

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

A. 510(k) Number:

k052469

B. Purpose for Submission:

New device submission

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Quantitative, utilizing glucose oxidase technology

E. Applicant:

HealthPia America Corp.

F. Proprietary and Established Names:

GlucoPack

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1345-Glucose test system

2. Classification:

Class 2

3. Product code:

NBW - System, test, blood glucose, over the counter

CGA - Glucose oxidase, glucose

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The GlucoPack Diabetes Monitoring System is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (in Vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes mellitus, or in clinical

settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.

3. Special conditions for use statement(s):

Do not use plasma or serum or use sites other than the fingertip to obtain the blood sample. It is not intended for use on neonates. It is not intended to diagnose diabetes. Dehydration may lower test results. Inaccurate results may occur when individuals are in shock, in hypotensive conditions, hyperglycemic or hyperosmolar states, with or without ketosis,

4. Special instrument requirements:

GlucoPack™ Meter

I. Device Description:

GlucoPack™ Meter

Components

This glucose-meter is composed of a strip sensor analog circuit unit, step perception unit, micro controller unit, and communication unit.

- Strip sensor analog circuit unit
Once the blood sample is injected into the strip sensor, the electricity is on; voltage amplification is generated through the electric current-voltage converter. The signal amplified is filtered and sent to AD input unit of MCU and then digitalized.
- Step perception unit
When a person moves his or her body, the movement is captured and the counter in MCU counts it.
- Micro controller unit
This unit digitalizes the signal which is an input from the analog signal process circuit on the A/D input terminal, and counts the signal which is transmitted through step perception unit and transfers that signal to external display device.
- Communication unit
This unit communicates with an external display device and transmits data to the display device.
- External display device
This unit displays data and test results transmitted from the communication unit.

Features of product

- Type and extent of protection against the electric shock: internal power supply system device, type B device
- Safety device: power protection circuit, which is applied for safe use of the Lithium Polymer battery, has following functions;
 - Over charge protect function: when the battery is overcharged by an external charger due to defective performance, this function shuts off the circuit and protects the device from overcharge.
 - Over discharge protect function: this function protects the battery from

- over discharge under the critical voltage.
- Over current shut off function: this function shuts off the over current flow as a result of the internal/external abnormal condition.
- Name and version of software:
 - Name of software for blood glucose meter: IAR Workbench target descriptor for MSP 430 (C-based)
 - Version: 1.26A/WIN
 - Name of the software for external display:
 - Brew (C-based)
 - Version: 1.1

EasyGluco™ Test Strip Cleared under k043512

Two control solutions are sold separately from the kit. Controls previously cleared under k031501

Auto-Lancet Device, Greelan Lancets and the Check Strip for Calibration

J. Substantial Equivalence Information:

1. Predicate device name(s):
LifeScan, Inc. OneTouch Ultra
2. Predicate 510(k) number(s):
k024194
3. Comparison with predicate:
The GlucoPack™ Blood Glucose Monitoring System provides the same glucose monitoring capability as the predicate device, the ONE TOUCH® Ultra®.

	GlucoPack™	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
Test range	10 ~ 600 mg/dL	20 ~ 600 mg/dL
Hematocrit Range	30 ~55%	30 ~ 55%
Test Time	9 seconds	5 seconds
Sample Volume	3uL	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)

	GlucoPack™	ONE TOUCH® Ultra®
Memory capability	Max 150 packet data on the external display device Unlimited memory on the datacenter	14-day average and last 150 tests in the memory
Power	Lithium-polymer DC 3.7V	3V Li battery (CR2032)
Battery life	Running 5,000 tests	Running 1,000 tests
Size: LxWxH (mm)	80.9x45x29.7	79x57x21
Weight	93g±1	42g (with battery)
Warranty	1 year	3 years
Software	GlucosePack : IAR Workbench target descriptor for MSP430 The external display device : Brew Application	IN TOUCH® diabetes management software

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

- 1) *Point-of-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guideline, 2nd Edition.* CLSI Document C30-A2
- 2) *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline.* CLSI Document EP10-A
- 3) *Evaluation of Matrix Effects; Approved Guideline,* CLSI Document EP14-A2
- 4) *Estimation of Total analytical Error for Clinical Laboratory Methods; Approved Guideline.* CLSI Document EP21-A
- 5) *User Demonstration of Performance for Precision and Trueness; Approved Guideline.* CLSI Document EP15-A2
- 6) *Interference Testing in Clinical Chemistry; Approved Guideline.* CLSI Document EP7-A2
- 7) *Evaluation of the Linearity of Quantitative Measurement Procedures; Approved Guideline,* CLSI Document EP6-A
- 8) *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.* CLSI Document EP5-A2
- 9) Clinical Chemistry, 2nd Edition
- 10) MERCK INDEX, 11th Edition.

