

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

A. 510(k) Number:

k061431

B. Purpose for Submission:

New Device

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Quantitative

E. Applicant:

US Diagnostics, Inc.

F. Proprietary and Established Names:

EASYGLUCO Diabetes Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1345, Blood Glucose Test System
21 CFR §862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
Class II
Class I, reserved
3. Product code:
NBW, system, test, blood glucose, over the counter
CGA, glucose oxidase, glucose
JJX, single (specified) analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for use below.
2. Indication(s) for use:
The EASYGLUCO™ 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. EASYGLUCO™ System is for testing outside the body (in vitro diagnostic use only). The EASYGLUCO Diabetes Monitoring System is not for use with neonatal blood specimens. Testing sites include

the traditional fingertip testing along with alternate site testing on the arm, palm, calf and thigh.

3. Special conditions for use statement(s):
Provides plasma equivalent results.
This product is intended for over-the-counter and point-of-care use.
Not for neonatal use.
4. Special instrument requirements:
EASYGLUCO Meter

I. Device Description:

The "Starter Kit" which includes the glucose meter, lancing device, lancets, test strips, and control solutions are included with the EASYGLUCO Diabetes Monitoring System. Also there is "Meter Kit" which includes the glucose meter, check strip, and control solutions only.

J. Substantial Equivalence Information:

1. Predicate device name(s):
LifeScan, Inc. One Touch Ultra®
2. Predicate 510(k) number(s):
k024194
3. Comparison with predicate:
The technological characteristics of the new device (EasyGluco™) in comparison to the predicate device (OneTouch® Ultra®):

The modified EasyGluco™ device has the same technological characteristics as the current legally marketed predicate device, the ONE TOUCH® Ultra®.

	EasyGluco™	ONE TOUCH® Ultra®
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	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode

The other ingredients of test strip, such as enzyme stabilizer, buffer and binder are different.

The EasyGluco™ Blood Glucose Monitoring System provides the same glucose monitoring capability as the predicate device, the ONE TOUCH® Ultra®. The primary differences are in the advanced memory function and battery lifetime.

	EasyGluco™	ONE TOUCH® Ultra®
Test range	20 ~ 600 mg/dL	20 ~ 600 mg/dL
Hematocrit Range	30 ~55%	30 ~ 55%
Test Time	9 seconds	5 seconds

	EasyGluco™	ONE TOUCH® Ultra®
Sample Volume	1.5uL	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 ~C40)	Button (C1 ~ C49)
Memory capability	From 7 to 90-day average and 200 tests in the memory	14-day average and last 150 tests in the memory
Power	3V Li battery (CR2032)	3V Li battery (CR2032)
Battery life	Running 5,000 test	Running 1,000 test
Size: LxWxH (mm)	76(±1)x56(±1)x22.5(±1)	79x57x21
Weight	40(±1)g(with battery)	42g (with battery)
Warranty	3 years	3 years
Software	EasyGluco™ diabetes management software	IN TOUCH® diabetes management software

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

The manufacturer of the EasyGluco Diabetes Monitoring System utilized NCCLS (EP6-P2) Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline – Second Edition (2001).

L. Test Principle:

This device is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the dehydrogenase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as the blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The sponsor established the performance characteristics of the EASYGLUCO Diabetes Monitoring System by conducting within-run precision, and day-to-day precision studies. Results of these two sets of studies are shown below:

a. *Precision/Reproducibility:*

Within day precision of the EASYGLUCO Diabetes Monitoring System was established by testing 4mL of blood that was treated with EDTA through a vacuum tube. Glucose was then added to the 4mL of blood to generate 10 different levels of glucose concentration for the test. Each of the test samples was measured 5 times. In order to obtain low samples <2.8 mmol/L (<50mg/dL), the sponsor collected

additional capillary blood samples in the appropriate anticoagulant and allowed glycolysis of the samples down to the appropriate test range. In order to obtain high samples with glucose concentration of >22.3 mmol/L (>400mg/dL), the sponsor collected additional capillary blood samples in the appropriate anticoagulant and supplemented the samples with glucose. Below are the glucose concentration ranges for each level that were measured.

Level	Glucose Conc. range
1	20 ~ 30 mg/dL
2	30 ~ 40 mg/dL
3	40 ~ 50 mg/dL
4	50 ~ 60 mg/dL
5	60 ~70 mg/dL
6	70 ~ 80 mg/dL
7	81 ~ 110 mg/dL
8	111 ~ 150 mg/dL
9	151 ~ 250 mg/dL
10	251 ~ 400 mg/dL

Summary of Test Results

Control Samples	No. of Assay	Within-Run Precision		
		Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	10	25.7	1.6	<u>6.4</u>
Level 2	10	35.4	2.2	<u>6.3</u>
Level 3	10	45.3	2.5	<u>5.4</u>
Level 4	10	56.8	2.9	<u>5.2</u>
Level 5	10	65.4	2.4	<u>3.6</u>
Level 6	10	75.0	2.9	<u>3.8</u>
Level 7	50	93.7	3.2	<u>3.4</u>
Level 8	50	134.8	4.8	<u>3.6</u>
Level 9	50	214.6	4.7	<u>2.2</u>
Level 10	50	328.9	8.5	<u>2.6</u>

Between Day Precision was assessed by testing three different 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. The tables below represent the lots that were used for the study.

