

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

A. 510(k) Number:

k080710

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose dehydrogenase (GDH-PQQ)

E. Applicant:

Home Diagnostics, Inc.

F. Proprietary and Established Names:

TRUE2go Blood Glucose System

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):

See indications for use below.

2. Indication(s) for use:

The TRUE2go Blood Glucose System is intended for the quantitative determination of glucose in human whole blood take 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
- Not for use in critically ill patients (e.g. those who are dehydrated, in shock, in a hyperosmolar state, etc.)
- **Not for patients who are using medications containing or metabolizing to maltose, galactose or xylose such as peritoneal dialysis solutions and immunoglobulin therapies.**

4. Special instrument requirements:

TRUE2go Blood Glucose Meter

I. Device Description:

The TRUE2go Blood Glucose System is comprised of the TRUE2go Blood Glucose Meter, TRUEtest Glucose Test Strips, and TRUEtest Control Solutions. The TRUE2go meter is designed to affix onto the cap of a TRUEtest strip vial. The test strip vial and its flip-top cap are molded as a single unit so that when the meter is attached to the vial cap, the meter and strip vial are handled by the user as a single unit, with the flip-top cap opening and closing with the meter attached. When the test strips from the vial are depleted, the TRUE2go meter can be removed from the empty strip vial and affixed to a new vial of test strips.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Accu-Chek Aviva Blood Glucose Monitoring System

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

k043474

3. Comparison with predicate:

Similarities		
Item	TRUE2go	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
Differences		
Item	Device	Predicate
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
Memory	99	500
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: 2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus

L. Test Principle:

The TRUE2go Blood Glucose System uses amperometric technology employing a glucose dehydrogenase reaction. When blood is applied to the test strip, electrons are formed by the reaction between the glucose in the sample and the chemicals on the test strip. The resulting

electric current is measured by the meter and correlates with the concentration of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated within-lot and within-vial precision using whole blood samples spiked with 5 different glucose concentrations, two test strip lots, and 10 meters. 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

YSI mean mg/dL	Meter Grand mean mg/dL	Pooled variance (mg/dL) ²	Pooled SD mg/dL	Pooled % CV
40	48	2.9	1.7	3.6
89	78	4.4	2.1	2.7
138	139	18.5	4.3	3.1
236	232	110	10.5	4.5
320	309	222	14.9	4.8

Lot 2

YSI mean mg/dL	Meter Grand mean mg/dL	Pooled variance (mg/dL) ²	Pooled SD mg/dL	Pooled % CV
37	47	2.0	1.4	3.0
89	77	4.4	2.1	2.7
138	138	18.5	4.3	3.1
233	211	98	9.9	4.7
320	312	187.7	13.7	4.4

In addition, the sponsor evaluated five replicates of three levels of control material with two test strip lots and 10 meters over 10 days. Results are summarized in the following table:

Strip lot		Level 1 %	Level 2 %	Level 3 %
1	Within-vial	1.71	1.76	2.60
	Pooled	1.91	1.97	2.96
2	Within-vial	1.53	1.55	2.51

Strip lot		Level 1 %	Level 2 %	Level 3 %
	Pooled	1.68	1.72	2.78

b. Linearity/assay reportable range:

The measuring range of the device is 20-600 mg/dL. Testing was performed using venous blood samples at 8 different blood glucose levels, ranging from 10-625 mg/dL, tested on 2 lots of test strips using 8 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 +/- 10% for glucose levels at or above 100 mg/dL were met. The linear regressions for lot 1 was $y = 1.046x - 1.40$, $r^2 = 0.9961$, and for lot 2 was $y = 1.044x - 1.1851$, $r^2 = 0.9958$. 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 used in these controls is traceable to NIST reference material SRM 917b glucose. For each level of control, values are assigned by repeat analysis using two lots of test strips on 10 meters over 10 days. For each lot, the mean, standard deviation, and % CV were calculated. The representative target value of Level 1 is 45 mg/dL, of Level 2 is 102 mg/dL, and of Level 3 is 295 mg/dL. The acceptable range is established as +/- 15mg/dL for Level 1 and +/- 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 18 months and the open vial stability is 90 days at the recommended storage of 36 °F to 86 °F.

d. Detection limit:

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

e. Analytical specificity:

Endogenous and exogenous substances were tested for interference on this assay at a low and high glucose concentration (75 and 240 mg/dL). Two test strip lots and eight meters were used in this study. Of those substances tested, galactose, maltose, maltotriose, maltotetraose and xylose failed to meet the sponsor's acceptance criteria of < 10 % bias between TRUE2go 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 TRUE2go 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 between 15-65%. Each glucose level/hematocrit combination was tested on 8 meters using 2 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. Results met the sponsor's acceptance criteria of +/- 10 mg/dL for glucose concentrations at or below 75 mg/dL and +/- 15 % for glucose concentrations above 75 mg/dL to support 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 10-40⁰C and at relative humidity ranging from 10-90%.