L. Test Principle:

The principle of the test relies on glucose in the blood sample to react to the 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 a glucose module integrated in the battery pack of the cell phone and the results of the blood glucose are displayed on the cell phone.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Within-Run precision

The procedure was conducted by taking 4mL of blood that was treated with EDTA through a vacuum tube. Glucose was added to the 4 mL of blood to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 50 times.

Between-Run precision

Three different control solutions of Low, Normal and High were measured twice a day, once in the morning (Run 1) and once in the afternoon (Run 2) during a month's time. For each Run, two measurement readings were taken in which the mean, standard deviation (SD), and coefficient variation percent (CV %) were calculated.

	Mean (mg/dL)	SD	CV %
Within-run (venous blood)	45.8	1.5	3.2
	99.6	2.5	2.5
	136.6	2.3	1.7
	196.8	3.3	1.7
	346.5	8.9	2.6
Between-run/Total (control solution)	56.6	2.1	3.7
	110.4	3.6	3.3
	300.2	9.7	3.2

- b. *Linearity/assay reportable range:*

Samples with equally spaced concentrations were evaluated. The linear range is defined by the highest and lowest measured concentrations where the response is linear.

The GlucoPack phone used in this test can display below 10 mg/dL over 600 mg/dL for checking linear range. The planned GlucoPack phone for sale displays “Low” below 10 mg/dl, “Hi” over 600 mg/dL.

Each of the glucose levels were 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:

1st order polynomial, $y = ax + b$, 2nd order polynomial, $y = aX^2 + bX + c$

In all dilution schemes, the applicant started with 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 611.8mg/dL and 8.8mg/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 84mg/dL $[(0.875*8.8 + 0.125*611.8)/(0.875+0.125)]$.

	GlucoPack™						YSI 2300 (Reference)		
Dilution	Rep1	Rep2	Rep3	Rep4	Rep5	<u>Mean</u>			<u>Mean</u>
1	8	8	9	10	9	<u>8.8</u>	8	8	<u>8.8</u>
2	88	87	89	86	89	<u>87.8</u>	86	85	<u>86.8</u>
3	166	158	160	159	170	<u>162.6</u>	163	161	<u>163.1</u>
4	240	241	238	234	248	<u>240.2</u>	238	237	<u>239.4</u>
5	325	316	319	311	314	<u>317</u>	315	315	<u>314.4</u>
6	363	387	378	393	388	<u>381.8</u>	430	339	<u>386.4</u>
7	451	445	460	479	470	<u>461</u>	460	457	<u>465.4</u>
8	538	509	541	539	574	<u>540.2</u>	538	535	<u>545.2</u>
9	608	620	600	610	612	<u>610</u>	612	615	<u>611.8</u>

The Polynomial Evaluation of Linearity

Dilution	Actual Mean	Predicted 1st order	Predicted 2nd order	Difference
1	<u>8.8</u>	12.1	10.3	1.8
2	<u>86.8</u>	87.1	86.7	0.5
3	<u>163.1</u>	162.1	162.7	-0.5
4	<u>239.4</u>	237.2	238.3	-1.1
5	<u>314.4</u>	312.2	313.5	-1.3
6	<u>386.4</u>	387.2	388.3	-1.1
7	<u>465.4</u>	462.2	462.7	-0.5
8	<u>545.2</u>	537.2	536.7	0.5
9	<u>611.8</u>	612.2	610.4	1.8

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 1.8 mg/dL from 8.8 mg/dl to 611.8 mg/dL. The R^2 of 1st order regression is a 0.9997

