

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k051285

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the GLUCOLAB™ Diabetes Monitoring System.

C. Analyte:

Whole Blood Glucose

D. Type of Test:

Quantitative, utilizing Glucose Oxidase technology.

E. Applicant:

Infopia, Co., Ltd.

F. Proprietary and Established Names:

GLUCOLAB™ 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 (analyte)

Class I (controls)

3. Product Code:

NBW, CGA (glucose)

JJX (control)

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The GLUCOLAB™ Diabetes Monitoring System is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings, including physician's office laboratories and point of care sites. The GLUCOLAB™ System provides plasma-equivalent results. The GLUCOLAB™ System is not intended to be used with neonatal blood samples. The GLUCOLAB™ 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 forearm, upper arm, palm, calf and thigh.

GlucoLab™ control is used with GlucoLab™ Brand System to check that the meter and test strips are working together as a system and that you are performing the test correctly. It is very important that you do control solution tests routinely to make sure you are getting accurate results. Control Solutions are sold separately.

3. Special condition for use statement(s):

Provides plasma equivalent results.

For over-the-counter or professional use

Not for use in neonates

Patients should not test on the forearm, upper arm, palm, calf or thigh when they think their blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with

a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with a forearm or palm sample.

Patients should not test on the forearm, upper arm, palm, calf or thigh when it has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or they think their glucose level is changing rapidly.

Patients should not test on the forearm, upper arm, palm, calf or thigh when they are concerned about the possibility of hypoglycemia.

4. Special instrument Requirements:

GLUCOLAB™ Blood Glucose Monitoring System

I. Device Description:

The GLUCOLAB™ Blood Glucose Monitoring System consists of the GLUCOLAB Meter, GLUCOLAB™ Test Strips, Control Solution, Lancing Device, Check Strip, Manual, Warranty registration card, Patient logbook, 1X3V Li-(CR2032) battery, Carrying Pouch. Control solutions are sold separately from the kit.

J. Substantial Equivalence Information:

1. Predicate device name(s):

LifeScan, Inc. OneTouch Ultra®
LifeScan, Inc. SureStep
Roche Diagnostics Corp. Accu-Chek

2. Predicate K number(s):

k024194
k984261
k021513

3. Comparison with Predicate:

The technological characteristics of the new device GlucoLab™ Blood Glucose Monitoring System are substantially equivalent to the LifeScan, Inc. ONE TOUCH Ultra® Blood Glucose Monitoring System previously cleared under (k024194). The GlucoLab™ Blood Glucose Monitoring System provides the same glucose monitoring capability as the predicate device, the ONE TOUCH® Ultra®. The primary differences are in the memory functions and battery lifetime. In addition, the ingredients of test strip, such as enzyme stabilizer, buffer and binder are different. The tables below list the similarities and differences between the Predicate and Proposed device.

Similarities

	GlucoLab (k051285)	ONE TOUCH® Ultra® (k024194)
Detection Method	Amperometry: current is generated by oxidation of reduced mediator.	Amperometry
Enzyme	Glucose Oxidase (<i>Aspergillus niger</i>)	Glucose Oxidase (<i>Aspergillus niger</i>)
Mediator	Hexaammineruthenium chloride	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode
Test range	10 ~ 600 mg/dL	20 ~ 600 mg/dL
Hematocrit Range	30 ~55%	30 ~ 55%
Test Time	5 seconds	5 seconds
Sample Volume	1uL	1uL
Temperature & Humidity range	50 ~ 104° F 10 ~ 40° C 10 ~ 90%	43 ~ 111° F 6 ~ 44° C 10 ~ 90%
Open use time	3 months	3 months
Coding	Button (C1 ~C45)	Button (C1 ~ C49)
Power	3V Li battery (CR2032)	3V Li battery (CR2032)
Warranty	3 years	3 years

Differences

	GlucoLab (k051285)	ONE TOUCH® Ultra®
Memory capability	From 7 to 99-day average and 250 tests in the memory	14-day average and last 150 tests in the memory
Battery life	Running 5,000 test	Running 1,000 test
Size: LxWxH (mm)	74x53x20	79x57x21
Weight	40g (with battery)	42g (with battery)
Software	GlucoLab™ diabetes management software	IN TOUCH® diabetes management software