Control Samples	No. of Assay	Day-to-Day Precision		
		Mean	SD	CV
		(mg/dL)	(mg/dL)	(%)
Low	80	50.7	1.9	<u>3.7</u>
Normal	80	111.5	2.4	<u>2.1</u>
High	80	304.3	6.6	<u>2.2</u>

b. *Linearity/assay reportable range:*

A laboratory study tested the linearity of the EASYGLUCO Diabetes Monitoring System using EASYGLUCO Test Strips with spiked or glycolyzed venous blood samples across the claimed system test range, (20-600mg/dL). Nine glucose concentrations were prepared using the below dilution schemes. Each of the spiked glucose levels were tested 5 times to test for precision.

Levels of Dilution Schemes

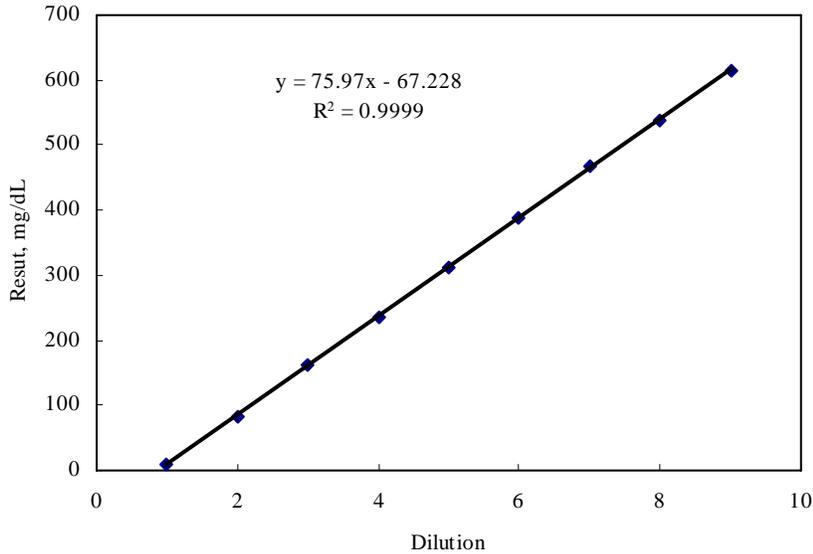
S = 9 Samples

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

Summary of nine dilutions that were measured five (5) times.

Dilution	Rep 1	Rep 2	Rep 3	Rep 4	Rep 5	Mean	YSI		Mean
							1 st	2 nd	
1	7	9	8	8	9	<u>8.2</u>	8.0	8.1	8.0
2	83	85	81	84	83	<u>83.2</u>	81.7	81.7	81.7
3	162	163	160	163	162	<u>162</u>	161	161	161
4	236	239	235	236	237	<u>236.6</u>	239	237	238
5	314	312	315	313	312	<u>313.2</u>	311	313	312
6	386	390	387	389	389	<u>388.2</u>	382	385	384
7	470	471	468	469	468	<u>469.2</u>	465	464	464
8	530	534	543	550	530	<u>537.4</u>	541	541	541
9	616	618	615	611	618	<u>615.6</u>	616	618	617

Glucose Linearity Study (Dilution 1-9)



According to the sponsor 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 1.3 mg/dL from 8.2 mg/dl to 615.6 mg/dL. The R² of 1st order regression is a 0.9999.

The Polynomial Evaluation of Linearity

Dilution	Actual Mean	Predicted 1st order	Predicted 2nd order	Difference	%Difference
1	<u>8.2</u>	8.7	7.5	1.3	14.4
2	<u>83.2</u>	84.7	84.4	0.3	0.4
3	<u>162</u>	160.7	161.0	-0.4	-0.2
4	<u>236.6</u>	236.7	237.4	-0.8	-0.3
5	<u>313.2</u>	312.6	313.5	-0.9	-0.3
6	<u>388.2</u>	388.6	389.4	-0.8	-0.2
7	<u>469.2</u>	464.6	464.9	-0.4	-0.1
8	<u>537.4</u>	540.5	540.2	0.3	0.1
9	<u>615.6</u>	616.5	615.2	1.3	0.2

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

The company supplies glucose control solutions to validate the performance of the meter. Each level of the EasyGluco Control solutions is prepared gravimetrically and

is provided in three levels. The controls are aqueous materials containing known concentration of glucose, stabilizers, buffers, preservatives and dyes. The controls targeted concentrations are 50 mg/dL, 110 mg/dL, and 300 mg/dL.

Stability: Accelerated stability data testing suggests that the EasyGluco test strip and control solution have a shelf life of 2 years if stored between 2~30 °C. Real-time stability studies are ongoing.

d. Detection limit:

See precision and linearity studies above. The operating range of the meter is 20 – 600 mg/dL.

e. Analytical specificity:

Potential endogenous and exogenous interferences of the EasyGluco system were tested in a dose-response method following NCCLS EP7-P. A series of test samples, systematically varying in the concentration of the interferent, was prepared by making quantitative, volumetric admixtures of two pools: one at the highest concentration to be tested and the other at the lowest. The below table provides a summary of the tested interferences.

