

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

A. 510(k) Number:

k050985

B. Purpose for Submission:

New Device

C. Measurand:

Glucose

D. Type of Test:

Quantitative Amperometric Assay (Glucose Dehydrogenase)

E. Applicant:

All Medicus Co. Ltd.

F. Proprietary and Established Names:

GlucoDr™ SuperSensor Blood Glucose Test Meter, Test Strips, and Controls

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR § 862.1660, Quality Control Material, Assayed and Unassayed

2. Classification:

Class II (Glucose Test System)

Class I (Quality Control Material)

3. Product code:

NBW, LFR (Glucose Test System)

JJX (Quality Control Material)

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use / Indication(s) for use:

The GlucoDr™ SuperSensor system is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in venous whole blood and capillary whole blood from the fingertip. The GlucoDr™ SuperSensor system may be used by healthcare professionals or for self testing by diabetic lay users in the home. The GlucoDr™ SuperSensor system is not intended for the diagnosis of or screening for diabetes mellitus. The GlucoDr™ SuperSensor system is not intended for use on neonates.

2. Special conditions for use statement(s):

This device is intended for use with capillary and venous whole blood and produces results equivalent to whole blood on a laboratory analyzer.

3. Special instrument requirements:

GlucoDr™ SuperSensor Blood Glucose Test Meter and test strips

I. Device Description:

This device consists of the GlucoDr™ SuperSensor Test Meter, GlucoDr™ SuperSensor Test Strips, a lancing device and lancets, a normal and high control,

and labeling. To operate the meter, the user presses the power button which turns on the meter and displays the strip code number currently stored in memory. If the code number matches the number on the vial of test strips, the user is instructed to proceed with testing of control or whole blood samples. If the code numbers do not match, the user is instructed to enter the “code mode” by pressing the power button for two seconds, after which the code number will begin to flash. The code number can be changed up or down by using a button on the side of the meter. When the codes match, users are instructed to press and release the power button, which saves the code number to memory.

To test control solutions, users are instructed to insert a test strip and apply a drop of control solution to the side of the strip. After the result is displayed, it can be marked so that it is not included with the whole blood readings. This must be done before the strip is removed.

To test blood samples, users are instructed to collect enough blood so that the confirmation window is filled before the meter begins to count down from 10 to 1. If insufficient sample is applied, the strip should be discarded and the test repeated. Once a correct result is achieved, it can be marked as a “Meal”, “Exercise”, or “Stress” result so that recalled results can be associated with these conditions.

The lancet supplied with this device was previously cleared under k833344.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Diagnostics Accu-Chek Advantage System
2. Predicate 510(k) number(s):
K032552
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Dehydrogenase
Mediator	Same	Potassium Ferricyanide
Operating Temperature Range	Same	10 - 40° C (50 - 104° F)
Operating Humidity Range	Same	<85%
Strip Storage Temperature	1 – 32° C	2 – 32° C
Hematocrit Range	20-60%	20-65% depending on glucose concentration

Differences		
Item	Device	Predicate
Specimen Types	Professionals may use the test strips to test capillary or venous blood samples; lay use is limited to capillary whole blood testing.	Professionals may use the test strips to test capillary, venous, arterial, and neonate blood samples; lay use is limited to capillary whole blood testing.
Strip Expiration After Opening	4 months	3 months
Electrode	Noble Metal Electrode	Carbon Electrode
Time to Result	10 seconds	15 seconds
Reportable Range	20 – 600 mg/dL	10 - 600 mg/dL
Sample Volume	2 µL	4 µL
Meter Size	63x100x23 mm	89x21x63 mm
Meter Weight	61 g (with battery)	60 g (without batteries)
Battery Type	One CR 2032	Two 1.5V
Memory Capability	250 results with date and time	100 results with date and time

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices

CLSI EP6-A: Evaluation of the Linearity of Quantitative Analytical Methods

CLSI EP7-A: Interference Testing in Clinical Chemistry

CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples

EN 61010-1:2001 (2nd edition): Safety requirements for electrical equipment for measurement, control, and laboratory use