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

- 1) National Committee for Clinical Laboratory Standards. *Point-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guideline*, 2nd Edition. NCCLS Document C30-A2 (ISBN1-56238-471-6).
- 2) National Committee for Clinical Laboratory Standards. *Statistical Quality Control for Quantitative Measurements; Principle and Definitions*; Approved Guideline, 2nd Edition. NCCLS Document C24-A2 (ISBN1-56238-371-X). 1999

- 3) National Committee for Clinical Laboratory Standards. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline*. NCCLS Document EP10-A (ISBN1-56238-348-5). 1998
- 4) National Committee for Clinical Laboratory Standards. *Evaluation of Matrix Effects; Approved Guideline*, NCCLS Document EP14-A (ISBN1-56238-434-1).
- 5) National Committee for Clinical Laboratory Standards. *Estimation of Total analytical Error for Clinical Laboratory Methods; Proposed Guideline*. NCCLS Document EP21-P (ISBN1-56238-456-2).
- 6) National Committee for Clinical Laboratory Standards. *User Demonstration of performance for Precision and Accuracy; Approved Guideline*. NCCLS Document EP15-A (ISBN1-56238-451-1).
- 7) National Committee for Clinical Laboratory Standards. *Interference Testing in Clinical Chemistry; Proposed Guideline*. NCCLS Document EP7-P (ISSN 0273-3099).
- 8) National Committee for Clinical Laboratory Standards. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline*, 2nd Edition. NCCLS Document EP6-P2 (ISBN1-56238-446-5).
- 9) National Committee for Clinical Laboratory Standards. *Evaluation of Performance of Clinical Chemistry Devices; Approved Guideline*. NCCLS Document EP5-A (ISBN1-56238-368-X).
- 10) Clinical Chemistry, 2nd Edition
- 11) MERCK INDEX, 11th Edition.
- 12) Korea Pharmacopeia, 5th Edition.

L. Test Principle:

The Test Principle used by this device is electrochemical biosensor technology using Glucose Oxidase. The strip uses the enzyme Glucose Oxidase to produce an electrical current that will stimulate a chemical reaction. This reaction is measured by the GlucoLab™ meter and displayed as a blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor indicated precision studies were assessed by taking 4mL of blood that was treated with EDTA drawn in a vacuum tube. Glucose was added to the 4 mL of blood to generate 5 different levels of glucose concentrations for the test. Each of the samples was measured 5 times for precision.

Day-to-Day precision also known as Between Day Precision

The sponsor prepared three control solutions of Low, Normal and High. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month.

Table 1 (below) shows a summary of the Within-Run Precision and the Day-to-Day Precision Tests.

Table 1: Summary of Test Results

Control Samples	No. of Assay	Within-Run Precision		
		Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	5	43	1.6	<u>3.7</u>
Level 2	5	81.6	2.1	<u>2.5</u>
Level 3	5	132.6	1.9	<u>1.5</u>
Level 4	5	211.6	5.9	<u>2.8</u>
Level 5	5	318.2	12	<u>3.8</u>

Control				
Samples	No. of Assay	Day-to-Day Precision		CV (%)
		Mean (mg/dL)	SD (mg/dL)	
Low	80	50.4	2.0	<u>3.9</u>
Normal	80	122.7	2.6	<u>2.1</u>
High	80	321.7	7.0	<u>2.2</u>

This study showed variability from strip to strip in blood tests of 3.8 % or less and from day to day in control tests of 3.9% or less.

b. Linearity/assay reportable range:

Test Procedure (Dilution Schemes)

The claimed detection range for the GlucoLab Blood Glucose Monitoring System is 10-600 mg/dL. The linearity study presented in this submission that utilizes NCCLS EP6-A with the recommended dilution schemes did not challenge the lower (10-40 mg/dL) or upper (550-600 mg/dL) claimed detection range. So the sponsor performed two additional studies of 30 different paired samples that compared the GlucoLab at the 10-40 mg/dL range and the 550-600 mg/dL range to the YSI analyzer (reference). In the first study the glucose range tested was 10-39 mg/dL with the following correlation:

$$\begin{aligned}y &= 0.9779x + 0.4296 \\R^2 &= 0.9869 \\n &= 30\end{aligned}$$

In the second study the glucose range tested was 550-598 mg/dL with the following correlation:

$$\begin{aligned}y &= 0.9791x + 15.162 \\R^2 &= 0.974 \\n &= 30\end{aligned}$$

The NCCLS EP6-P2 recommends dilution schemes to estimate the linearity of the Quantitative Analytical Method.

