

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

A. 510(k) Number:

k073416

B. Purpose for Submission:

Clearance of a New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:

ARKRAY Factory USA, Inc

F. Proprietary and Established Names:

ARKRAY GLUCOCARD™ 01 Blood Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
21 CFR § 862.1660, Quality controls (assayed and unassayed)
2. Classification:
Class II, Class I (reserved)
3. Product code:
NBW, CGA, JJX
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See Indications for use.
2. Indication(s) for use:
GLUCOCARD™ 01 Blood Glucose Monitoring System:
The GLUCOCARD™ 01 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is

indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD™ 01 Blood Glucose Meter:

The GLUCOCARD™ 01 Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. GLUCOCARD™ 01 SENSOR Blood Glucose Test Strips must be used with the GLUCOCARD™ 01 Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD™ 01 SENSOR Blood Glucose Test Strips:

GLUCOCARD™ 01 SENSOR Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. GLUCOCARD™ 01 SENSOR Blood Glucose Test Strips must be used with the GLUCOCARD™ 01 Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD™ 01 CONTROL:

For use with GLUCOCARD™ 01 Blood Glucose Meter and GLUCOCARD™ 01 SENSOR Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in three levels - Low (L), Normal (N) and High (H).

3. Special conditions for use statement(s):

- For over the counter use.
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Alternative site testing is for use at times of steady state only
- Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state

4. Special instrument requirements:

GLUCOCARD™ 01 Blood Glucose Monitoring System

I. Device Description:

The GLUCOCARD™ 01 system consists of the Glucose Meter, 01 SENSOR Blood Glucose Test Strip (glucose oxidase), and Control Solutions (low, normal, and high).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Advance Micro-draw

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

k041881

3. Comparison with predicate:

Similarities		
Item	New Device: GLUCOCARD 01	Predicate: Advance Micro-draw
Enzyme	Glucose Oxidase (<i>Aspergillus niger</i> sourced)	Same
Measurement Range	20 to 600 mg/dL	Same
Reference	Plasma	Same
Sample Type	Capillary whole blood	Same
Sample Application	Apply blood to end, capillary fill	Same
Maximum Altitude	10,000 ft	Same
Operating T° Range	50°F to 104°F	Same
Operating Humidity Range	20% to 80% (relative humidity)	Same
Display	Liquid crystal display	Same
Test Start	Insert strip into meter	Same
Power Source	One 3V Lithium CR2032	Same
Blood Source	Fingertip and Palm	Same

Differences		
Item	New Device: GLUCOCARD 01	Predicate: Advance Micro-draw
Minimum Sample Volume	0.3 µL	1.5 µL
Test Time (sec.)	7	15
Units of Measurement	mg/dL only	mg/dL or mmol/L
Calibration Curve	Automatic with strip insertion	Automatic w/ keycode insertion
Hematocrit Range	30-54%	30-55%
Control Solution(s)	Three levels available	Two levels available
Memory Capabilities	360 results	250 results
Button number/pattern	Two buttons on side of meter	Three buttons on front of meter
Dimensions	2" x 3.9" x 0.5" (50mm x 100mm x 12 mm)	3.5" x 3" x 0.8"
Weight	1.6 ounces	1.4 ounces

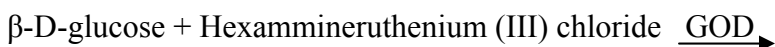
K. Standard/Guidance Document referenced (if applicable):

- Interference testing in Clinical Chemistry - CLSI EP7-A2
- Evaluation of Precision Performance of Quantitative Measurement Procedures - CLSI EP5-A2
- Method Comparison and Bias Estimation Using Patient Samples - CLSI EP9-A
- In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus – ISO 15197

L. Test Principle:

The sample (whole blood) is drawn by capillary action at the tip of the test strip. Glucose in

the sample reacts with glucose oxidase (GOD) and Hexaammineruthenium (III) chloride in the test strip. This produces Hexaammineruthenium (II) chloride. Hexaammineruthenium (II) chloride is produced in proportion to the glucose concentration of the blood sample. Oxidation of the Hexaammineruthenium (II) chloride produces an electric current. The meter converts the current to the glucose concentration and displays it as the test result.