Interferences	Mean of Test Results			
	High Test Level (mg/dL)	Low (mg/dL)	High (mg/dL)	Error %
Acetaminophen	20	93.0	101.6	9.2
Bilirubin	40	123.4	136.2	10.4
Gentistic acid	50	132.2	170.4	28.9
Uric acid	20	117.8	136.4	15.8
Levo-Dopa	4	120.2	125.6	4.5
Creatinine	30	108.2	112.6	4.1
Methyl-Dopa	2.5	106.4	111.8	5.1
Tolazamide	5	119.0	122.6	3.0
Dopamine	13	132.2	156.8	18.6
Ascorbate	3	122.2	125.6	2.8
EDTA	640	114.0	117.8	3.3
G;itatjopme	1	131.4	134.6	2.4
Heparine	1,000	122.2	124.2	1.6
Ibuprofen	40	102.4	106.8	4.3
Salicylic acid	50	121.3	124.4	2.3
Tetracycline	0.4	133.0	135.4	1.8
Tolbutamide	100	98.0	102.0	4.1
Urea	500	113.4	112.4	-0.9
Cholesterol	500	1343	142.6	6.2
Triglyceride	2890	120.3	137.3	14.1
Glactose	50	119.0	117.0	-1.7
Xylose	10	112.0	111.7	-0.3
Maltose	300	116.6	120.3	3.2

A series of five levels that included the maximum concentration of the substance that would be expected to be encountered in clinical practice were used for each substance. The interferent effect was calculated from the linear relationship between the tested concentrations of each substance.

The EasyGluco Test Strips are specific to D-glucose and do not react with other sugars which may be present. Hematocrit levels less than 30% may cause falsely high readings. Hematocrit levels greater than 55% may cause falsely low readings. Blood samples that contain large amounts of ascorbic acid and uric acid may cause a slightly higher result than the actual glucose level. High concentrations of Dopamine, Gentistic acid and other reducing substances may cause inaccurately high results. Lipemic samples; Cholesterol up to 500 mg/dL or triglycerides up to 2890 mg/dL do not significantly affect the results.

Temperature

Temperature studies for the EasyGluco Blood Glucose Monitoring System demonstrate that the instrument performs acceptably over the allowable operating range of the meter (10°C to 40°C or 50°F to 104°F).

High-Altitude

A simulated high-altitude study was conducted to test the effect on pO₂ by changing the pO₂ level in a whole blood sample from 153mmHg to 76mmHg by Tonometry method, blowing a humidified mixed gas (O₂, CO₂, and N₂.) into the blood sample to adjust the pO₂ level of the sample. As described in the table below that shows the barometric pressure (standard atmosphere) and equivalent tracheal pO₂ at increasing altitudes, at 10,000 feet pO₂ is 100mmHg that is 32% lower than at sea level (149mmHg).

(Simulation pO₂ vs. altitude simulation below is referred to Bert, P., “La Pression Barometrique”, Masson et Cie, Paris: 1878

ALTITUDE				ALTITUDE			
m	Ft	Pressure mm Hg	pO ₂ Tracheal air mm Hg	m	Ft	Pressure mm Hg	pO ₂ Tracheal air mm Hg
0*	0*	760	149	5500	18050	379	69
500	1640	716	140	6000	19690	354	64
1000	3280	674	131	6500	21330	330	59
1500	4920	634	123	7000	22970	308	55
2000	6560	596	115	7500	24610	287	50
2500	8200	560	107	8000	26250	267	46
3000	9840	526	100	8500	27890	248	42
3500	11840	493	93	Everest 8848	29028	232**	38.5**
4000	13120	462	87	9000	29530	230	38
4500	14650	433	81	9500	31170	214	35

4500	14650	433	81	9500	31170	214	35
5000	16400	405	75	10000	32800	198	32
				19215	63000	47	0

- * Taken at sea level
- * Subject to fluctuations of approximately +/- 2%, due to weather and environmental factors

The sponsor collected venous blood from healthy donors and added the proper volume of glucose to create a low, medium, and high sample. The samples pO₂ content was then adjusted to 76, 94, and 153 mmHg by tonometry. The pO₂ content of the blood samples was measured by using the Nova STAT Profile M, blood gas/electrolyte analyzer. The glucose concentration of the blood samples were measured by the YSI glucose analyzer, EasyGluco, and predicate OneTouch Ultra Blood Glucose Monitoring System. See below summary of interference by pO₂ change.

YSI (serum)	Level 1 67 mg/dL			Level 2 255 mg/dL			Level 3 451 mg/dL			
pO ₂ (mmHg)	153	94	76	153	94	76	153	94	76	
EasyGluco	mg/dL	67	68	70	246	265	269	454	469	475
	Error	0.0	1.5	4.5	-3.5	3.9	5.5	0.7	4.0	5.3
OneTouch Ultra	mg/dL	68	72	73	249	264	273	450	477	481
	Error	1.5	7.5	9.0	-2.3	3.5	7.0	-0.2	5.8	6.6
Simulated Altitude	153 mmHg						Sea level			
	94 mmHg						9,840 – 11,840			
	76 mmHg						14,650 – 16,400			

The sponsor's acceptance criteria were the bias% is ± 10% at the range of 80-150 mmHg with the standard 100 mmHg. The error % of the OneTouch Ultra is -2.3 – 9.0% and EasyGluco is -3.5 – 5.5 % which met the sponsor's established acceptance criteria.

The sponsor performed an additional altitude study in an aircraft cabin at an altitude of approximately 1,500m³. The altitude study results indicate that the EasyGluco Blood Glucose Monitoring System showed no evidence to suggest a systematic effect due to lack of atmospheric oxygen at 11,568 m which is equal to 37,953 feet.

Hematocrit

Samples of blood were taken randomly from 64 diabetic patients. Adjustments were made to the hematocrit values to span a range of 30% to 55%. A total of eighty samples with glucose ranging from 50 to 580 mg/dL were tested using the EasyGluco meter and the YSI. The results indicated that for 17 samples below 75mg/dL the bias ranged from -2% to 9% and for the 63 samples above 75 mg/dL the bias ranged from

-21% to 13%. There did not appear to be a significant change in glucose with different hematocrit values in the range tested.

