

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

A. 510(k) Number:

k082201

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Whole blood glucose

D. Type of Test:

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

E. Applicant:

U.S. Diagnostics, Inc.

F. Proprietary and Established Names:

G5 Infinity Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Blood Glucose Test System, Glucose Oxidase

21 CFR § 862.1660, Quality control material (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 below.

2. Indication(s) for use:

The G5 Infinity Meter device is used along with the G5 Infinity Test Strips for the quantitative measurement of glucose level in whole blood as an aid in monitoring the

effectiveness of diabetes management in the home by patients with diabetes and in clinical settings by healthcare professionals. G5 Infinity System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the dorsal palm, ventral palm, forearm, upper arm, calf and thigh. The G5 Infinity Blood Glucose Monitoring System is not intended for screening or diagnosis of diabetes and also not for use with neonates.

3. Special conditions for use statement(s):
 - Not for use with neonates
 - Not intended for the screening or diagnosis of diabetes
 - For In Vitro diagnostic use only
4. Special instrument requirements:
G5 Infinity Blood Glucose Meter

I. Device Description:

The device consists of the G5 Infinity Blood Glucose Meter along with G5 Infinity Test Strips, a lancing device, lancets, owner’s manual, log book, quick reference guide, carrying case, and control solution. The G5 Infinity Blood Glucose Meter, when used with the G5 Infinity Test Strips, quantitatively measures glucose in capillary whole blood. The control solution is used to verify the performance of the G5 Infinity Test Strips.

J. Substantial Equivalence Information:

1. Predicate device name(s):
LifeScan, Inc., OneTouch Ultra Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k024194
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Equivalency	Plasma equivalent	Plasma equivalent
Test Time	5 seconds	5 seconds

Differences		
Item	Device	Predicate
Volume Required	0.5 µL	1.0 µL
Hematocrit Range	20-60%	30-55%
Alternate Site Testing	Yes	No

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

None referenced

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip’s electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated within-run precision of the device using whole blood collected in an EDTA collection tube. The blood was then spiked with glucose to create five different levels for testing. Each level was tested 50 times using a single lot of test strips and a single device lot. Results are summarized below:

Average glucose concentration (mg/dL)	40.0	87.5	129.2	217.6	367.6
SD (mg/dL)	1.6	2.9	3.6	6.5	6.5
CV (%)	4.0	3.3	2.8	3.0	1.8

The sponsor evaluated day-to-day precision of the device using 3 levels of control solution. Each of the controls was measured twice a day, once in the morning (Run 1) and once in the afternoon (Run 2) during a month’s time. For each Run, two measurement readings were taken in which the mean, standard deviation (SD), and coefficient variation percent (CV%) were calculated. The same test strip lot and device lot were used for the evaluation. In addition, the same lot of the 3 control solutions (low, normal, high) was used. Results are summarized below.

Average glucose concentration (mg/dL)	50.4	109.7	302.6
SD (mg/dL)	1.8	3.0	7.3
CV (%)	3.6	2.7	2.4

b. *Linearity/assay reportable range:*

To establish the linearity of the system through the range of 20 to 600 mg/dL, 14 glucose adjusted whole blood samples (actual range tested was 20 to 602 mg/dL according to YSI and 20.8 to 602.8 mg/dL when tested with the meters) were compared to YSI 2300 using 5 replicate measurements. Linear regression yields the following statistics:

	Slope	y-intercept	r ²
G5 Infinity BGMS	1.0006	0.3031	0.9999

The sponsor claims 20 mg/dL as the lowest detectable limit in the labeling.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The reference instrument used is the YSI 2300 Glucose Analyzer and is calibrated by YSI 2747 Glucose Standard, a NIST traceable glucose standard.

The three control solutions (low, normal, and high) consist of buffered aqueous solutions of D (+)-glucose containing stabilizers, preservatives, and other non-reactive ingredients.

Closed Vial Stability of Control Solution: The measured glucose levels of 3 lots of control solutions during the shelf lifetime period (26 months) are all within the acceptance criteria of $\pm 15\%$, and the average bias with respect to the mean value throughout the lifetime is less than $\pm 4\%$.

Opened Vial Stability of Control Solution: The measured glucose levels of 3 lots of control solutions during the use lifetime period (3 months) are all within the specified ranges (50 ± 15 mg/dL for low level, 110 ± 16.5 mg/dL for normal level, 300 ± 45 mg/dL for high level solutions), and the average bias with respect to the mean value throughout the lifetime is less than $\pm 0.7\%$.