M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Analysis was performed using fresh venous whole blood obtained from 6 non-diabetic volunteers. Glucose concentrations in the whole blood were adjusted to obtain 6 glucose concentrations encompassing the 30-600 mg/dL range following CLSI EP5-A.

Within-Day precision tests consisted of twenty replicates of each of the six whole blood glucose samples. The Within-Day precision tests were performed within 4 hours of collection of the venous blood sample in each case, with exception of the very low blood glucose sample, which was permitted to undergo glycolysis with time to achieve a glucose level within the 30-50 mg/dL range. This, however, did not exceed 6 hours. The YSI 2300 reference blood glucose analyzer was used to obtain the target blood glucose values. Between-Day precision testing involved performing the same test over a period of six days. Three (3) separate Lots of test strips were tested.

Within- Run Precision Summary

Test Strip Lot 1					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean (mg/dL)	32.7	62.4	128.8	235.7	557.5
% CV	3.2	3.2	3.5	1.8	1.9
Test Strip Lot 2					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean (mg/dL)	24.5	63.3	124.2	224.8	506.2
% CV	3.1	2.3	2.5	2.1	2.1
Test Strip Lot 3					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean (mg/dL)	25.0	62.9	123.5	227.7	519.8
% CV	3.3	2.5	2.6	3.6	2.4

Between-Run Precision Summary:

Between-Run (Day-To-Day) Precision by Glucose Level [mg/dL] and Lot

Test Strip Lot 1					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Average	35.0	61.6	125.9	241.0	531.5
SD	1.2	1.7	3.8	6.3	12.8
CV%	3.4	2.8	3.0	2.6	2.4

Test Strip Lot 2					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Average	35.2	61.8	125.7	238.6	529.4
SD	1.3	2.1	3.7	6.9	12.4
CV%	3.5	3.4	2.9	2.9	2.3

Test Strip Lot 3					
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Average	35.5	61.7	125.2	238.3	533.2
SD	1.1	1.7	3.5	7.3	14.1
CV%	3.3	2.7	2.8	3.1	2.6

b. *Linearity/assay reportable range:*

To assess the linearity range of the device, testing was performed using venous whole blood collected in a 10mL vacuum sample tube. Glucose was adjusted to 11 concentration levels ranging from 13 mg/dL to 712 mg/dL. Five 01 Meter measurements were performed at each glucose concentration. This process was repeated at three temperatures (10, 25, and 40 degrees centigrade). The five 01 Meter measurements were averaged and bias was calculated against the GA-1150 reference analyzer.

The regression equations were as follows:

10°C: $y = 1.0838x - 19.04$ with an R² value of 0.9972

25°C: $y = 1.0097x - 3.3104$ with an R² value of 0.9975

40°C: $y = 1.0032x - 7.7337$ with an R² value of 0.9964

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

The traceability for the Control Solution Glucose Assignment is described relating directly to the Hitachi Hexokinase reference, traceable to NIST Solution SRM 917a (Hexokinase Calibrator) and SRM 917b (Reference Standard).

Shelf life studies show that the unopened test strips have an 18 month life-span and 3 months shelf-life once a vial of strips is opened. Unopened controls have an 18-month

shelf life and are stable for 3 months after opening.

d. Detection limit:

The detection limit is 20 mg/dL. See linearity/assay reportable range section above.

e. Analytical specificity:

Hematocrit: A study was conducted to evaluate hematocrit interference at high hematocrit levels. All blood was fully oxygenated and adjusted to eight concentration levels (34, 52, 73, 121, 195, 264, 334, 528 mg/dL) and five hematocrit levels (30, 33, 36, 42, 50, 53, 54 and 55%). Table 1 summarizes the average percent bias deviation at each glucose level and each upper hematocrit level.

Bias calculation (%) from 42% nominal Hct.