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

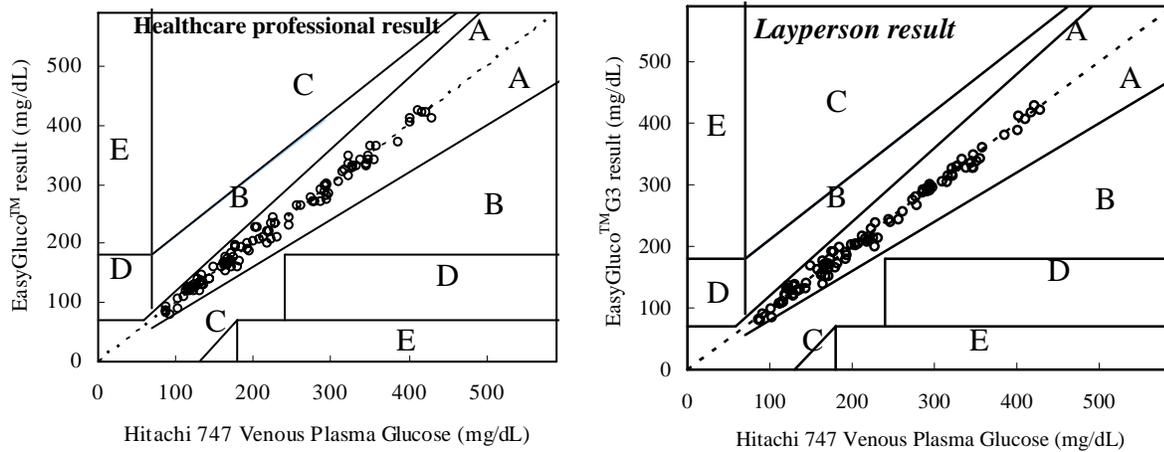
2. Comparison studies:

a. *Method comparison with predicate device:*

The EasyGluco Blood Glucose Monitoring 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 fresh capillary blood specimens by 100 diabetic patients (layperson) and a trained healthcare professional. Separated results were recorded by patient and healthcare professional within 2 minutes and a venous blood sample was collected within 5 minutes for testing on the Hitachi lab instrument.

100% of the test results done by technician and 100% of the test results by consumer were within zone A of the Error Grid.

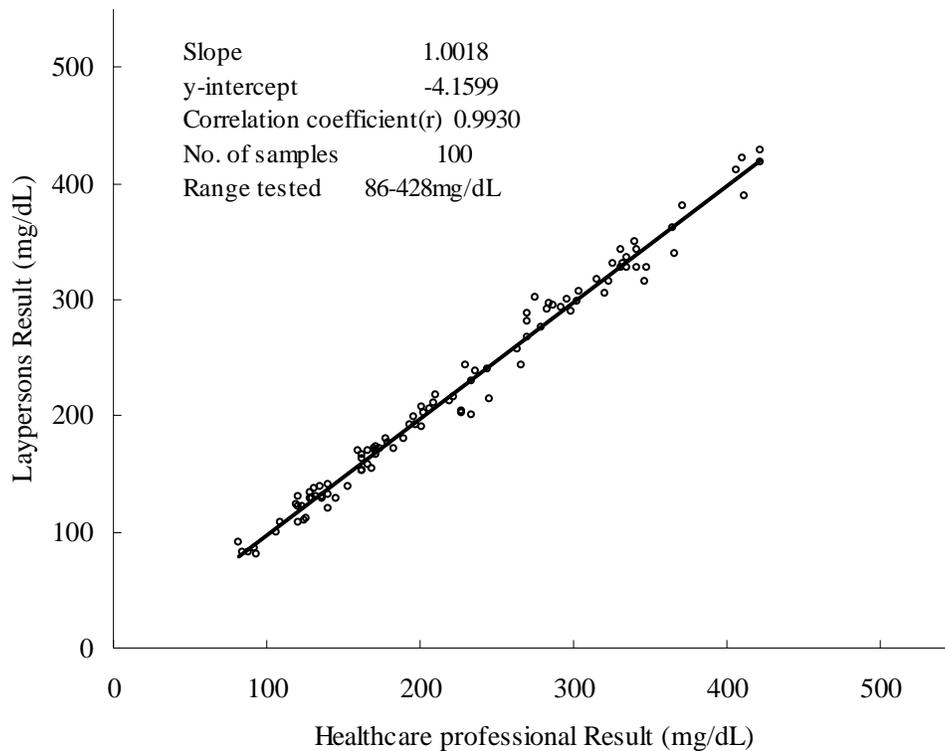
Error Grid Analysis-Hitachi 747 Vs. EasyGluco™



Summary of Error Grid Analysis Results

Total	100	100	100	100
	Healthcare		Layperson	
	Professional			
Zone	Number	%	Number	%
A	100	100	100	100
B	-	0	-	0
C	-	0	-	0
D	-	0	-	0
E	-	0	-	0

Linear regression of the test result-Healthcare professional Vs. Layperson results



The slope is 1.0018; the 95% confidence interval is 0.97 to 1.02

The y-intercept is -4.15; the 95% confidence interval is -9.91 to 1.59

The correlation coefficient is 0.9930.