According to the NCCLS EP6-P2 protocol, a blood sample of 25 mL was taken, treated with the EDTA in a vacuum tube, and let set for a day. Two glucose concentrations of 10 mL (high and low concentrations) were prepared. As a measuring tool, nine glucose concentrations were prepared using the following dilution schemes (see Table 2).

Table 2: Levels of Dilution Schemes

S=9 Samples

Level 1(Low, L)	L
Level 2	$0.875L + 0.125H$
Level 3	$0.750L + 0.250H$
Level 4	$0.625L + 0.375H$
Level 5	$0.500L + 0.500H$
Level 6	$0.375L + 0.625H$
Level 7	$0.250L + 0.750H$
Level 8	$0.125L + 0.875H$
Level 9(High, H)	H

The meter used in this test can display below 10 mg/dL and over 600 mg/dL for checking linear range.

Each of the glucose levels was measured 5 times to test for precision.

In order to evaluate the straight line for the Sensory Strip that was used, the following formula was used:

$$1^{\text{st order}} \text{ polynomial, } y = ax + b, \quad 2^{\text{nd order}} \text{ polynomial, } y = aX^2 + bX + c$$

All dilution schemes start with a high and low concentration samples in which the concentrations meet or exceed the range of interest. For the test, the highest and lowest glucose concentration used was 661mg/dL and 8mg/dL. If a strip sensor has an ideal linearity ($r^2=1$) from Lowest to highest concentration, the ideal concentration of level 2 mixed with 0.875L and 0.125H volume ratio is a 99mg/dL $[(0.875*37.4 + 0.125*530.2)/(0.875+0.125)]$.

Table 3, below, shows a summary of the nine dilutions that were measured five times for precision.

Table 3: Test Result Summary

Dilution	Rep1	Rep2	Rep3	Rep4	Rep5	Mean
1*	9	9	8	8	7	8.2
2	90	84	85	90	91	88
3	160	162	155	155	161	158.6
4	240	240	235	235	234	236.8
5	320	321	330	340	305	323.2
6	400	405	407	410	415	407.4
7	500	510	515	498	510	506.6

Dilution	Rep1	Rep2	Rep3	Rep4	Rep5	Mean
8	570	575	565	565	570	569
9*	650	665	650	670	670	661

The dilution number **at** Table 3 and Figure 1 corresponds to the Level number in Table 2.

*meter would report HI or LO for these levels

Figure 1: Glucose Linearity Study (Dilution 1-9)