Nominal Glucose Level (mg/dL)	HEMATOCRIT								
	30	33	36	42	49	50	53	54	55
35	-4.9	-2.8	-4.6	0	0.6	0	2.7	0.7	5.2
55	-1.4	-2.1	-3.2	0	-7.5	-3.7	1.9	0.9	1.3
77	-4.5	-2.6	-4	0	-7.6	-3.6	1.6	3.3	-1.7
127	1.6	-0.9	2.2	0	-8.4	-6.4	-6.5	-8.6	-8.6
191	7.8	5.9	2.6	0	-9.9	-6	-10.5	-10.6	-12.7
258	11.2	7.4	4.3	0	-7.4	-10.5	-13	-14.6	-14.3
337	11.2	8.9	3.4	0	-10.9	-10.5	-12.3	-13.5	-15.7
510	13.4	10.4	9	0	-11.2	-12.4	-12.7	-14.9	-17.6

The data for samples between 30 and 54% hematocrit were within $\pm 15\%$ and support a claim of 30%-54% hematocrit range.

Interference Testing:

Interfering substances were dissolved in venous blood at several concentrations each, then these were divided into three aliquots and spiked to nominal glucose concentrations of 60 mg/dL, 120 mg/dL or 320 mg/dL. These samples were tested against control samples which had a blank solvent added at the same volume as the interferent. Samples were tested $n=10$ and the percent difference of the interfering samples were calculated compared to control samples. The following substances were tested.

Table 1: List of Tested Potential Interferents

Compound	Concentrations tested
Acetaminophen	10, 20 mg /dl
Acetyl-salicylic acid	13, 40, 65 mg/dl

Compound	Concentrations tested
Ascorbic Acid	3 mg/dl
Bilirubin – unconjugated	10, 20 mg/dl
Bilirubin – conjugated	20, 40 mg/dl
Cholesterol	150, 250, 300, 500 mg/dl
Creatinine	1.5, 5.0 mg/dl
L-Dopa	1.0, 3.4, 6.8, 13.0 mg/dl
L-Dopamine	0.05, 0.10 mg/dl
Ephedrine	0.014, 0.056 mg/dl
Fructose	15, 30 mg/dl
Galactose	30, 60 mg/dl
Gentisic acid	1.0, 1.8 mg/dl
L-Glutathione	0.79, 1.05, 3.00 mmol/L
Hemoglobin	735, 1470 mg/dl
Ibuprofen	1, 7, 10, 50 mg/dl
Lactose	15, 30 mg/dl
Maltose	150, 300, 450 mg/dl
Maltotetraose	60, 120 mg/dl
Maltotriose	120, 240 mg/dl
Mannitol	100, 200, 400, 800 mg/dl
Mannose	8, 16, mg/dl
Methyl-L-Dopa,	0.10, 0.75, 1.50 mg/dl
Mono-iodoacetic acid	1X, 2X, and 10X
Sorbitol	5, 10 mg/dl
Tetracycline	0.2, 0.5, 1.5 mg/dl
Tolazamide	1.5, 3.0, 8.4 mg/dl
Tolbutamide	5.4, 10.8, 64 mg/dl
Triglyceride	500, 3000 mg/dl
Urea	20, 40, 80, 260 mg/dl
Uric Acid	6.35, 11.35, 21.35 mg/dl
Warfarin	0.1, 0.3, 1.0 mg/dl
Xylitol	25, 50 mg/dl
Xylose	40, 80 mg/dl

When mono-iodo acetic acid was tested at 2X and 10X it showed between 19 and 29 mg/dl bias at low levels (56 mg/dl) of glucose and showed interferences of between 17% and 48% at normal glucose levels (122 mg/dl). At high glucose level (307 mg/dl), there was over 32% interference at 10X mono-iodacetic acid. Inteferece was also seen with EDTA and Flouride-oxalate anticoagulant. No interference was seen up to 5X heparin at all three levels of glucose tested.

A warning was included in the labeling to use only heparin treated samples of blood and no other preservatives.