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

See k043512 and k031501

d. *Detection limit:*

10 – 600 mg/dL (linearity study above)

e. *Analytical specificity:*

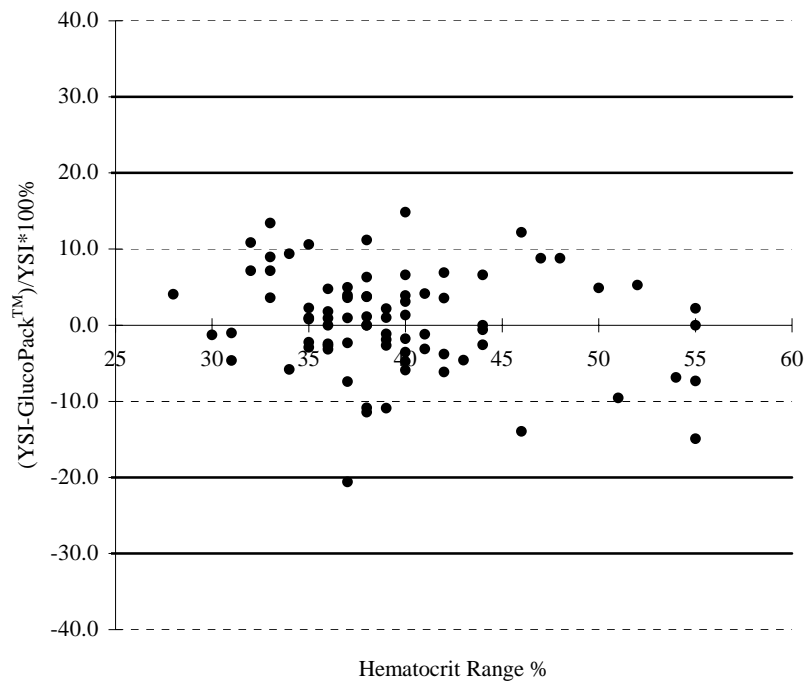
Approximately 2 mL of blood was taken from 64 random diabetic individuals. The blood samples were treated with the EDTA vacuum tube and the glucose concentration was adjusted to < 50 ~ < 580 mg/dL by adding an adequate amount of the phosphate buffer (20mM with pH 7.4) that contains a different level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

Blood glucose range	number of samples
< 50 mg/dL	8
51 ~ 110 mg/dL	9
111 ~ 150 mg/dL	11
151 ~ 250 mg/dL	18
251 ~ 400 mg/dL	24
< 580 mg/dL	10
Total	80

The Hematocrit level and glucose concentration in the blood was assessed by using the YSI2300 STAT PLUS.

The sponsor's acceptance criteria are that all the data should be within +/- 30 % bias and that over 90% of data are within +/- 20%.

Bias between GlucoPack result and the corresponding comparison YSI result.



The % bias of the assay value of the GlucoPack system is relative to the YSI and does not have a negative or positive correlation to hematocrit level in this experiment. 99% of the data is within +/- 20% bias in the overall range of glucose and hematocrit.

Interferences (see k043512):

- GlucoPack™ Test Strips are specific to D-glucose and do not react with other sugars which may be present in the blood.
- GlucoPack™ Test Strips do not interfere with the hematocrit at a normal range (30-55%) of blood glucose.
- Extreme levels in hematocrit may affect test results. 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 bilirubin, gentistic acid and other reducing substances in the blood may cause inaccurately high results.
- Lipemic samples; cholesterol up to 500mg/dL or triglycerides up to 3000 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.

- Dopamine treatment may increase the test result.
- Antiglycolysis may affect the test results.

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The accuracy of the GlucoPack System was assessed by comparing blood Glucose levels on 410 diabetic patients obtained and tested by three healthcare professionals at three different clinical centers compared to matching venous plasma samples run on the Roche Hitachi 747 analyzer.