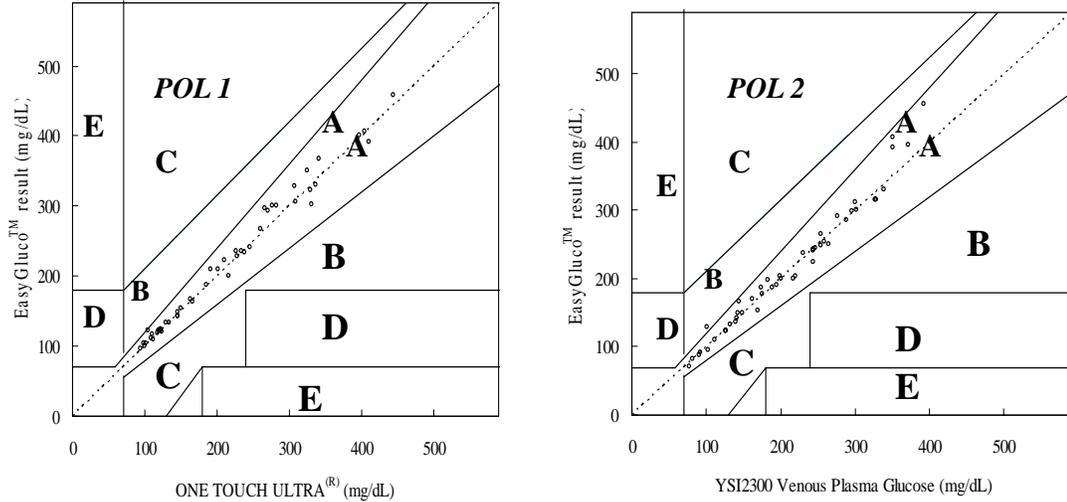
All test results were within the sponsor's established acceptance criteria.

Physician's Office Laboratory (POL) Study

The EasyGluco Blood Glucose Monitoring System was also evaluated at 3 independent physician's offices. The EasyGluco test results were compared to comparative blood glucose monitoring devices currently used at the 3 POL sites. 98% of the comparison

results carried out at the 3 different POL sites was in Zone A, and 2% were in Zone B. The glucose concentration of samples used in the POL study is 85-420 mg/dL (in POL 1, OneTouch Ultra), 85-391 mg/dL (in POL 2, YSI 2300), and 70-325 mg/dL (in POL 3, Glucotrend).

Test results of three independent POL sites



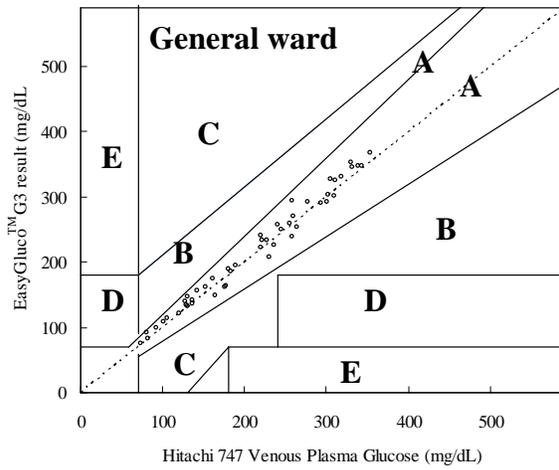
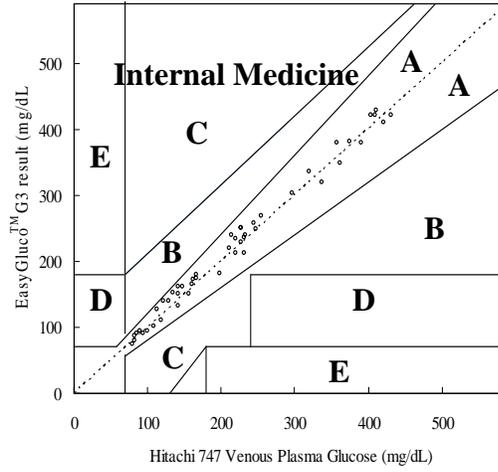
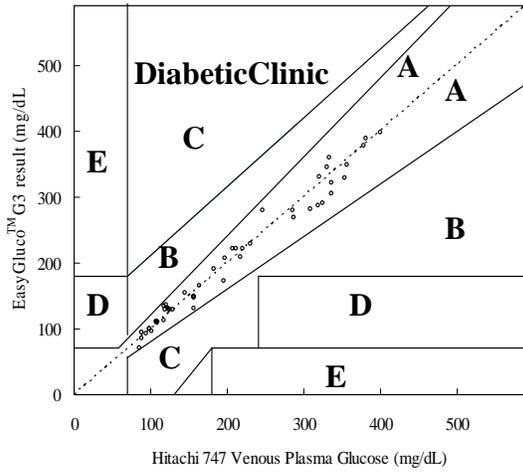
Error Grid Analysis Results of POL sites.

Zone	<u>POL 1</u>		<u>POL 2</u>		<u>POL 3</u>	
	Number	%	Number	%	Number	%
A	50	100	49	98	50	100
B	-	-	1	2	-	-
C	-	-	-	-	-	-
D	-	-	-	-	-	-
E	-	-	-	-	-	-
Total	50	100	50	100	50	100

Point-of-Care (POC) Study

For POC use, the EasyGluco Blood Glucose Monitoring System was evaluated at 3 different POC sites, a General Ward, Internal Medicine, and Diabetic Clinic. The EasyGluco capillary test results were compared to the Hitachi 747 venous plasma results. 100% of the comparison results carried out at the 3 different POC sites was in Zone A. The glucose concentration of samples used in the POC study is 68-410 mg/dL (in General Ward), 81-425 mg/dL (in Internal Medicine), and 75-352 mg/dL (in Diabetic Clinic).

Test results of three POC sites at the same hospital



Error Grid Analysis Results of POC sites.

