL
Caffeine	30 mg/dL
Cefoxitin	66 mg/dL
Cyclosporine A	1 mg/dL
Doxycycline	3 mg/dL
Glyburide	20 mg/dL
Hydroxyzine dihydrochloride	30 mg/dL
Heparin	3000 U/L
Ibuprofen	50 mg/dL
Levodopa (L-dopa)	2 mg/dL
Dopamine	2 mg/dL
Methyldopa	1.5 mg/dL
Metformin	5.1 mg/dL
Metronidazole	12 mg/dL
Rifampicin	6.4 mg/dL
Glibenclamide	0.2 mg/dL

Hemoglobin derivative interference

Interference from hemoglobin derivatives (acetylated hemoglobin, carbamylated hemoglobin, labile A1c) was assessed in two K2-EDTA venous whole blood samples (approximately 5.5% or 9.6% HbA1c). Acetylated hemoglobin was derived in the presence of acetylsalicyclic acid, carbamylated hemoglobin was derived in the presence of sodium cyanate, and labile A1c was derived in the presence of glucose. Test samples measured on the PixoTest POCT System were compared to K2-EDTA venous whole blood control samples (containing no potential interferent) measured on the PixoTest POCT System. Test samples and control samples were tested in replicates of five. The sponsor defined non-significant interference as $\leq \pm 6\%$ change in the HbA1c measurements from the control value. The following hemoglobin derivatives demonstrated no significant interference at the concentrations described below:

Hemoglobin derivative	Highest concentration without interference
Acetylated hemoglobin	200 mg/mL (20000 mg/dL)
Carbamylated hemoglobin	20 mg/mL (2000 mg/dL)
Labile A1C	2000 mg/mL (200000 mg/dL)

Hemoglobin variant interference:
A hemoglobin variant study was performed using K2-EDTA venous whole blood samples (ranging from 5.0% to 9.7% HbA1c) containing known concentrations of hemoglobin variants C, D, E, S, F, and A2. Samples measured by PixoTest POCT System were compared to the assigned HbA1c concentration. The sponsor defined non-significant interference as ≤ ± 7% change in HbA1c from the reference value. The data demonstrate no significant interference for the hemoglobin variants at the following concentrations: Hemoglobin C (≤ 36%), Hemoglobin D (≤ 41%), Hemoglobin E (≤ 28%), Hemoglobin S (≤ 40%), Hemoglobin F (≤ 19%) and Hemoglobin A2 (≤ 6.5%).

The labeling contains the following information regarding hemoglobin variant interference:

Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the PixoTest POCT System show that there is no significant interference for samples containing Hemoglobin C (≤ 36%), Hemoglobin D (≤ 41%), Hemoglobin E (≤ 28%), Hemoglobin S (≤ 40%), Hemoglobin F (≤ 19%) and Hemoglobin A2 (≤ 6.5%).

Total hemoglobin
The effect of different levels of total hemoglobin was evaluated using three K2-EDTA venous whole blood samples containing approximately 5.3%, 7.1%, or 12.2% HbA1c. Samples measured by PixoTest POCT System were compared to the HbA1c concentration assigned by TOSOH G7 method (k011434). The sponsor defined non-significant interference as ≤ ± 6% change in HbA1c from the reference value. The data supports the claimed hemoglobin range of 7 to 23 g/dL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted at three point of care sites with three intended use operators at each site. K2-EDTA venous whole blood samples from 120 subjects (40 subjects per site) were collectedand tested in singlicate with the PixoTest POCT System using three lots of PixoTest POCT A1c Test Kits at each site. The

results obtained with the PixoTest POCT System were compared to the results obtained for the same samples with the TOSOH G7 comparative method (k011434). The range of HbA1c tested was 4.6% to 14.2% HbA1c as determined by TOSOH G7 method. Results of the linear regression analysis are shown below.

Site	N	HbA1c range (%)	Slope	Intercept	R
1	40	4.6 – 13.4	0.988	0.157	0.987
2	40	5.0 – 13.3	1.054	-0.281	0.989
3	40	4.8 – 14.2	1.049	-0.242	0.991
Combined	120	4.6 – 14.2	1.024	-0.112	0.988

b. Matrix comparaison :

Testing was performed to validate the use of venous whole blood samples with different anticoagulants with the PixoTest POCT System. Fifty venous whole blood samples (ranging from 5.0% to 13.0% HbA1c) were drawn into each of the intended anticoagulant tube types. Values for sodium heparin, lithium heparin, and sodium fluoride venous whole blood samples measured on PixoTest POCT System were compared to values obtained for K2-EDTA venous whole blood samples measured on PixoTest POCT System. Results of the linear regression analyses are shown below.

Anticoagulant	Slope	Intercept	R
Sodium heparin	1.0192	-0.1801	0.9929
Lithium heparin	0.9983	0.0327	0.9907
Sodium fluoride	1.0146	-0.1055	0.9953

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:

   The American Diabetes Association (ADA) recommended a reasonable A1c goal for many non-pregnant adults is < 7 % (53 mmol/mol). Providers might reasonably suggest more stringent A1C goals (such as 6.5 % [48 mmol/mol]) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment.

   Reference: American Diabetes Association. Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018 Jan; 41 Suppl. 1: S55-S64.

N. Instrument Name:

PixoTest POCT Analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ____X____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____X____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   There is no specimen identification (other than the time stamp) for the PixoTest POCT system.

4. Specimen Sampling and Handling:

   This device is intended to be used with venous whole blood. Using the spoit, the venous whole blood sample will be mixed with the provided buffer and latex tablet first and then applied to the test strip.

5. Calibration:

   There is no calibration required by the user for the PixoTest POCT system. The meter must scan the corresponding QR Code, which stores the calibration information for each test kit lot, on the inside of the PixoTest A1c Test kit box prior to using a new lot.

6. Quality Control:

   iXensor does not provide control solutions. Users are recommended to check the accuracy of the meter using the Bio-Rad Liquicheck Diabetes Control (Level 1, Level 2). The control solutions are sold separately.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

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

R. Conclusion:

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