The expected values of the glucose control solutions were established by testing the solutions 5 times with YSI 2300. If the solutions are within the acceptance criteria, the solutions are then tested 5 times on the Nova Biomedical Stat Profile M. Solutions that pass these two QC checks are then tested 100 times on the candidate device, and the reported range of the control solutions are based on the average of these 100 tests.

- d. *Detection limit:*
The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity study (above section M.1.b.).

- e. *Analytical specificity:*
Spiked whole blood samples containing 3 levels of glucose (low glucose at <60 mg/dL, normal glucose at 150 mg/dL, and high glucose at >300 mg/dL), with and without interfering substances, were prepared to test common endogenous and exogenous substances for interference. Each interferent was tested at five different levels, in accordance with CLSI EP7-P. The highest levels tested for which no interference was observed are summarized below:

Interferent	(mg/dL)
Acetaminophen	20
Bilirubin	40
Gentistic Acid	50
Uric Acid	20

Interferent	(mg/dL)
Levo-Dopa	4
Creatinine	30
Methyl-Dopa	2.5
Tolazamide	5
Dopamine	13
Ascorbate	3
EDTA	640
Glutathione	1
Heparin	1000
Ibuprofen	40
Salicylic Acid	50
Tetracycline	0.4
Tolbutamide	100
Urea	500
Cholesterol	500
Triglycerides	3000
Galactose	50
Xylose	10
Maltose	300

The acceptance criteria were as follows:

At <75 mg/dL samples, interferences over ± 15 mg/dL

At ≥ 75 mg/dL samples, interferences over ± 15 %

Interference testing showed that the candidate device results were within the acceptance criteria at the above interferent concentrations. The sponsor states that acetaminophen, uric acid, ascorbic acid, and other reducing substances do not significantly affect results when occurring in normal blood or normal therapeutic concentrations. However, an abnormally high concentration may cause inaccurately high results. The sponsor also states that lipemic samples, with cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL do not significantly affect results.

An altitude study was performed in an altitude simulation chamber with capillary whole blood from volunteers which was then spiked to 3 levels (52, 153, and 352 mg/dL). The simulation chamber was set to 10,000 feet. The test data using capillary blood samples using both meters showed that the bias versus YSI at 10,000 feet is the same bias versus YSI as that observed at sea level. These data indicate no additional effect due to altitude up to 10,000 feet.

To test the accuracy of the hematocrit effect, blood samples adjusted to hematocrit levels of 20%, 30%, 40%, 50% and 60% at glucose concentrations of 40, 70, 110, 160, 260, 350, 450, and 550 mg/dL were tested a total of 15 times at each concentration. The acceptance criteria were as follows:

At < 75 mg/dL sample, all data should be within ± 15 mg/dL difference and that over 90% of data within ± 10 mg/dL difference (Test hematocrit range 20~60%)

At ≥ 75 mg/dL sample, all data should be within $\pm 15\%$ error and that over 90% of data within $\pm 10\%$ error (Test hematocrit range 20~60%)

*Difference (mg/dL): assay value-average value of 40% Hct sample (at < 75 mg/dL)

* Error (%): (assay value-average value of 40% Hct sample)/average value of 40% Hct sample x 100 (at ≥ 75 mg/dL)

The results are as follows:

Glucose Concentration	number of samples within ± 10 mg/dL	percentage of sample	number of samples within ± 15 mg/dL	percentage of sample
< 75 mg/dL	119	99%	120	100%
At < 75 mg/dL sample, total test number is 120				
Glucose Concentration	number of samples within $\pm 10\%$ error	percentage of sample	number of samples within $\pm 15\%$ error	percentage of sample
≥ 75 mg/dL	356	99%	360	100%
At ≥ 75 mg/dL sample, total test number is 360				

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

2. Comparison studies:

a. *Method comparison with predicate device:*

To demonstrate the accuracy performance of the candidate device, trained specialists tested the capillary blood samples from the finger of 160 patients (with samples ranging from 38 to 496 mg/dL) and compared the results to the results from a laboratory reference method (Hitachi 747) using samples taken at the same time.