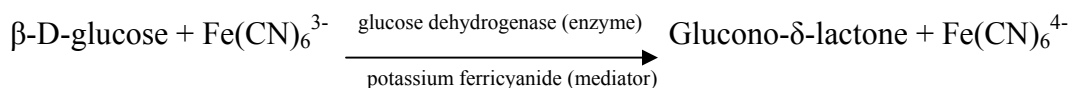
EN 13640: Stability testing of in vitro diagnostic reagents

ISO 14971: Medical Devices – Application of risk management to medical devices

ISO 15197: *In vitro* diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

The following reaction occurs when a blood sample is drawn into the slit of the test strip by capillary action:



The Fe(CN)_6^{4-} produced is then oxidized, producing electrons and a measurable current, which is proportional to the concentration of glucose in the original sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-Run Precision. The sponsor evaluated the within-run precision of the device using spiked venous whole blood samples. Five levels were prepared. Each level was analyzed ten times with three lots of glucose strips at two sites. At a third site the same strip lots were used with one of the lots analyzed in duplicate. Results were as follows:

Level 1	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	53	50	52	52	50	49	48	47	48	48
SD	1.6	2.1	1.9	2.5	2.9	2.0	2.8	1.8	2.7	2.1
CV %	3.2	4.2	3.6	4.8	5.7	4.1	5.9	3.9	5.6	4.3

Level 2	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	97	95	96	95	94	95	93	95	95	94
SD	3.6	1.8	3.2	2.4	3.3	3.2	2.4	4.1	3.2	3.0
CV %	3.7	1.9	3.4	2.5	3.5	3.4	2.5	4.3	3.4	3.2

Level 3	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	131	134	132	132	131	133	131	131	131	130
SD	4.3	3.3	2.9	2.2	2.1	4.0	3.2	3.6	2.9	4.5
CV %	3.3	2.4	2.2	1.7	1.6	3.0	2.5	2.7	2.2	1.9

Level 4	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	211	210	214	214	204	206	208	203	204	202
SD	5.4	4.0	3.1	3.0	3.4	2.5	3.0	5.5	2.2	4.6
CV %	2.5	1.9	1.4	1.4	1.6	1.2	1.5	2.7	1.1	2.2

Level 5	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	300	302	300	296	296	294	288	290	287	291
SD	2.9	4.5	4.0	6.2	4.9	4.3	4.8	5.2	4.1	3.1
CV %	1.0	1.5	1.3	2.1	1.6	1.5	1.7	1.8	1.4	1.1

Day-To-Day Precision. The sponsor evaluated the day-to-day precision of the device using three levels of glucose controls. Each level was analyzed twenty times over twenty days at each of three sites. Three lots of glucose strips were used.

Level 1	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	47	45.8	46.5	46.4	48	47	48	48	45.9	46.8
SD	2.9	2.9	3.3	3.2	3.3	3.2	3.0	3.2	2.5	2.6
CV %	6.3	6.3	7	6.8	6.8	6.9	6.2	6.6	5.4	5.5

Level 2	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	108	108	107	108	107	107	108	108	107	107
SD	3.3	3.5	3	4.11	3.82	4.4	3.32	2.86	3.07	3.62
CV %	3.05	3.25	2.82	3.82	3.58	4.11	3.08	2.66	2.86	3.38

Level 3	Site 1			Site 2			Site 3			
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 3
Mean (mg/dL)	308	306	306	305	307	307	305	308	309	306
SD	7.24	7.38	6.32	7.08	9.44	6.9	7.98	7.94	7.47	7.06
CV %	2.35	2.41	2.07	2.32	3.08	2.25	2.62	2.58	2.42	2.31

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by analyzing eighteen samples prepared in a whole blood matrix. The sponsor used three lots of strips on the GlucoDr™ and compared the mean of 3 replicates per lot to a glucose reference method. The eighteen samples ranged in concentration from a low of approximately 20 mg/dL to a high of approximately 600 mg/dL.