An altitude study was performed with whole blood samples from 107 patients ranging from 37- 498 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 339 fingertip and forearm samples from sample from 170 patients with glucose concentrations distributed over the range of 24 – 549 mg/dL were evaluated at 4 sites. Each blood sample from the volunteers was tested by YSI and by the TRUE2go system. Percent distribution of the samples corresponding to the glucose concentration ranged as follows: 20-50 mg/dL = 5%; 51-80 mg/dL = 15%; 81- 120 mg/dL =20%; 121-200 mg/dL = 30%; 201- 300 mg/dL = 15%; 301-400 mg/dL = 10%; and > 400 mg/dL = 5%. To obtain the blood glucose concentrations less than 50 mg/dL, a pooled capillary whole blood specimen was incubated at 37⁰C, and to obtain concentrations greater than 400 mg/dL, a pooled specimen was spiked with the desired glucose levels. 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 ±15mg/dL of the YSI value at glucose concentrations <75mg/dL, and within ±20% at glucose concentrations ≥75mg/dL. In comparison with YSI, the linear regression was $y = 1.01x - 1.18$, with $r^2 = 0.9800$. 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
24/47 (51%)	44/47 (94%)	47/47 (100%)

System accuracy results for glucose concentrations ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
148/292 (51%)	247/292 (85%)	280/292 (96%)	289/292 (99%)

A user performance test was performed by a total of 166 volunteers. 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 forearm sticks and tested themselves using two lots of test strips. Immediately after the users self-tested, samples were obtained by healthcare professionals and tested on the YSI. Test results are summarized below as linear regressions and in ISO format.

TRUE2go user finger vs. YSI $y = 0.95x + 4.92, r^2 = 0.9700$

System accuracy results for glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
15/22 (68%)	22/22 (100%)	22/22 (100%)

System accuracy results for glucose concentrations ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
171/310 (55%)	255/310 (82%)	299/310 (96%)	309/310 (99.7%)

TRUE2go user forearm vs. YSI $y = 1.03x - 4.29, r^2 = 0.9700$

System accuracy results for glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
11/19 (58%)	17/19 (89%)	19/19 (100%)

System accuracy results for glucose concentrations ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
176/311 (57%)	261/311 (84%)	298/311 (96%)	309/311 (99.4%)

TRUE2go user forearm vs. finger $y = 1.07x - 7.55, r^2 = 0.9700$

System accuracy results for glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
14/19 (74%)	19/19 (100%)	19/19 (100%)

System accuracy results for glucose concentrations ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
203/311 (65%)	269/311 (86%)	299/311 (96%)	306/311 (98.4%)

b. *Matrix comparison:*

Venous blood samples from 118 patients were assayed on the TRUE2go meter and the YSI using 2 lots of strips. The linear regression comparing TRUE2go results to YSI results is $y = 1.11x - 3.52$, $r^2 = 0.9900$. 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 $\pm 20\%$
69/232 (30%)	153/232 (66%)	223/232 (96%)	231/232 (99.6%)

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):*

See section 2a above

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

In the labeling expected blood glucose levels for people without diabetes (referenced from American Diabetes Association Standards of Care, 2008) are presented as follows:

Before eating - less than 110mg/dL

Two hours after meals - less than 140 mg/dL

bedtime – less than 120 mg/dL

At

N. Instrument Name:

TRUE2go Blood Glucose Meter

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 capillary whole blood from the finger or forearm. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

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 meter when the test strip is inserted into the meter.

6. Quality Control:

Glucose control solutions at two concentrations should be tested with this device. The labeling recommends that the user test control materials before testing blood samples. 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 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 when this product is used for glucose measurements.

R. Conclusion:

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