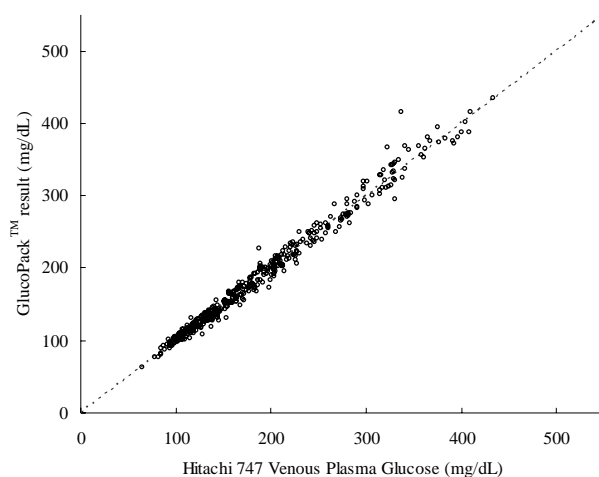
A consumer study was conducted using 104 diabetics self tested with the GlucoPack System compared to matching venous plasma samples run on the Roche Hitachi 747 analyzer.

The sponsor's acceptance criteria are as follows:

Slope greater than 0.96 and less than 1.05

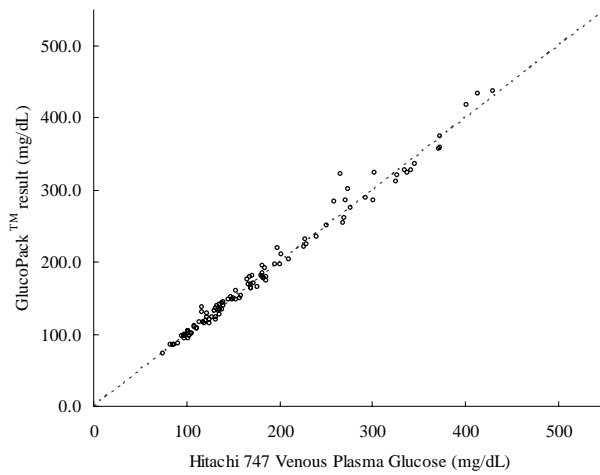
Correlation coefficient greater than 0.96

Obtained by Healthcare Professionals in Clinical Center



Slope 1.0081
y-intercept -1.976
Correlation coefficient(r) 0.9844
No. of samples 410
Range tested 65-433mg/dL

C. Obtained by Lay diabetics

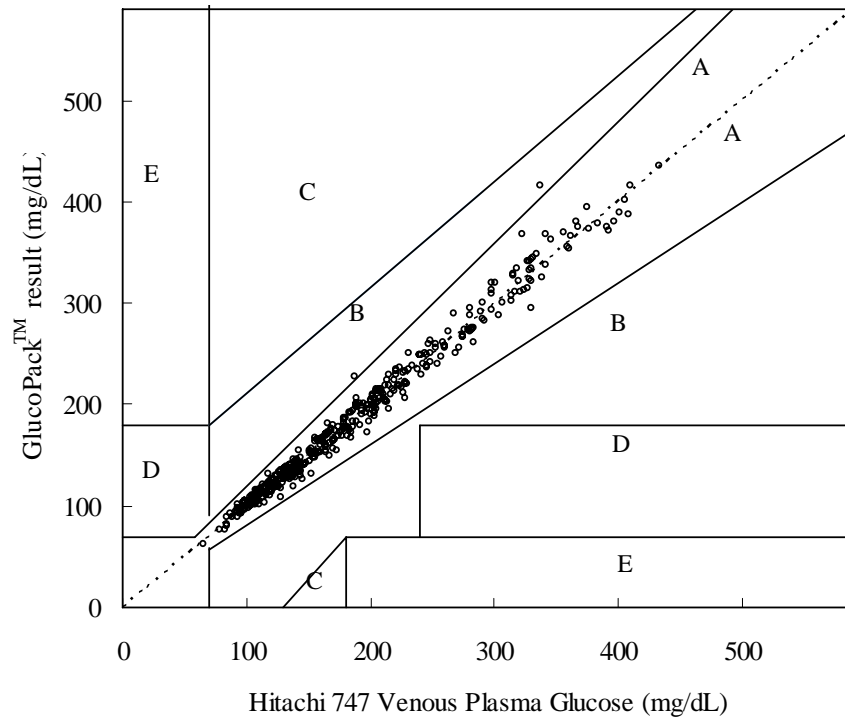


Slope 1.0069
y-intercept -0.8198
Correlation coefficient(r) 0.9854
No. of samples 104
Range tested 74-429 mg/dL

Using the Clark Error Grid Analysis the study done by the clinical centers resulted in 99.51% of the tested specimens, in region marked A, had glucose values that deviated from the reference method of less than 20% or are less than 70 mg/dL by both methods.