Linear regression of the comparison data yielded the following relationships:

Lot 1	GlucoDr = 1.0096x - 3.715 mg/dL	$r^2 = 0.9978$
Lot 2	GlucoDr = 1.0061x - 5.196 mg/dL	$r^2 = 0.9968$
Lot 3	GlucoDr = 0.9989x - 3.953 mg/dL	$r^2 = 0.9972$

The reportable range of the GlucoDr meter is 20 – 600 mg/dL

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

Two levels of control material are provided for use with the test system and are traceable to NIST and NBS standards. Values are assigned to the controls by comparing to a glucose reference method. The shelf life and in use stability were tested and verified.

d. *Detection limit:*

20 to 600 ng/dL (see linearity study above)

e. *Analytical specificity:*

The specificity of the device was assessed by preparing three venous whole blood control samples at concentrations of 64, 143, and 249 mg/dL. Various endogenous and exogenous compounds were then tested at the levels in the table below:

Potential Interferent	Low Concentration	High Concentration
Bilirubin	0.2 mg/dL	4 mg/dL
Hemoglobin	5.0 mg/dL	500 mg/dL
Oleic Acid	0.4 mmol/L	1.4 mmol/L
Palmitic Acid	0.2 mmol/L	1.0 mmol/L
Triglycerides	190 mg/dL	300 mg/dL
Acetaminophen	2 mg/dL	6 mg/dL
Ascorbic Acid	0.3 mg/dL	4 mg/dL
Creatinine	3.0 mg/dL	30 mg/dL
Dopamine	1.0 mg/dL	13 mg/dL
Ephedrine	3.0 mg/dL	30 mg/dL
Ibuprofen	4 mg/dL	40 mg/dl
L-dopa	1.0 mg/dL	13 mg/dL
Methyl dopa	1.0 mg/dL	13 mg/dL
Salicylate	5 mg/dL	50 mg/dL
Tetracycline	0.4 mg/dL	4 mg/dL
Tolazamide	10 mg/dL	100 mg/dL
Tolbutamine	10 mg/dL	100 mg/dL
Uric Acid	7 mg/dL	10 mg/dL
Citric Acid	3.0 mg/dL	30 mg/dL
Albumin	5.0 g/dL	6.0 g/dL
Maltose	5.0 mg/dL	20 mg/dL

If the tested compound produced a change of less than ± 10 mg/dL at glucose concentrations less than 75 mg/dL or less than $\pm 10\%$ at glucose concentrations greater than 75 mg/dL, this was considered no interference.

Two compounds showed slight interference in this experiment:

Glucose Concentration	Interferent Concentration	Bias
64 mg/dL	Acetaminophen @ 6 mg/dL	+ 10.5 mg/dL
142.5 mg/dL	Maltose @ 20 mg/dL	+ 10.5 %

f. Assay cut-off:
Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor performed a consumer study that included paired whole blood samples at three sites from a total of 115 patients. Glucose concentrations ranged from 63 to 423 mg/dL. The consumers collected and analyzed their own capillary blood sample from the fingertip. Within ten minutes, a healthcare professional collected and analyzed a second fingertip sample. An aliquot of the same sample was used for testing on a laboratory reference analyzer. Linear regression of the data showed the following relationships:

Consumer results (GlucoDr) vs. laboratory analyzer

Slope = 0.9858 (95% confidence interval 0.9595 to 1.0121)
Y-intercept = 5.85 mg/dL (95% confidence interval 0.736 to 10.957)
Correlation Coefficient = 0.9899

Consumer results (GlucoDr) vs. Healthcare Professional (GlucoDr)

Slope = 0.9866 (95% confidence interval 0.9690 to 1.0042)
Y-intercept = 1.03 mg/dL (95% confidence interval 0.969 to 1.004)
Correlation Coefficient = 0.9955