Zone	Diabetic Clinic		Internal Medicine		General ward	
	Number	%	Number	%	Number	%
A	50	100	50	100	50	100
B	-	-	-	-	-	-
C	-	-	-	-	-	-
D	-	-	-	-	-	-
E	-	-	-	-	-	-
Total	50	100	50	100	50	100

Alternate Site Testing with the EasyGluco System:

Alternate Site Testing of the EasyGluco Blood Glucose Monitoring System was previously accessed with clearance of 510(k) submission k043512. Testing on the palm, forearm, thigh, calf, and fingertips were evaluated by using the same lancing device included with this meter. Glucose values from alternate sites were assessed in an in-house study of 160 subjects with Type 1 or Type 2 diabetes during a normally scheduled clinic visit by a trained technician. The technician first obtained fingerstick glucose readings from the subjects using the EasyGluco and OneTouch Ultra and then obtained alternate site glucose readings from the arm, palm, calf and thigh of the subjects on the EasyGluco and One Touch Ultra. The readings were taken as close in time as possible.

Within 5 minutes a venous whole blood sample was drawn from alternate sites and centrifuged for obtaining serum samples. The serum samples were tested on the Hitachi 727 chemistry analyzer.

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

		Site 1	95% confidence intervals	Site 2	95% confidence intervals	Site 3	95% confidence intervals
One Touch (Palm) vs. Hitachi 747	Slope	0.9777	0.9430 to 1.0124	0.9877	0.9461 to 1.0293	0.9465	0.9140 to 0.9790
	Y-intercept	-4.7190	-11.5285 to 2.0904	-0.6590	-9.3169 to 7.9988	9.9481	1.9211 to 15.9751
	correlation coefficient	0.9921		0.9894		0.9929	
EasyGluco™ (Palm) vs Hitachi 747	Slope	0.9777	0.9607 to 1.0346	0.9924	0.9506 to 1.0342	0.9683	0.9285 to 1.0079
	Y-intercept	-4.5480	-11.7994 to 2.7033	0.2117	-8.4862 to 8.9096	1.0728	-7.5158 to 9.6613
	correlation coefficient	0.9914		0.9894		0.9900	
EasyGluco™ (Capillary) vs Hitachi 747	Slope	0.9899	0.9665 to 1.0132	0.9988	0.9608 to 1.0369	0.9678	0.9338 to 1.0018
	Y-intercept	-1.7286	-6.3085 to 2.8513	-1.4878	-9.4055 to 6.4299	1.2087	-7.3271 to 7.6058
	correlation coefficient	0.9965		0.9913		0.9926	
EasyGluco™ (Palm) vs. EasyGluco™ (Capillary)	Slope	1.0027	0.9621 to 1.0433	0.9829	0.9377 to 1.0281	0.9923	0.9502 to 1.0344
	Y-intercept	-1.9023	-9.7312 to 5.9265	3.6644	-5.6925 to 13.0212	1.3687	-3.2000 to 20.0982
	correlation coefficient	0.9898		0.9874		0.9893	

		site 1	site 2	site 3
OneTouch (Palm) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
EasyGluco™ (Palm) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
EasyGluco™ (Capillary) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
EasyGluco™ (Palm) vs EasyGluco™ (Capillary)	A-region	100%	99%	99 %
	B-region	0%	1 %	1 %

Summary of test results with finger capillary blood and Arm blood.

		site 1	95% confidence intervals	site 2	95% confidence intervals	site 3	95% confidence intervals
One Touch (arm) vs Hitachi 747	Slope	1.0289	0.9844 to 1.0734	1.0289	0.9844 to 1.0734	1.0114	0.9681 to 1.0547
	Y-intercept	-2.6678	-12.6040 to 7.2684	-2.6678	-12.604 to 7.2684	-0.7990	-10.1027 to 8.5046
	correlation coefficient	0.9886		0.9910		0.9888	
EasyGluco™ (Arm) vs Hithchi747	Slope	1.0005	0.9684 to 1.0325	1.0005	0.9685 to 1.0325	0.9997	0.9704 to 1.0291
	Y-intercept	-5.2097	-12.9422 to 1.5275	-5.2097	-12.3667 to 1.9474	-0.5469	-6.8605 to 5.7668
	correlation coefficient	0.9937		0.9916		0.9947	
EasyGluco™ (Capillary) vs Hitachi 747	Slope	0.9857	0.9570 to 1.0144	0.9857	0.9570 to 1.0144	0.9513	0.9261 to 0.9764
	Y-intercept	-1.654	-8.0630 to 4.7550	-1.654	-12.5883 to 4.0284	4.7927	-0.6164 to 10.2017
	correlation coefficient	0.9948		0.9888		0.9957	
EasyGluco™ (arm) vs EasyGluco™ (Capillary)	Slope	1.0049	0.9623 to 1.0476	1.0049	0.9623 to 1.0480	1.0411	0.9881 to 1.0840
	Y-intercept	-1.6301	-10.9663 to 7.7060	-1.6301	-10.9663 to 7.7060	-3.7530	-12.7306 to 5.2246
	correlation coefficient	0.9890		0.9872		0.9896	

		site 1	site 2	sie 3
OneTouch (Arm) vs Hithchi747	A-region	99 %	99 %	100%
	B-region	1 %	1 %	0%
EasyGluco™ (Arm) vs Hithchi747	A-region	100%	100%	99%
	B-region	0%	0%	1%

EasyGluco™ (Capillary) vs Hithchi747	A-region	100%	99%	100%
	B-region	0%	1%	0%
EasyGluco™ (arm) vs EasyGluco™ (Capillary)	A-region	100%	99%	100 %
	B-region	0%	1%	0 %