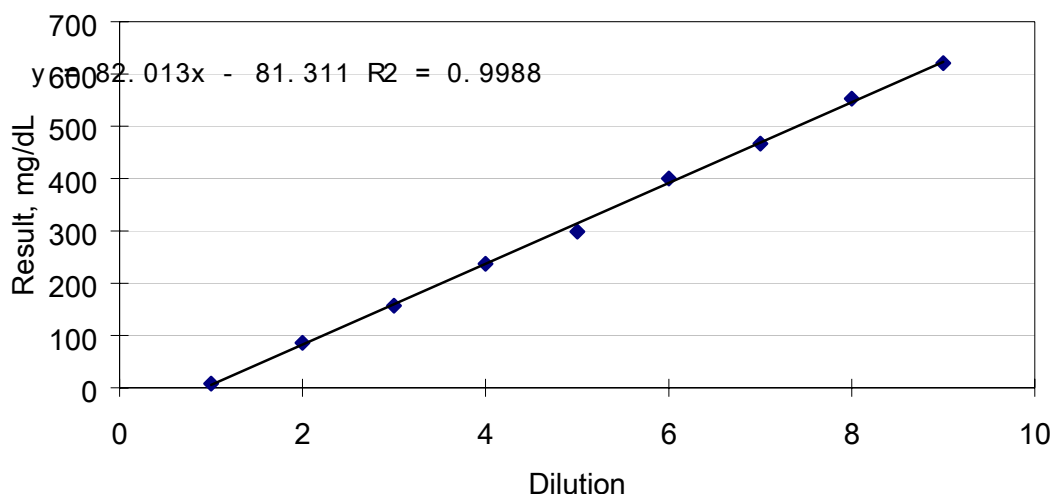


Table 4: The Polynomial Evaluation of Linearity

Dilution	Actual Mean	Predicted 1st order	Predicted 2nd order	Difference
1	<u>8.2</u>	0.7	6.8	-6.1
2	<u>88</u>	82.7	84.2	-1.5
3	<u>158.6</u>	164.7	163.0	1.7
4	<u>236.8</u>	246.7	243.3	3.7
5	<u>323.2</u>	328.8	324.4	4.3
6	<u>407.4</u>	410.8	407.1	3.7
7	<u>506.6</u>	492.8	491.1	1.7
<i>Dilution</i>	<i>Actual Mean</i>	<i>Predicted 1st order</i>	<i>Predicted 2nd order</i>	<i>Difference</i>
8	<u>569</u>	574.8	576.3	-1.5
9	<u>661</u>	656.8	662.9	-6.1

It has been determined that the polynomial evaluation of linearity assumes that the data set is not linear. This approach assumes that the data points fall perfectly on a line or curve in the absence of random error. The method consists of two parts. The first part examines whether a nonlinear polynomial fits the data better than a linear one. The second part assesses whether the difference between the best-fitting nonlinear and linear polynomial is less than the amount of allowable bias for the method, which should be predefined.

The nonlinear 2nd fits the data better than a linear one, but the difference is lower than 4.3 mg/dL from 8.2 mg/dL to 661.8mg/dL. The R² of 1st order regression is a 0.9988

c. Traceability (controls, calibrators, or method):

Traceability referenced to NBS, NIST Standards

Users are directed to use the control solutions before the expiration date printed on the bottle. The controls are stable for three months after opened.

d. Detection limit:

Reportable range = 10 – 600 mg/dL
1.7 to 33.3 mmol/L
See linearity study above.

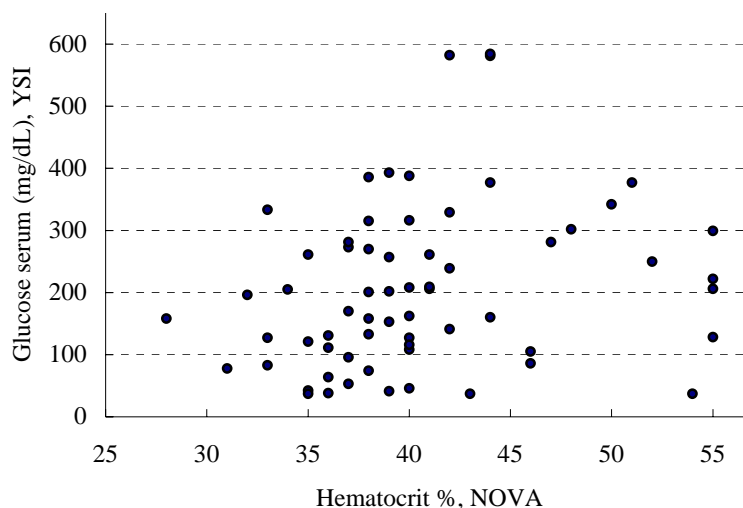
e. Analytical specificity:

Interference testing was conducted to determine the effect of select endogenous and exogenous substances.

Hematocrit Study

In this study, approximately 2 mL of blood was taken from 64 random diabetic individuals. The blood samples were treated with the EDTA vacuum tube and the glucose concentration was adjusted to approximately 50 - 580 mg/dL by adding an adequate amount of the phosphate buffer (20mM with pH 7.4) that contains a different level of glucose. In order to adjust the Hematocrit value (30 ~ 55%), a proper volume of the centrifuged plasma (serum) was removed.

The Hematocrit level and glucose concentration in the blood was assessed by using the Nova Stat Profile M and the YSI2300 STAT (respectively).

Figure 2: Blood glucose conc. Vs Hematocrit %

The % bias of the assay value of the GlucoLab™ system is relative to the YSI and does not have a negative or positive correlation to hematocrit level in this experiment. 98% of the data is within +/- 20% bias and 86% lies within +/- 10% in the overall range of glucose and hematocrit.

The potential interference of various exogenous and endogenous substances was tested by spiking the levels listed below in Table 5 into non-spiked control samples. The results were compared and the % error was calculated for the highest level tested.

