

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

A. 510(k) Number:

k080641

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative glucose dehydrogenase / Pyrroloquinolinequinone (GDH-PQQ)

E. Applicant:

Home Diagnostics, Inc.

F. Proprietary and Established Names:

TRUEresult Blood Glucose System (meter)
TRUEtest Blood Glucose Test Strips

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose Test System

2. Classification:

Class II

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter
LFR – Glucose Dehydrogenase, Glucose

4. Panel:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use

2. Indication(s) for use:

The TRUEresult Blood Glucose System is intended for the quantitative determination of glucose in human whole blood taken from the finger or forearm. The System is intended to be used to assist the patient and Healthcare Professional in the management of diabetes.

Healthcare Professionals may use the device to test venous whole blood; home-use is limited to capillary whole blood testing.

Not for neonatal use.

3. Special conditions for use statement(s):

- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Alternative site testing is for use at times of steady state only
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Peritoneal dialysis patients receiving dialysis solutions containing Icodextrin (e.g., Extraneal®, Icodial) should not use the TRUEresult System. The dialysis solution may falsely raise glucose results.
- Injection or infusion of solutions containing galactose or maltose (includes some human immunoglobulin preparations) may falsely raise glucose results.
- Blood concentrations of galactose > 10 mg/dL, maltose > 12.5mg/dL, maltotriose > 20mg/dL and maltotetraose >10 mg/dL may falsely raise glucose results.
- Do not use TRUEresult Systems during a xylose absorption test. This may falsely raise glucose results.

- Blood samples containing high uric acid concentration (> 9 mg/dL) at glucose levels < 240 mg/dL may be detected as control samples by the TRUEresult meter.

4. Special instrument requirements:

TRUEresult Blood Glucose meter

I. Device Description:

The TRUEresult Blood Glucose System is comprised of TRUEtest glucose reagent test strips, a TRUEresult meter and TRUEtest glucose control solutions. The TRUEtest test strip formulation utilizes glucose dehydrogenase based chemistry. When a user inserts a test strip into the meter, the meter turns on. While the test strip is in the meter, the user obtains a blood or glucose control sample, and then applies the sample to the test strip by touching the edge of the test strip to the sample. When an adequate amount of sample has been applied to the test strip, the meter emits a beep and the test begins. The meter's liquid crystal display (LCD) shows a test is in process. When the test is complete, the meter displays the glucose result. TRUEresult blood glucose results are plasma-calibrated to facilitate comparison to standard laboratory methods of blood glucose measurement.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACCU-CHEK Aviva Blood Glucose System

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

k043474

3. Comparison with predicate:

Similarities		
Item	TRUEresult	Accu-Chek Aviva
Detection method	Amperometric technology, electrochemical biosensor	Same
Enzyme	Glucose dehydrogenase PQQ	Same
Sample type	Whole blood	Same
Altitude	10,150 ft.	Same
Temperature range	10-40 °C	Same
Humidity range	10-90%	Same
Memory	500 results	500 results

Differences		
Item	TRUEresult	Accu-Chek Aviva
Sample volume	0.5 uL	0.6 uL
Test time	4 seconds	5 seconds
Hct range	20-60%	20-70%
Test sample	Fingertip, forearm	Fingertip, forearm, palm, upper arm, thigh and calf
Test range	20-600 mg/dL	10-600 mg/dL
Coding	Automatic, on strip	Code key

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

ISO 15197: In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus

L. Test Principle:

The TRUEresult glucose measurement is based on an electrochemical measurement of the reaction of glucose with the reagents contained on the electrodes of the test strip. The glucose in the sample is oxidized by the enzyme glucose dehydrogenase-PQQ, producing gluconolactone and the reduced form of an electron mediator. The amount of the reduced mediator produced by the oxidation of glucose is proportional to the amount of glucose present in the sample. The reduced electron mediator is then oxidized at the surface of the measurement electrodes when a specified voltage is applied across the electrodes by the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision studies using both spiked whole blood and the glucose controls included with the meter. For the spiked whole blood studies, the sponsor collected whole blood samples and adjusted the glucose concentration to the following target ranges (mg/dL): 30-50, 51-110, 111-150, 151-250, and 251-400. The sponsor used three strip lots and ten meters to collect the data. One hundred replicate measurements were tested for each concentration per strip lot. Results for overall precision for each test strip lot are summarized in the tables below:

Lot 1

Glucose (YSI Plasma) mg/dL	Meter Grand Mean mg/dL	Pooled Variance (mg/dL) ²	Pooled SD mg/dL	Pooled %CV %
37	45	1.0	1.0	2.2
80	78	4.0	2.0	3.0
139	130	16.0	4.0	3.2
250	250	144	12	4.9
318	315	144	12	3.9

Lot 2

Glucose (YSI Plasma) mg/dL	Meter Grand Mean mg/dL	Pooled Variance (mg/dL) ²	Pooled SD mg/dL	Pooled %CV %
37	44	1.4	1.2	2.5
80	77	9.0	3.0	3.5
139	130	16.0	4.0	3.2
250	214	96.0	9.8	4.6
318	319	144	12	3.9

For the studies using glucose control materials, the sponsor analyzed the three levels of control materials that will be available with the meter. The sponsor used three strip lots and ten meters to collect the data over 10 days. Results were as follows:

Strip Lot		Level1	Level 2	Level 3
1	Within-vial %CV	2.50	2.03	2.74
	Pooled %CV	2.56	2.06	2.92
2	Within-vial %CV	2.40	2.16	3.04
	Pooled %CV	2.44	2.16	3.37
3	Within-vial %CV	1.48	1.62	3.09
	Pooled %CV	1.69	1.57	4.05

b. Linearity/assay reportable range:

The measuring range of the device is 20-600 mg/dL. Testing was performed using venous whole blood at 8 glucose concentrations ranging from 10 to 625 mg/dL. The study used two strip lots (16 replicates each) and eight TRUEresult meters. The YSI was used as the reference method.

The sponsor's acceptance criteria of ± 10 mg/dL for glucose levels below 100 mg/dL and $\pm 10\%$ for glucose levels at or above 100 mg/dL were met.

The linear regressions were as follows:

	Lot 1	Lot 2	Lot 3
Slope	0.9554	0.9439	1.0146
Intercept	3.9894	2.7229	-2.5465
r^2	0.99	0.99	0.997

This testing also demonstrated that readings of "Lo" and "Hi" were consistently obtained for glucose levels < 20 mg/dL and > 600 mg/dL respectively.

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

The glucose concentration used in the TRUEtest controls is traceable to NIST reference material SRM 917b for glucose. Control ranges are established by repeat analysis across multiple strip lots. For each lot, the mean, standard deviation, and % CV were calculated. The representative target value of Level 1 is 46 mg/dL, of Level 2 is 107 mg/dL, and of Level 3 is 295 mg/dL. The acceptable range is established as ± 15 mg/dL for Level 1 and $\pm 15\%$ for Levels 2 and 3.

Stability characteristics of the control solutions were determined using real-time and accelerated studies. The unopened shelf-life is expected to be 18 months at the recommended storage of 36° F to 86° F once the real-time stability studies are completed. Open vial stability at 36° F to 86° F is 90 days.

d. Detection limit:

The detection limit is 20 mg/dL as described in section M.1.b above.

e. Analytical specificity:

Endogenous and exogenous substances were tested for interference with this system at a low and high glucose concentration (75 and 240 mg/dL). Two test strip lots and 16 meters were used in this study.

The study revealed that blood samples containing uric acid concentrations ≥ 9 mg/dL at glucose concentrations ≥ 240 mg/dL may be identified as control samples by the TRUEresult meter. This limitation is noted in the labeling.

In addition, of those substances tested, galactose, maltose, maltotriose, maltotetraose and xylose failed to meet the sponsor's acceptance criteria of $< 10\%$ bias between TRUEresult values of spiked samples compared to controlled samples.

There is a warning in the labeling that when substances containing or metabolizing to maltose, galactose, or xylose are used in patient management, the TRUEresult System must not be used. Falsely elevated results can occur. Devices that use methodologies other than GDH-PQQ should be used to measure the patient's glucose.

The effect of hematocrit was evaluated in a study using samples with 5 glucose concentrations (40, 75, 150, 240, and 450 mg/dL) and varying hematocrit levels from 15 - 65%. Each glucose level/hematocrit combination was tested on 16 meters using 3 lots of test strips, by comparing the results of samples at each of the varying hematocrit levels to the sample of the same glucose concentration at a normal (43%) hematocrit level. Each glucose level/hematocrit combination was also compared to the YSI. The data supports the sponsor's claimed hematocrit range of 20-60%.

