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

A. 510(k) Number:

k112653

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

On Call ® Vivid Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA –Glucose oxidase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry
JJX – Single Analyte control	Class I, reserved	21 CFR § 862.1660	75 – Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

The On Call ® Vivid Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Fingertip, forearm and palm testing sites should be used alternately only when blood glucose level is not changing rapidly. The On Call ® Vivid Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

The On Call ® Vivid Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The On Call ® Vivid Blood Glucose Test Strips are used with the On Call Vivid Blood Glucose Meter in the quantitative measurement of glucose in capillary blood form the finger and the alternate sites specified above.

The On Call ® Vivid Blood Glucose Control Solution is for use with the On Call® Vivid Blood Glucose Meter and Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):
   - For over-the-counter use
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
   - Alternative site testing (AST) can be used only during steady-state blood glucose conditions.
   - AST should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.
   - Single-patient use only and should not be shared

4. Special instrument requirements:

The On Call ® Vivid Blood Glucose Meter

I. Device Description:

The On Call ® Vivid Blood Glucose Monitoring System Starter Kit consists of the following components: a glucose test strip vial containing 10 On Call Vivid Blood Glucose Test Strips, a On Call ® Vivid Blood Glucose meter, one bottle of glucose control solution, a lancing device, 10 lancets in each package, a clear cap for testing on forearm and palm, Instructions for Use (test strip, control solution), User's Manual, Log Book, a warranty card, carrying case, and a quick reference guide.

The following can be purchased as separate individual products for use with the On Call ® Vivid Blood Glucose System: one vial containing 25 test strips per box, 2 vials containing 25 test strips per box, 4 vials containing 25 test strips per box, and

25 individually wrapped test strips per box. 2 bottles of control solution (On Call ® Vivid Glucose control solution 1 and control solution 2) per box, and 4 packages per box containing 25 lancets.

1. Predicate device name(s):

   OneTouch Ultra Blood Glucose Monitoring System

2. Predicate K number(s):

   k002134

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	One Touch Ultra Blood Glucose Monitoring System (predicate device), k002134	On Call ® Vivid Blood Glucose Monitoring System (candidate device)
Intended Use/ Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the finger, forearm and palm as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Setting	Only for single patient use at home	Same
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Manual Coding by manually selecting code by pressing button	No user coding required
Power supply	One (1) CR 2032 3.0V coin cell battery	Two (2) CR 2032 3.0V coin cell batteries
Memory	150 blood glucose and control solution tests	Up to 500 records with time and date
Test range	10 - 600 mg/dL	20 – 600 mg/dL
Hematocrit range	30 – 55%	20 – 70%
Sample type	Fresh capillary whole blood	Same
Sample sites	Fingertip and forearm	Fingertip, forearm, and palm
Sample volume	1.0 µL	0.8 µL
Sample test time	5 seconds	Same

Similarities and Differences of the control solution		
Item	One Touch Ultra Blood Glucose Monitoring System (predicate device), k002134	On Call ® Vivid Blood Glucose Monitoring System (candidate device)
Intended Use/ Indications for Use	To check that the glucose meter and test strips are working together properly and that the test is performing correctly.	Same
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of levels	2	Same

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

1. EN ISO 15197: 2003, In vitro diagnostic test systems - Requirements for In Vitro Whole Blood Glucose.
2. EN 11137 -1: 2006 Sterilization of healthcare products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices.
3. EN 11137 – 2: 2007 Sterilization of healthcare products. Radiation. Part 2: Establising the sterilization dose.
4. EN 11137 – 3: 2006 Sterilization of healthcare products. Radiation. Guidance on dosimetric aspects.
5. EN 61326 – 1: 2006 Class B Electrical Equipment for Measurement, Control and Laboratory Use. EMC Requirements. General Requirements.
6. EN 61326 – 2 – 6: 2006 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements. Particular requirements. In vitro diagnostics (IVD) medical equipment.
7. EN 61010 – 1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1. General requirements.