*Samples with blood glucose levels below 50 mg/dL were obtained by glycolysis of patient samples, and samples above 400 mg/dL were supplemented with glucose.

Results are summarized below:

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)		
Within ± 5 mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15 mg/dL (within ± 0.83 mmol/L)
43/56 (77 %)	56/56 (100%)	56/56 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
149/264 (56%)	224/264 (85%)	251/264 (95%)	262/264 (99%)

The linear regression was $Y = 0.9977x + 0.4729$, $R^2 = 0.9832$

Lay-user studies were also performed involving 150 individuals fluent in English at 3 clinical sites (50 users per site). Each participant was given a readability questionnaire and draft labeling and instructions for the US market. No other instruction was given. The participants performed their own fingersticks using the G5 Infinity system. These results were then compared to fingerstick results obtained by health care professionals within 5 minutes of the lay user test, also using the G5 Infinity. The acceptance criteria were as follows:

95% of the individual glucose results shall fall within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentration < 75 mg/dL and within 20% at glucose concentration (≥ 75 mg/dL).

The results are as follows:

System accuracy results for glucose concentration < 75 mg/dL (4.2 mmol/L)		
Within ± 5 mg/dL (within ± 0.28 mmol/L)	Within ± 10 mg/dL (within ± 0.56 mmol/L)	Within ± 15 mg/dL (within ± 0.83 mmol/L)
8/25 (32 %)	24/25(96 %)	25/25(100%)

System accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
74/125(59%)	108/125(86%)	121/125(97%)	123/125(98%)

The linear regression was $Y = 0.9934x + 0.955$, $R^2 = 0.9849$

To demonstrate the accuracy performance of the candidate device using alternate sites, a study was performed with lay users who read the user manual on their own, without additional instruction on use of the device by technicians. Samples were taken by the lay users from the fingertip, palm, upper arm, forearm, thigh, and calf and were compared to the users fingerstick result. Samples ranged from 64 - 482 mg/dL. Results are summarized below for samples < 75 mg/dL being within ± 15 mg/dL and ≥ 75 mg/dL within $\pm 20\%$ of the G5 infinity fingerstick:

G5 Infinity AST vs. G5 Infinity Fingerstick	Palm vs. Fingerstick	Forearm vs. Fingerstick	Upper Arm vs. Fingerstick	Calf vs. Fingerstick	Thigh vs. Fingerstick
Total	201/202 (99%)	99/100 (99%)	99/100 (99%)	98/100 (98%)	99/100 (99%)

Within 5 minutes of the lay-users testing their own sample, a healthcare professional collected blood from the fingerstick site and tested it using the Hitachi 747 analyzer. The results are summarized below for the G5 Infinity alternate site samples obtained by the lay user, with < 75 mg/dL being within ± 15 mg/dL and with ≥ 75 mg/dL within $\pm 20\%$ of samples taken by healthcare professionals and analyzed using the Hitachi 747.

G5 Infinity BGM AST vs. Hitachi 747 Fingerstick	Palm vs. Fingerstick	Forearm vs. Fingerstick	Upper Arm vs. Fingerstick	Calf vs. Fingerstick	Thigh vs. Fingerstick
Total	199/202 (98%)	99/100 (99%)	100/100 (100%)	96/100 (96%)	100/100 (100%)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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):

The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following expected glucose values for people without diabetes in their strip labeling:

Fasting: 70 mg/dL – 110 mg/dL (3.9 mmol/L – 6.1 mmol/L) ¹

Two hours after meals: less than 140 mg/dL (7.8 mmol/L) ²

They also include the following statement: “For people with diabetes: your diabetes team will determine the appropriate blood glucose target range individually and jointly with you.”

¹⁾ Stedmans Medical Dictionary, 27th edition, 1999, p755.

2) American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care Supplement 1, pS9

N. Instrument Name:

G5 Infinity Blood Glucose Monitoring 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.

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

Yes or No

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

Yes or No

2. Software:

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

Yes 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 capillary whole blood from the finger, palm, upper arm, forearm, thigh, and calf. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number is associated with the meter by inserting a test strip and entering the code number to match that found on the test strip bottle. No further calibrations are required of the user.

6. Quality Control:

The sponsor has three levels of controls available for this meter with one level coming with the kit and the others being available through the distributor. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section in the control test instructions section of the owner's manual to identify possible reasons control results fall outside these ranges.

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

None

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.