Error Grid Analysis – Hitachi 747 Vs. GlucoPack™

Obtained by Healthcare Professionals in Clinical Centers



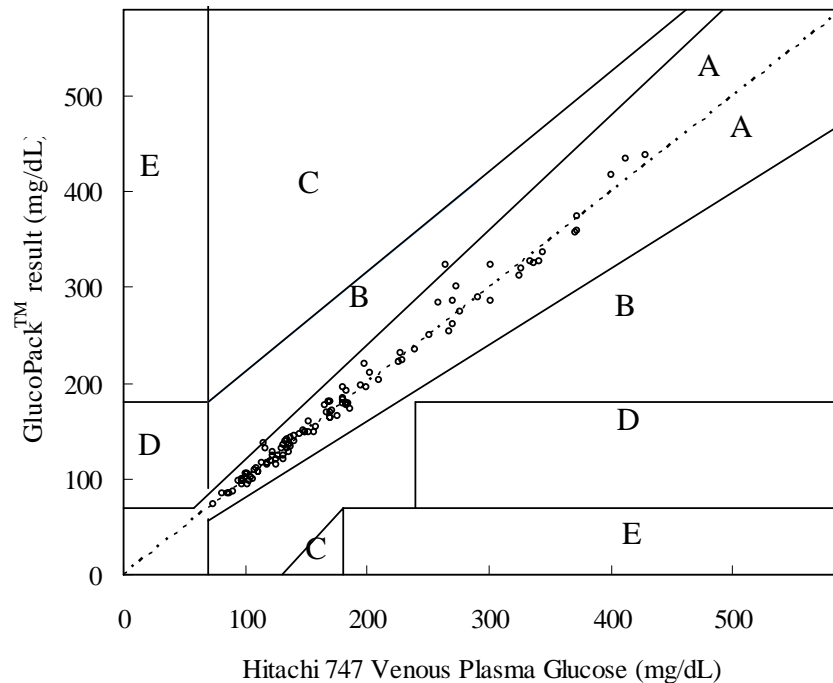
Summary of Professional Error Grid Analysis Results

Zone	Number	%	
A	408	99.51	Zone A = clinically accurate, leading to correct treatment decisions
B	2	0.49	Zone B = deviation from the reference by more than 20%, leading to benign or no treatment.
C	-	0	Zone C = over-correcting of acceptable blood glucose levels.
D	-	0	Zone D = represent a potentially dangerous failure to detect and treat glucose levels outside the desired target range.
E	-	0	Zone E = represents results that would lead to an erroneous treatment.
Total	410	100	

The study done with the lay diabetics resulted in 99% of the tested subjects, in region marked A, had glucose values that deviated from the reference method of less than 20% or are less than 70 mg/dL by both methods.

Error Grid Analysis – Hitachi 747 Vs GlucoPack

Obtained by Lay Diabetics



Summary of Consumer Error Grid Analysis Results

Zone	Number	%	
A	103	99	Zone A = clinically accurate, leading to correct treatment decisions
B	1	1	Zone B = deviation from the reference by more than 20%, leading to benign or no treatment.
C	-	0	Zone C = over-correcting of acceptable blood glucose levels.
D	-	0	Zone D = represent a potentially dangerous failure to detect and treat glucose levels outside the desired target range.
E	-	0	Zone E = represents results that would lead to an erroneous treatment.
Total	104	100	

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):
See the consumer method comparison study above.
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:

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:

HealthPia GlucoPack™ Meter

O. System Descriptions:

1. Modes of Operation:

Manual fingerstick

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

FDA has reviewed applicant's Hazard Analysis and software development processes for this device has determined the device was developed under good software lifecycle processes.

3. Specimen Identification:

No sample identification

4. Specimen Sampling and Handling:

Individual Fingerstick

5. Calibration:

Utilizes a Check Strip for Calibration

6. Quality Control:

Two control materials are available for use with the meter. The meter does not have a quality control data analysis software application.

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.