Table 5: Summary of Tested Interferences:

	Levels Tested		Mean of Test Results		
	Non-spiked Control (mg/dL)	Highest Level Tested(mg/dL)	Control (mg/dL)	High (mg/dL)	Error %
Acetaminophen	0	20	98.7	100.7	2.0
Bilirubin	0	40	97.3	96.0	-1.4
Gentistic acid	0	50	114.3	140.3	22.7
Uric acid	0	20	92.3	86.0	-6.9
Levo-Dopa	0	4	98.0	109.3	11.6
Creatinine	0	30	119.3	126.0	5.6
Methyl-Dopa	0	2.5	105.3	113.3	7.6
Tolazamide	0	5	94.0	114.3	21.6
Dopamine	0	13	108.3	121.3	12.0

Interferences	Levels Tested		Mean of Test Results		
	Non-spiked Control (mg/dL)	Highest Level Tested(mg/dL)	Control (mg/dL)	High (mg/dL)	Error %
Ascorbate	0	3	112.3	115.3	2.7
EDTA	0	640	100.0	104.3	4.3
Glutathione	0	1	119.7	129.0	7.8
Heparin	0	1,000	126.3	127.7	1.1
Ibuprofen	0	40	121.3	130.7	7.7
Salicylic acid	0	50	135.7	137.3	1.2
Tetracycline	0	0.4	126.3	129.1	2.2
Tolbutamide	0	100	101.0	103.3	2.3
Urea	33	500	112.3	113.0	0.6
Cholesterol	209	500	123.0	138.7	12.7
Triglyceride	210	2,890	110.7	123.3	11.4

The sponsor states that high test concentrations were referenced to NCCLS Document EP7-P.

The sponsor states that:

- Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Cholesterol up to 500 mg/dL or triglycerides up to 2890 mg/dl do not significantly affect the results. Glucose values, however, in specimens beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- Tolazamide or Gentistic acid treatment may increase the test result.
- Antiglycolytic agents and anticoagulants in blood samples may affect the test results.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison to the predicate device was assessed with One hundred sixty subjects with Type 1 or Type 2 diabetes during a normally scheduled clinic visits. In the study protocol, both the lay user and a trained technician obtained fingerstick

glucose readings on the GlucoLab™ and ONETOUCH ULTRA, as well as alternate site glucose testing on the forearm, palm, upper arm, thigh and calf using both the GlucoLab™, and ONETOUCH ULTRA meters. No effort was made to determine whether patients were in the steady state or had rapidly changing blood glucose concentrations.

The readings were taken as close in time as possible. Within 5 minutes, a venous whole blood sample was drawn and centrifuged for making serum. The serum sample was tested by Hitachi 747. The sponsor indicated that during the comparison studies, alternate sites were vigorously rubbed by the lay user and trained technician before testing, and in some cases a warming pad was used.

Table 6. Summary of test results with finger capillary blood and palm blood

		Site 1	Site 2	Site 3
OneTouch (Palm) vs Hithchi747	Slope:	0.9789	0.9877	0.9520
	Y-intercept:	-4.2446	-0.1052	9.8344
	R ² :	0.9849	0.9702	0.9821
GlucoLab™ (Palm) vs Hithchi747	Slope:	0.9995	0.9892	0.9339
	Y-intercept:	-4.8527	1.4874	6.7677
	R ² :	0.9829	0.9757	0.9707
GlucoLab™ (Capillary) vs Hithchi747	Slope:	0.9864	0.9791	0.9784
	Y-intercept:	-0.6224	1.1418	0.5512
	R ² :	0.9921	0.9740	0.9848
GlucoLab™ (Palm) vs GlucoLab™ (Capillary)	Slope:	1.0048	0.9872	0.9418
	Y-intercept:	-3.097	4.5952	8.5922
	R ² :	0.9781	0.9565	0.9596

Clarke Error Grids

		Site 1	Site 2	Site 3
OneTouch (Palm) vs Hithchi747	A-region	100%	98%	98%
	B-region	0%	2%	2%
GlucoLab™ (Palm) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
GlucoLab™ (Capillary) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
GlucoLab™ (Palm) vs GlucoLab™ (Capillary)	A-region	100%	96 %	96 %
	B-region	0%	4 %	4 %

Table 7. Summary of test results with finger capillary blood and forearm, upper arm blood.

