

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

A. 510(k) Number:

k062555

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:

Apex Biotechnology Corp.

F. Proprietary and Established Names:

Gluco Track Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR § 862.1660, Single (specified) analyte 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:

The Gluco Track Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary, fingerstick whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for both lay use by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus.

3. Special conditions for use statement(s):

For Over-the-Counter use.

4. Special instrument requirements:

Gluco Track Blood Glucose Monitoring System

I. Device Description:

The Gluco Track Blood Glucose Monitoring System is based on an electrochemical biosensor technology and the principle of capillary action. Capillary action at the end of

the test strip draws the blood into the action chamber and your blood glucose result is displayed in 6 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Glucosure Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k011233
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase

Differences		
Item	Device	Predicate
Sample Source	The glucose concentration is measured with capillary whole blood from the fingertip.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip.
Test Range	20 – 600 mg/dL	30 – 550 mg/dL
Volume Required	1.0 µL	3.0 µL
Test Time	6 seconds	30 seconds

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

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

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 the precision of the device using replicate measurements of glucose adjusted venous whole blood with 3 different strip lots. Within-run precision was performed using ten replicates each of 5 glucose concentrations and 2 levels of glucose control solutions. Between-run precision was performed using ten replicates per day of 5 glucose concentrations and 2 levels of glucose control solutions for ten days were tested on ten meters each tested with 3 strip lots. Results are summarized below.

Whole Blood Samples							
		Within-Run		Between Run		Overall	
Strip Lot	Mean (mg/dL)	SD	%CV	SD	%CV	SD	%CV
FS001A	48	3.6	--	3.0	--	3.4	--
	116	5.9	5.1%	4.7	4.1%	4.8	4.1%
	194	7.7	4.0%	7.2	3.7%	7.2	3.7%
	293	13.2	4.3%	11.0	3.8%	12.3	4.2%
	415	14.5	3.2%	19.3	4.7%	23.0	5.5%
FS001B	48	4.2	--	4.2	--	4.2	--
	114	6.3	5.6%	6.4	5.6%	6.4	5.6%
	190	4.9	2.6%	7.3	3.8%	7.2	3.8%
	290	11.8	3.8%	12.4	4.3%	14.7	5.0%
	409	14.5	3.4%	18.3	4.5%	18.7	4.6%
FS001C	46	1.7	--	3.8	--	4.0	--
	112	4.8	5.6%	6.4	5.7%	6.2	5.6%
	187	7.7	2.6%	8.1	4.3%	8.2	4.4%
	286	10.9	3.8%	11.9	4.2%	11.8	4.1%
	404	13.0	3.4%	17.5	4.3%	17.1	4.2%

Control Samples							
		Within-Run		Between Run		Overall	
Strip Lot	Mean (mg/dL)	SD	%CV	SD	%CV	SD	%CV
FS001A	111	4.5	3.9%	3.4	3.1%	3.8	3.5%
	219	6.1	2.7%	5.6	2.5%	5.7	2.6%
FS001B	108	4.3	3.8%	4.5	4.2%	4.7	4.3%
	214	3.1	1.5%	5.4	2.5%	5.2	2.4%
FS001C	109	3.1	2.7%	3.9	3.6%	3.9	3.6%
	215	4.5	2.1%	5.2	2.4%	5.2	2.4%

Results meet the sponsors acceptance criteria of a standard deviation ≤ 4.5 mg/dL when the glucose concentration was <75 mg/dL and $\leq 6\%$ CV for glucose concentrations ≥ 75 mg/dL.

b. Linearity/assay reportable range:

To establish the linearity of the Gluco Track system whole blood samples were compared to YSI 2300 with three lots of test strips using 8 different glucose concentrations. For each lot of test strips, 10 meters where tested for each concentration. Linear regression yields the following statistics:

Lot	FS001A	FS001B	FS001C
N	320	320	320
Glucose Concentrations	22, 48, 80, 123, 200, 303, 445, and 593 mg/dL	22, 48, 80, 123, 200, 303, 445, and 593 mg/dL	19, 40, 76, 124, 204, 298, 456, and 599 mg/dL
Slope	0.9894	1.0072	1.0275
y-intercept	-1.7579	-0.7606	-2.8419
r ²	0.997	0.9974	0.9962

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

The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a).

Stability characteristics of both levels of control solutions were determined using real time aging studies to determine the open vial storage stability at room temperature to be 18 months and unopened vial stability to be 24 months.

The expected values for the two glucose control solutions were established by repeat testing (10 times) on two meters using one lot of strips for both glucose levels. The expected results may change with each new lot, but the control range is listed in the product insert.

d. *Detection limit:*

The measuring range of the Gluco Track Blood Glucose Monitoring System is 20 - 600 mg/dL. This level was determined to be detectable by the linearity study (above).

e. *Analytical specificity:*

The sponsor tested the following substances for interference. Interference was identified as having a percent bias greater than $\pm 20\%$. The following results were determined with regard to interfering substances:

Substance	Therapeutic Concentration	Test Concentration (Low)	Interference at stated concentration	Test Concentration (High)	Interference at stated concentration
Exogenous Substances					
Acetaminophen	1-2 mg/mL	1.25 mg/dL	No	20 mg/dL	Yes
L-Dopa	Not applicable	1.25 mg/dL	No	20 mg/dL	Yes
Tolbutamide	5.3-10 mg/dL	5 mg/dL	No	20 mg/dL	No
Dopamine	<87 pg/mL	3 mg/dL	Yes	20 mg/dL	Yes
Ibuprofen	0.5-4.2 mg/dL	1.25 mg/dL	No	20 mg/dL	No
Salicylic acid	15-30 mg/dL	12.5 mg/dL	No	50 mg/dL	No
Methyl-Dopa	0.1-0.5	0.1 mg/dL	No	10 mg/dL	Yes