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 10-40°C and at relative humidity ranging from 10-90%. The results were compared to YSI and the stated acceptance criteria were ± 10 mg/dL for glucose concentrations ≤ 75 mg/dL and $\pm 15\%$ for glucose concentrations > 75 mg/dL. The results were considered acceptable if any part of the 95% confidence range of the differences fell within these ranges. The stated acceptance criteria were met.

An altitude study was performed with whole blood samples from 264 patients ranging from 37 - 500 mg/dL and tested at 4 sites. All samples met the sponsor's acceptability criterion of 95% of results falling within 15 mg/dL of YSI results at glucose levels < 75 mg/dL and within 20% at glucose levels ≥ 75 mg/dL. The data submitted supports use of the device up to 10,150 feet.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

A total of 346 fingertip samples from 173 patients with glucose concentrations distributed over the range of 47 – 500 mg/dL were evaluated at 3 sites. Each blood sample was tested by a health care professional on the TRUEresult meter and was compared to YSI. Based on the data analysis, the device met the minimum system accuracy requirement based on the ISO 15197 guideline, which is that 95% of the individual results are within ± 15 mg/dL of the YSI value at glucose concentrations < 75 mg/dL, and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. Results presented in ISO format for all sites combined are as follows:

System accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
18/27 (67%)	26/27 (96%)	27/27 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
158/319 (50%)	226/319 (83%)	304/319 (95%)	318/319 (99%)

In comparison with YSI, the linear regression was $y = 0.97x + 1.68$, with $r^2 = 0.97$.

A user performance test was performed by a total of 173 volunteers using three strip lots and conducted at three clinical sites. The only instructions provided to the volunteers were the device instructions for use. After reviewing the materials, the user performed their own finger sticks, and the results were compared to YSI. Test results are summarized below as linear regressions and in ISO format.

System accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/25 (64%)	23/25 (92%)	25/25 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
169/321 (53%)	271/321 (84%)	310/321 (97%)	319/321 (99%)

TRUEresult user finger vs. YSI: $y = 0.97x + 1.54$, $r^2 = 0.97$

The sponsor also conducted a user study to demonstrate the performance of the TRUEresult meter using whole blood from the forearm when compared to the fingertip. The study included 172 patients and was conducted at three clinical sites. Both the fingertip and forearm samples were tested by patients. Based on data analysis, the device met the minimum system accuracy requirement based on the ISO 15197 guideline, which is that 95% of the individual results are within ± 15 mg/dL of the YSI value at glucose concentrations < 75 mg/dL, and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. Results presented in ISO format for all sites combined are as follows:

System accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
17/25 (68%)	23/25 (92%)	25/25 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
193/319 (61%)	285/319 (89%)	311/319 (97%)	314/319 (98%)

b. Matrix comparison:

Venous blood samples from 118 patients were assayed on the TRUEresult meter and the YSI using one strip lot. The linear regression comparing TRUEresult to YSI results is $y = 1.11x - 4.40$, $r^2 = 0.99$. The data presented in ISO format is as follows:

System accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
0/4 (0%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
68/232 (29%)	167/232 (72%)	223/232 (96%)	232/232 (100%)

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:

The sponsor's expected blood glucose values for persons without diabetes are taken from the American Diabetes Association Standards of Care, 2008. They are presented in the labeling as follows:

Before eating <110 mg/dL

Two hours after meals <140 mg/dL

Bedtime <120 mg/dL

N. Instrument Name:

TRUEresult Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single-use and disposable 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 capillary whole blood from the fingertip or forearm. Since these whole blood samples are applied directly to the test strip, there are no special handling or storage issues.

Health care professionals can also test venous whole blood on this system. Users are instructed to mix the blood thoroughly before testing.

5. Calibration:

Strip lot-specific calibration is accomplished by embedding a Calibration Code onto each TRUEtest test strip, which then provides the Calibration Code information to the TRUEresult meter when the strip is inserted.

6. Quality Control:

Glucose control solutions at two concentrations should be tested with this device. An acceptable range for each control is printed on the test strip vial. The user is instructed to contact the Customer Help line 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.

In addition to the labeling required under CFR 809.10, the sponsor has developed a professional educational program designed to assure Home Diagnostics, Inc. that professional users understand that interference in patients who are being treated with peritoneal dialysis solutions and immunoglobulin therapies containing or metabolizing to maltose, galactose or xylose results in falsely elevated glucose measurements when this product is used.

R. Conclusion:

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