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

		site 1	95% confidence intervals	site 2	95% confidence intervals	site 3	95% confidence intervals
OneTouch (calf and thigh) vs Hithchi747	Slope	0.9946	0.9602 to 1.0290	0.9932	0.9621 to 1.0202	0.9962	0.9555 to 1.0370
	Y-intercept	-2.063	-7.1885 to 6.7759	1.0257	-4.134 to 6.1854	-1.0028	-9.7787 to 7.1956
	correlation coefficient	0.9925		0.9956		0.9896	
EasyGluco™ (calf and thigh) vs Hithchi747	Slope	0.9860	0.9535 to 1.0186	0.9794	0.9534 to 1.0053	0.9584	0.9304 to 0.9865
	Y-intercept	1.5489	-5.0593 to 8.1572	1.8367	-2.9695 to 7.7908	4.5479	-1.2942 to 10.3900
	correlation coefficient	0.9932		0.9956		0.9946	
EasyGluco™ (Capillary) vs Hithchi747	Slope	1.0158	0.9885 to 1.0431	0.9767	0.9492 to 1.0041	0.99927	0.9616 to 1.0238
	Y-intercept	-4.0603	-9.5960 to 1.4754	0.2492	-5.6556 to 5.6541	0.8385	-5.6464 to 7.3233
	correlation coefficient	0.9955		0.9950		0.9938	
EasyGluco™ (calf and thigh) vs EasyGluco™ (Capillary)	Slope	0.9625	0.9224 to 1.0025	0.9947	0.9603 to 1.0291	0.9526	0.9098 to 0.9954
	Y-intercept	6.9714	-1.1366 to 15.0795	2.9687	-3.6572 to 9.5945	8.8938	-2.7562 to 15.0230
	correlation coefficient	0.9892		0.9925		0.9875	

		site 1	site 2	site 3
OneTouch (calf and thigh) vs Hithchi747	A-region	100%	99 %	100%
	B-region	0%	1 %	0%
EasyGluco™ (calf and thigh) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
EasyGluco™ (Capillary) vs Hithchi747	A-region	100%	100%	100%
	B-region	0%	0%	0%
EasyGluco™ (calf and thigh) vs EasyGluco™ (Capillary)	A-region	100%	100%	100%
	B-region	0%	0%	0%

Test results with finger capillary blood and palm blood

The EasyGluco® meter and EasyGluco® reagent strips blood glucose meter system was tested on 216 finger capillary blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the Hitachi laboratory method. The tables below show how the two methods compared:

The tables show differences in glucose values between the “EasyGluco®” and the Hitachi.” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Hitachi value and the EasyGluco® value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	71% (29/41)	95% (39/41)	100% (41/41)	100% (41/41)

Difference range in values between the Hitachi value and the EasyGluco® value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	71% (125/175)	97% (170/175)	100% (175/175)	100% (175/175)

The EasyGluco® meter and EasyGluco® reagent strips blood glucose meter system was tested on 220 palm blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the finger capillary blood sample. The tables below show how the two sites compare:

The tables show differences in glucose values between the “EasyGluco (Palm)” and the EasyGluco (Capillary).” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75mg/dL.

Difference range in values between the finger capillary value and the palm value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the palm and capillary value were within the difference range shown in the top row.	80% (36/45)	96% (43/45)	100% (45/45)	100% (45/45)

Difference range in values between the finger capillary value and the palm value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the palm and capillary value were within the difference range shown in the top row.	55% (96/175)	85% (149/175)	94% (165/175)	99% (174/175)

Test results with finger capillary blood and forearm and upper arm blood

The EasyGluco® meter and EasyGluco® reagent strips blood glucose meter system was tested on 217 capillary blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the Hitachi laboratory method. The tables below show how the two methods compared:

The tables show differences in glucose values between the “EasyGluco®” and the Hitachi.” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Hitachi value and the EasyGluco® value	Within 5 %	Within 10%	Within 15%*	Within 20%
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	68% (24/41)	93% (38/41)	100% (41/41)	100% (41/41)

Difference range in values between the Hitachi value and the EasyGluco® value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	57% (101/176)	86% (152/176)	99% (174/176)	99% (174/176)

The EasyGluco® meter and EasyGluco® reagent strips blood glucose meter system was tested on 217 forearm & upper arm blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the Hitachi laboratory method. The tables below show how well the two methods compared:

The tables show differences in glucose values between the “EasyGluco ®” and the Hitachi.” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	66% (27/41)	95% (39/41)	100% (41/41)	100% (41/41)

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	61% (107/176)	91% (160/176)	97% (171/176)	99% (175/176)

The EasyGluco ® meter and EasyGluco ® reagent strips blood glucose meter system was tested on 218 forearm & upper arm blood samples, (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL). The results were compared to the fingertip capillary blood sample. The tables below show how well the two sites compare:

The tables show differences in glucose values between the “EasyGluco (Forearm & Upper Arm)” and the EasyGluco (Capillary).” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75mg/dL.