NOTE: The sponsor also supplemented their method comparison studies by preparing 20 whole blood samples and comparing them on the GlucoDr and the laboratory analyzer. This brought the total number of samples to 135, ranging from a low of 25 mg/dL to a high of 586 mg/dL. The GlucoDr was operated by healthcare professionals with the following results:

Healthcare Professional results (GlucoDr) vs. laboratory analyzer

Slope = 0.9834 (95% confidence interval 0.9676 to 0.9993)
Y-intercept = 6.99 mg/dL (95% confidence interval 3.4 to 10.57)
Correlation Coefficient = 0.9956

The sponsor's original consumer study was performed using labeling written in Korean which was translated to English after the completion of the study. A second, smaller consumer study was performed entirely in English to demonstrate that the sponsor's English labeling could be understood and the device used appropriately by persons fluent in English. Thirty capillary whole blood samples were compared with glucose concentrations ranging from 72 to 187 mg/dL. The consumers collected and analyzed their own capillary blood

sample from the fingertip. Within ten minutes, a healthcare professional collected and analyzed a second fingertip sample. An aliquot of the same sample was used for testing on a laboratory reference analyzer. Linear regression of the data showed the following relationships:

Consumer results (GlucOdr) vs. laboratory analyzer

Slope = 1.069 (95% confidence interval 0.992 to 1.147)

Y-intercept = -6.88 mg/dL (95% confidence interval -14.55 to 0.199)

Correlation Coefficient = 0.9829

Healthcare Professional results (GlucOdr) vs. laboratory analyzer

Slope = 1.056 (95% confidence interval 0.981 to 1.13)

Y-intercept = -5.17 mg/dL (95% confidence interval -12.52 to 2.19)

Correlation Coefficient = 0.9839

Consumer results (GlucOdr) vs. Healthcare Professional results (GlucOdr)

Slope = 1.008 (95% confidence interval 0.968 to 1.049)

Y-intercept = -1.21 mg/dL (95% confidence interval -5.286 to 2.861)

Correlation Coefficient = 0.9946

b. Matrix comparison:

The sponsor wishes to use both capillary and venous whole blood with their device. Comparison of capillary whole blood vs. a laboratory reference method was presented in 2.a above. To evaluate performance using venous blood, 60 samples were collected by venipuncture and analyzed on the GlucOdr. Aliquots of the same sample were analyzed with a reference laboratory analyzer. Results were as follows:

Venous whole blood (GlucOdr) vs. laboratory analyzer

Slope = 0.9911 (95% confidence interval 0.9580 to 1.0242)

Y-intercept = -2.5 mg/dL (95% confidence interval -8.22 to 3.21)

Correlation Coefficient = 0.9921

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 sponsor has included the following Expected Values in their labeling:

For non-pregnant, non-diabetic adults

Fasting Values: 70-110 mg/dL (3.9-6.1 mmol/L)

Two Hour Oral Glucose Tolerance Test Values

Less than 140 mg/dL (7.8 mmol/L)

N. Instrument Name:

All Medicus Co. GlucoDr™ SuperSensor Blood Glucose Test Meter

O. System Descriptions:

1. Modes of Operation:

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

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 venous whole blood or capillary whole blood from the fingertip. For capillary whole blood, since the sample is applied directly to the test strip there are no special handling or storage issues. For venous whole blood, the sponsor recommends the use of EDTA or heparin as an anticoagulant and has provided data demonstrating that either can be used with the GlucoDr.

5. Calibration:

The user is instructed to check that the calibration code number displayed at power-on matches the number on the test strip vial. If it is necessary to change the number, the meter can be placed into “code mode” by pressing the power button for two seconds. The new code number is then entered by using the up or down buttons on the side of the meter. When the correct number is reached, it is saved by pressing the power button. No further calibrations or adjustments are required of the user until a new lot of test strips are opened.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. After obtaining a control reading, users are instructed to mark the result with an “Attention icon” so that the result is not stored into memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the User’s Manual if control results fall outside these ranges.

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.