		Site 1	Site 2	Site 3
OneTouch (Arm) vs Hithchi747	Slope: Y-intercept: R^2 :	1.0291 -2.4835 0.9774	0.9604 5.2987 0.9828	1.011 -0.6795 0.9782
GlucoLab TM (Arm) vs Hithchi747	Slope: Y-intercept: R^2 :	1.0014 -5.3191 0.9872	1.0311 -6.0259 0.9824	1.0018 -0.6571 0.9887
GlucoLab TM (Capillary) vs Hithchi747	Slope: Y-intercept: R^2 :	0.9828 -1.4284 0.9881	1.008 -3.8832 0.9783	0.9568 3.6514 0.9898
GlucoLab TM (Palm) vs GlucoLab TM (Capillary)	Slope: Y-intercept: R^2 :	1.0067 -1.5563 0.9754	1.0076 0.4899 0.9744	1.0347 -2.1928 0.9755

Clarke Error Grids

		Site 1	Site 2	Site 3
OneTouch (Arm) vs Hithchi747	A-region B-region	98 % 2 %	98 % 2 %	100% 0%
GlucoLab TM (Arm) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
GlucoLab TM (Capillary) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
GlucoLab TM (Palm) vs GlucoLab TM (Capillary)	A-region B-region	100% 0%	98% 2%	98 % 2 %

Table 8. Summary of test results with finger capillary blood and calf, thigh blood.

		Site 1	Site 2	Site 3
OneTouch (calf and thigh) vs Hithchi747	Slope:	0.9942	0.9913	0.9960
	Y-intercept:	0.5819	1.8588	-0.7162
	R ² :	0.9839	0.9893	0.9784
GlucoLab™ (calf and thigh) vs Hithchi747	Slope:	0.9863	0.9756	0.9502
	Y-intercept:	2.2320	2.8426	5.2581
	R ² :	0.9846	0.9901	0.9804
GlucoLab™ (Capillary) vs Hithchi747	Slope:	1.017	0.9729	0.9963
	Y-intercept:	-3.791	0.7884	-0.2352
	R ² :	0.9899	0.9890	0.9812
GlucoLab™ (Palm) vs GlucoLab™ (Capillary)	Slope:	0.9608	0.9935	0.9348
	Y-intercept:	7.5222	3.6716	3.9854
	R ² :	0.9763	0.9825	0.9800

Clarke Error Grids

		Site 1	Site 2	Site 3
OneTouch (calf and thigh) vs Hithchi747	A-region	100%	98 %	100%
	B-region	0%	2 %	0%
GlucoLab™ (calf and thigh) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
GlucoLab™ (Capillary) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
GlucoLab™ (Palm) vs GlucoLab™ (Capillary)	A-region	100%	100%	100%
	B-region	0%	0%	0%

The comparison test results demonstrated similar results from both meters, with OneTouch at alternate site, GlucoLab™ at alternate site, and GlucoLab™ at fingerstick capillary according to the slope, Y-intercept, linearity and error % in Clark Error Grid region. Test results with GlucoLab™ at the alternative site of hand versus fingerstick capillary blood, correlation coefficient are 0.9339 ~ 1.0048. Test results with GlucoLab at alternative site of arm (forearm n = 84 and upper arm n = 72) versus fingerstick capillary blood, correlation coefficient are 0.9568 ~ 1.0347. Test results with GlucoLab at alternative site of leg (calf n = 85 and thigh n = 74) versus fingerstick capillary blood, correlation coefficient are 0.9704~0.9988. The GlucoLab Blood Glucose Monitoring System demonstrated equivalence to the OneTouch Ultra predicate device.

b. Matrix comparison:

Not Applicable

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 accuracy of the GlucoLab™ System was assessed by comparing blood glucose results obtained by patients with those obtained using the Hitachi 747, a laboratory instrument. Glucose levels were measured on 410 fresh capillary blood specimens by 104 diabetic patients and three healthcare professionals at three different clinical centers.

The correlation between Hitachi 747 and GlucoLab™ were confirmed in the blood samples with correlation coefficients of $R=0.9840$ (healthcare professionals) and $R=0.9830$ (lay users) (Fig. 1 and Fig. 2 respectively). Results indicate that the use of the GlucoLab™ generate results similar to the Hitachi 747.