Substance	Therapeutic Concentration	Test Concentration (Low)	Interference at stated concentration	Test Concentration (High)	Interference at stated concentration
	mg/dL				
Tetracycline	0.4 mg/dL	1 mg/dL	No	10 mg/dL	No
Glibenclimide	0.6 mg/dL	1 mg/dL	No	10 mg/dL	Yes
Ketoprofen	6 mg/dL	5 mg/dL	No	20 mg/dL	No
Diclofenac	4 mg/dL	5 mg/dL	No	20 mg/dL	No
Indomethacin	8 mg/dL	5 mg/dL	No	20 mg/dL	No
Amiloride	0.8 mg/dL	1.25 mg/dL	No	20 mg/dL	No
Colchicin	0.2 mg/dL	1.25 mg/dL	No	20 mg/dL	No
Atenol	20 mg/dL	5 mg/dL	No	20 mg/dL	No
Maltose	Not applicable	20 mg/dL	No	100 mg/dL	No
Galactose	Not applicable	100 mg/dL	No	100 mg/dL	No
EDTA	Not applicable	20 mg/dL	No	1000 mg/dL	No
Lactose	Not applicable	100 mg/dL	No	100 mg/dL	No
Heparin	Not applicable	100 mg/dL	No	1000 mg/dL	No
Maltotriose	Not applicable	20 mg/dL	No	100 mg/dL	No
Maltotetraose	Not applicable	20 mg/dL	No	100 mg/dL	No
Endogenous Substances					
Ascorbic acid	0.8-1.2 mg/dL	1.25 mg/dL	No	20 mg/dL	Yes
Creatinine	1.5 mg/dL	1.25 mg/dL	No	20 mg/dL	Yes
Uric acid	7 mg/dL	10 mg/dL	No	20 mg/dL	Yes
Cholesterol	250 mg/dL	250 mg/dL	No	500 mg/dL	No
Bilirubin	1.3 mg/dL	12.5 mg/dL	No	25 mg/dL	No
Triglyceride	36-165 mg/dL	260 mg/dL	No	360 mg/dL	No

An altitude study was performed with 20 tests each of 5 different concentrations of glucose spiked whole blood spanning 51 to 405 mg/dL. The tested samples met the sponsor's acceptance criteria of a standard deviation ≤ 4.5 mg/dL when the glucose concentration was <75 mg/dL and $\leq 6\%$ CV for glucose concentrations ≥ 75 mg/dL and 95% of samples falling within ± 15 mg/dL when the glucose concentration was <75 mg/dL and $\pm 20\%$ for glucose concentrations ≥ 75 mg/dL. The altitude study was performed at 7464 feet (2275 meters); however the sponsor will make the claim of no effect on blood glucose measurements of up to 6562 feet (2000 meters).

To test the accuracy of the hematocrit effect, three lots, and 20 meters per lot, with blood adjusted to hematocrit levels of 30%, 40%, 50%, and 55% at glucose concentrations of 20-40, 41-80, 100-150, 151-250, 300-500, 501-580 mg/dL were tested. The sponsor's acceptance criteria was a bias of ± 15 mg/dL when the glucose concentration was < 75 mg/dL and $\pm 20\%$ for glucose concentrations ≥ 75 mg/dL when compared to the 40% hematocrit values.

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

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor demonstrated that the Gluco Track Blood Glucose Monitoring System for finger stick is equivalent to a standard methods (YSI-2300) by having 153 patient samples from 54 to 480 mg/dL (according to YSI) with a hematocrit range of 31-53% test their blood. A technician was also present to test the blood of the patients as well as testing 7 contrived samples that were 32 to 48 mg/dL. The studies are summarized below:

	YSI vs. Patient Finger	YSI vs. Technician Finger	Patient Finger vs. Technician Finger
N	153	160	153
Slope	1.0233	0.9989	1.0165
Intercept	-6.5829	-1.967	-2.8355
r ²	0.9765	0.9836	0.988

The three above studies each met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations for samples < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. These results from are summarized in the table below.

Site	YSI vs. Patient Finger	YSI vs. Technician Finger	Patient Finger vs. Technician Finger
N	153	160	153
Percentage That Met ISO Requirement	99% (152/153)	99% (159/160)	100% (153/153)

b. *Matrix comparison:*

See above: *Method comparison with predicate device*

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 included the following Expected Values for normal glucose levels in their strip labeling:

<u>Status</u>	<u>Range (mg/dL)</u>
Before meals	100
2 hours after meals	<140

Source: American Diabetes Association: "All about Diabetes" (web site information)
<http://www.diabetes.org/aboutdiabetes.jsp>.

N. Instrument Name:

Gluco Track Blood Glucose Monitoring System

O. System Descriptions:

- Modes of Operation:
Each test strip is single use and must be replaced with a new strip for additional readings.
- Software:
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes ☒ or No ☐
- Specimen Identification:
There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.
- Specimen Sampling and Handling:
This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.
- Calibration:
A code strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.
- Quality Control:
The sponsor is providing single level control solution with this device, and a second level is available. 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 the troubleshooting section of the owner's manual if 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.