All other compounds tested showed biases of $<\pm 15\%$

Altitude Study:

An altitude study was performed with venous whole blood adjusted to four different

glucose concentrations ranging from approximately 56 to 540 mg/dL. One aliquot of each sample was tested on the ground at 900 feet above sea level and the other was tested at 10,000 \pm 20 feet in a small non pressurized airplane. The result of each sample tested at 10,000 feet was within \pm 10% of the sample tested on the ground. This demonstrates that the meter may be used up to an altitude of 10,000 feet above sea level.

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 50°F to 104°F and at relative humidity ranging from 20% to 80%.

- f. *Assay cut-off:*
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The method comparison study was performed with 113 capillary fingerstick patient samples. Testing included men and women, ages from 21 to 83 years with a wide range of educational levels. Participants also tested the Low, Normal, and High Control Solutions on either the 01 Meter or the X-METER (approximately half of Participants were tested on each type of meter)

Regression Statistics for Finger Stick Clinical Study as compared to YSI

System		Slope	Intercept	r
01 Meter	Participant	0.96	1.1	0.97
	Professional	0.96	-1.9	0.98

System accuracy results for glucose concentrations <75 mg/dl

Within \pm 5mg/dl	Within \pm 10mg/dl	Within \pm 15mg/dl
10 of 30 (33%)	21 of 30 (70%)	30 of 30 (100%)

System accuracy results for glucose concentrations \geq 75 mg/dl

Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
46 of 111 (41%)	88 of 111 (79%)	106 of 111 (95%)	109 of 111 (98%)

Method comparison studies were performed using alternate site testing (AST) samples compared to professional fingerstick samples. The studies were performed using 104 samples by professional and participant taken from the palm and fingertip. The results are shown below:

Regression statistics for AST Data as compared to YSI

System	Row #	Comparison	slope	y-intercept (mg/dL)	r
01 Meter	3	Part. Palm vs. Prof. Fingertip	1.08	-3	0.98
	4	Prof. Palm vs. Prof. Fingertip	1.07	-5	0.99

System accuracy results for glucose concentrations <75 mg/dl

Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl
2 of 3 (66%)	3 of 3 (100%)	3 of 3 (100%)

System accuracy results for glucose concentrations >75 mg/dl

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
39 of 101 (39%)	72 of 101 (72%)	84 of 101 (84%)	95 of 101* (95%)

b. *Matrix comparison:*
Not applicable.

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:

Expected blood glucose levels for non-diabetics ^{1,2}

Fasting	70-110 mg/dL
1 to 2 hours after meals	<120 mg/dL

1. Burtis, C.A. Ashwood, E.R., eds.: Tietz Textbook of Clinical Chemistry. 2nd Edition. Philadelphia: W.B. Saunders. (1994), 2190.

2. Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Fibiger (1989), 138.

N. Instrument Name:

GLUCOCARD™ 01 Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for each additional reading.

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 sample identification function with this device. Samples are applied directly to the test strip as they are collected.
4. Specimen Sampling and Handling:
This device is intended to be used with the capillary whole blood. Since the whole blood is applied directly to the test strip, there are no special handling or storage issues.
5. Calibration:
The meter automatically detects the code number when a test strip is inserted. The user must check to see if the code number the meter displays matches the number on the test strip vial. If the number matches, the user is instructed to begin testing. If the number does not match, or if no number appears, the user is instructed to try another test strip. If this fails the user is instructed to try a new vial of strips and to call customer service if this also fails. No other calibration is required from the user.
6. Quality Control:
One control level is provided with the device and two additional control levels are available. The user is instructed to call their supplier or pharmacy to obtain controls and to call Arkray customer service if the supplier or pharmacy does not stock the controls. The user is instructed to run controls when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, when they suspect the meter or strips are not working correctly, when test results are not consistent with the patient's symptoms or the patient does not think the results are accurate, if the meter is dropped, to check their technique, if the test strip bottle had been left open or stored outside its recommended temperature range, or when the Glucocard X-Meter has been stored outside its recommended temperature range. The acceptable results ranges are shown on the test strip vial label. If the results are outside the expected range, the user is instructed to repeat the test. If the repeated test falls outside the range the user is instructed to repeat the test using a new control solution or test strip. If the control continues to read outside the expected range the user is told not to use the test system until the control result reads within the acceptable range.

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

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.