Figure 3: Linear regression (healthcare professionals)

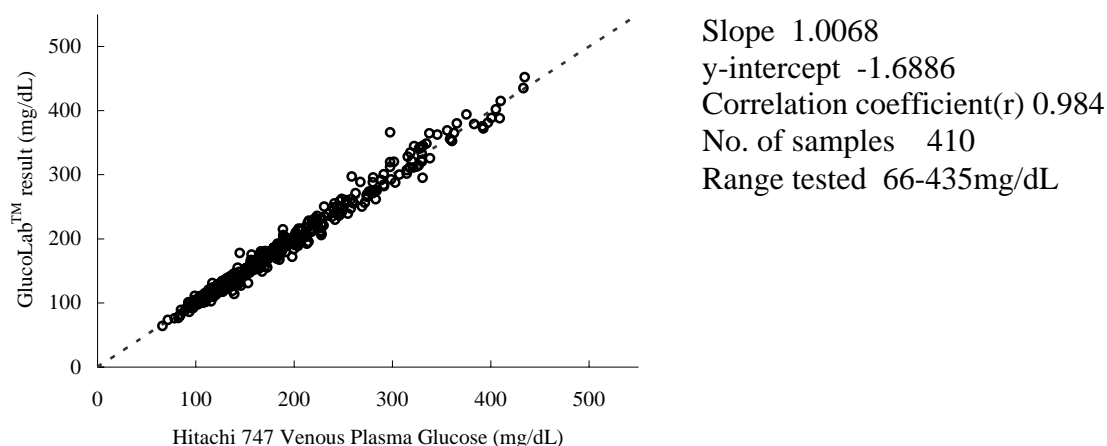
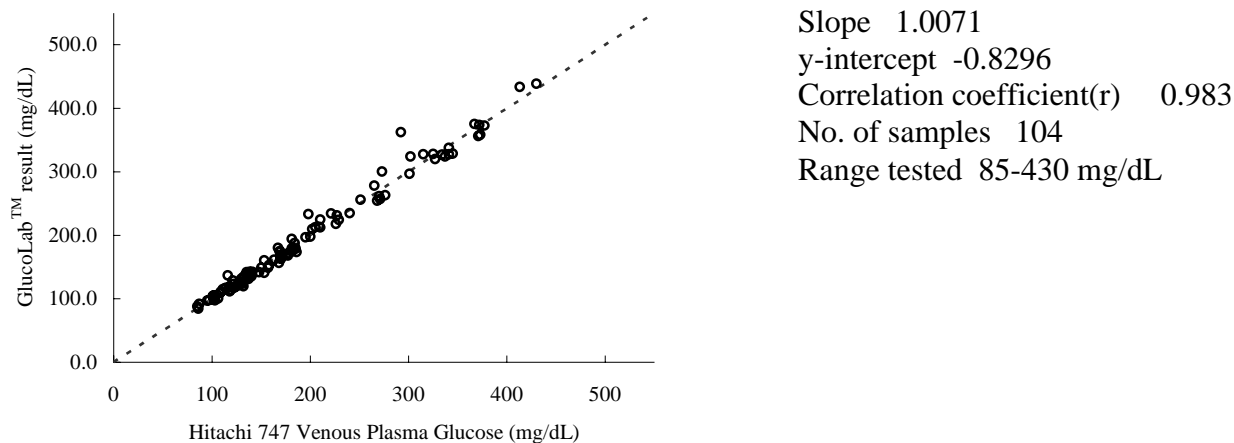


Figure 4: Linear regression (Lay users)

Readability of lay-user labeling was assessed by Flesch Kincaid testing. The sponsor reports that the labeling reads at a 7.71 grade reading level.

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The Range of Expected Values was referenced from the Joslin Diabetes Manual.

Expected blood glucose levels for people **without** diabetes:

Time	Range (mg/dL)	Range (mmol/L)
Before Breakfast:	70-105	3.9-5.8
Before lunch or dinner:	70-110	3.9-6.1
1 hour after meals:	Less than 160	Less than 8.9
2 hours after meals:	Less than 120	Less than 6.7
Between 2 and 4 AM:	Greater than 70	Greater than 3.9

N. Instrument Name:

GLUCOLAB blood glucose meter

O. System Descriptions:

1. Modes of Operation:

Automatic once sample is applied

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:

manual

4. Specimen Sampling and Handling:

Fingerstick (capillary blood samples)

5. Calibration:

Check strip, meter coding

6. Quality Control:

Two levels of control materials are available

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

Altitude – testing can be conducted at elevations up to 10,000 feet above sea level

Acceptable temperature range = 10 – 40 °C

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.