Difference range in values between the Capillary value and the Forearm & upper arm value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the Forearm & upper arm and Capillary value were within the difference range shown in the top row.	67% (28/42)	90% (38/42)	98% (41/42)	100% (42/42)

Difference range in values between the Capillary value and the Forearm & upper arm value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the Forearm & upper arm and Capillary value were within the difference range shown in the top row.	49% (87/176)	77% (136/176)	85% (150/176)	95% (167/176)

Test results with finger capillary blood and calf & thigh blood

The EasyGluco ® meter and EasyGluco ® reagent strips blood glucose meter system was tested on 219 capillary blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the Hitachi laboratory method. The tables below show how the two methods compared:

The tables show differences in glucose values between the “EasyGluco ®” and the Hitachi.” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	68% (27/40)	93% (37/40)	100% (40/40)	100% (40/40)

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	72% (128/179)	96% (172/179)	100% (179/179)	100% (179/179)

The EasyGluco ® meter and EasyGluco ® reagent strips blood glucose meter system was tested on 219 calf & thigh blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the Hitachi laboratory method. The tables below show how well the two methods compared:

The tables show differences in glucose values between the “EasyGluco ®” and the Hitachi.” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	55% (22/40)	95% (38/40)	100% (40/40)	100% (40/40)

Difference range in values between the Hitachi value and the EasyGluco ® value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the EasyGluco® and Hitachi value were within the difference range shown in the top row.	73% (131/179)	97% (173/179)	100% (179/179)	100% (179/179)

The EasyGluco ® meter and EasyGluco ® reagent strips blood glucose meter system was tested on 219 calf & thigh blood samples (combining the data obtained from the 160 patients above and additional samples below 75 mg/dL) where the results were compared to the capillary blood sample. The tables below show how the two sites compared:

The tables show differences in glucose values between the “EasyGluco (Calf & thigh)” and the EasyGluco (Capillary).” The first table represents samples for glucose results lower than 75 mg/dL. The second table represents samples for glucose results greater than 75mg/dL.

Difference range in values between the Capillary value and the Calf & thigh value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL *	Within 20 mg/dL
The percent (and number) of samples for which the difference between the Calf & thigh and Capillary value were within the difference range shown in the top row.	68% (27/40)	93% (37/40)	98% (39/40)	100% (40/40)

Difference range in values between the Capillary value and the Calf & thigh value	Within 5 %	Within 10%	Within 15%	Within 20%*
The percent (and number) of samples for which the difference between the Calf & thigh and Capillary value were within the difference range shown in the top row.	56% (100/179)	89% (160/179)	99% (178/179)	100% (179/179)

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):*

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The EasyGluco Diabetes Monitoring System labeling states that self-testing of blood glucose levels provides a way to control your diabetes. Diabetics should consult with their physician to determine the best range of expected blood glucose values for them.

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

<u>Time</u>	<u>Range (mg/dL)</u>	<u>Range (mmol/L)</u>
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

Blood glucose levels can appear to be lower or higher after a meal, physical exercise or any other event that may affect blood glucose levels. Before taking the EASYGLUCO™ blood glucose test, wait two hours prior or after a meal, physical exercise to retrieve more accurate results.

- If the test result is below 20mg/dL (1.2mmol/L), “LO” will appear on the meter display. “LO” results indicate severe hypoglycemia (low blood glucose). Consult with your physician immediately in how to treat hypoglycemia.

- If the test result is above 600mg/dL (33.3mmol/L), “HI” will appear on the meter display. “HI” results indicate severe hyperglycemia (high blood glucose). Seek medical assistance immediately.

IMPORTANT Notices:

- If the test result is below 60mg/dL (3.3mmol/L) or over 240mg/dL (13.3mmol/L) contact your physician immediately.
- If the blood glucose result is unusually low or high, or you do not feel the way the result indicates, repeat the test again with a new test strip.
- If the results are still inconsistent, contact a physician before making any decision to control your diabetes.

These expected values are referenced from the below references.

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.

N. Instrument Name:

US Diagnostics Inc. EasyGluco Diabetes Monitoring System

O. System Descriptions:

1. Modes of Operation:

The EasyGluco Diabetes Monitoring System used with the EasyGluco Reagent Strips and EasyGluco Control Solution is a single use test system used to quantitatively measure blood glucose levels, also known as blood sugar, from fresh capillary whole blood samples taken from the fingertips, arm, palm, and thigh. The EasyGluco Diabetes Monitoring System is for in vitro diagnostic use only. The EasyGluco Diabetes Monitoring System is not intended for use with neonates.

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:

The EasyGluco Blood Glucose Monitoring System memory will store from 7 to 90-day average and 200 tests in the memory.

4. Specimen Sampling and Handling:

Refer to the EasyGluco Blood Glucose Monitoring System User's Manual.

5. Calibration:

Code numbers are used to calibrate the EasyGluco Test Strips with the EasyGluco Meter for accurate results. The operator must confirm the code number of the meter and test strips are the same before using the meter. Once the EasyGluco test strip is inserted in the EasyGluco meter, the meter will turn on and the code number will be displayed for 3 seconds. The operator will then compare the code number on the meter LCD to the code number on the test strip vial.

If the codes do not match the operator must change the meter code to match the test strip vial code. The test strips are tested at the manufacturer at the time they are released. Based on performance characteristics for each lot of strips they are assigned code numbers. These code numbers represent the slope and intercept characteristics for each of the lots. The code number is embedded in reagent test strip.

6. Quality Control:

There are three EasyGluco Controls Solutions available: low, normal, and high that correspond to whole blood glucose concentrations of approximately 50 ± 15 mg/dL, 100 ± 16.5 mg/dL , and 300 ± 45 mg/dL respectively. A control test, using an EasyGluco Control, can be used to check the meter and test strips performance. The meter test strips and testing technique are acceptable if the control test result falls within a specific control range. Users are instructed to follow the illustrated directions in the EasyGluco User Guide. Quality control testing should be performed as required by the user's institution's quality control policy or local regulatory requirements.

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.

R. Conclusion:

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