L. Test Principle:

The On Call Vivid Blood Glucose Monitoring System uses glucose oxidase enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated for the redox reaction as the measureable response.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. *Precision/Reproducibility:*

Within-run precision was measured by using heparinized venous whole blood as the anti-coagulant at five different glucose concentrations. Each blood sample was adjusted to a 42% ± 2% hematocrit level and verified by a hematocrit reader. Each sample was tested on 3 lots of test strips on 10 meters. Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per glucose concentration tested). Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30 – 50 mg/dL	1	41.7	1.64	3.9
	2	42.7	1.57	3.7
	3	40.1	1.26	3.2
51 – 110 mg/dL	1	78.0	3.06	3.9
	2	79.8	2.47	3.1
	3	77.7	2.73	3.5
111 - 150 mg/dL	1	132.3	3.97	3.0
	2	131.0	4.04	3.1
	3	129.3	3.67	2.8
151 – 250 mg/dL	1	200.8	4.39	2.2
	2	191.7	4.44	2.3
	3	196.8	5.82	3.0
251 – 400 mg/dL	1	278.0	6.03	2.2
	2	272.7	7.47	2.7
	3	273.0	6.50	2.4

Between-day precision was measured by reading three different control materials on 3 lots of test strips, using 10 test strips on 10 meters (1 strip per meter), over 10 days (N=100 per glucose concentration tested). Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
30 - 50	1	36.0	1.58	4.4
	2	36.6	1.52	4.1
	3	37.2	1.57	4.2
96 - 144	1	118.9	3.36	2.8
	2	121.2	3.37	2.8
	3	122.4	4.24	3.5
280 - 420	1	359.3	8.48	2.4
	2	355.2	11.55	3.3

	3	359.7	10.95	3.0

b. Linearity/assay reportable range:

The linearity study was designed following CLSI EP6-A guideline. Venous whole blood samples were drawn and spiked to target analyte levels. Eleven target levels were prepared with glucose stock solutions to glucose concentrations ranging from 10 to 650 mg/dL (10, 25, 50, 80, 110, 170, 220, 330, 450, 550, 650). All samples were also tested on a YSI analyzer to generate the expected values. The observed values were plotted against an average of the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Strip Lot	Slope	Intercept	R^2
1	0.9998	4.2445	0.9992
2	1.0202	2.8045	0.9989
3	1.0318	2.3263	0.9990

The sponsor's claimed measurement range for glucose is 20 -600 mg/dL.

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

Traceability: On Call ® Vivid Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material.

Value assignment:

The value assignment of the On Call Vivid Blood Glucose control solutions were determined by an in-house procedure. The control solutions were prepared by gravimetric addition of glucose to achieve target values of 120 mg/dL for level 1 and 350 mg/dL for level 2 and values were confirmed by the YSI method. Verification of the control solutions were tested with 240 test strips and 2 meters with each level and the target ranges were set at the following:

Glucose control solution	Target Concentration	Acceptable range
Level 1 (medium)	120 mg/dL	120 ± 20% (96 – 144 mg/dL)
Level 2 (high)	350 mg/dL	280 – 420 mg/dL (280 – 420 mg/dL)

Stability:

Accelerated stability studies were conducted to assess the shelf – life and open

vial stability of the control solutions and test strips. Real-time stability studies are still on-going. Unopened control solutions have a 24 month shelf life and are stable for 6 months after first opening when stored at 5-30ºC (41-86ºF). The sponsor claims that the unopened test strips have a 24 month shelf life and are stable for 6 months after first opening when stored at 25-30ºC (77-86ºF). This information is provided in the labeling of the test strips and control solution materials.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

The sponsor states that the interference study was designed according to CLSI EP7-A2 guideline. Common endogenous and exogenous interference substances were evaluated by spiking venous whole blood (collected in tubes containing heparin) with three levels glucose concentrations (level 1 : 40 – 60 mg/dL, Level 2: 80 – 120 mg/dL, Level 3: 300 – 400 mg/dL).

The glucose samples were spiked with the potentially interfering compounds and tested on 3 lots of test strips. Each glucose concentration was evaluated at a low and a high concentration of the interfering substances. Bias was calculated as the difference between the test and control concentration groups. The following tables show the test concentrations for each potential interfering substance:

		Test Concentration	
Endogenous Compounds	Therapeutic Level (mg/dL)	Low Concentration (mg/dL)	High Concentration (mg/dL)
Ascorbic Acid	0.4 – 2.0	3	6
Conjugated Bilirubin	<0.4	34	50
Unconjugated Bilirubin	0.3 – 1.3	20	40
Cholesterol	114 - 300	250	500
Creatinine	0.6 – 1.3	1.5	5
Glutathione	0.01 – 0.3	0.5	1
Hemoglobin	100 – 200	200	500
Triglycerides	150 - 500	1500	3000
Urea	6.6 – 85.8	260	600
Uric Acid	2.5 – 8.0	8	23.5

		Test Concentration	
Exogenous	Therapeutic	Low	High Concentration

Substances	Level (mg/dL)	Concentration (mg/dL)	(mg/dL)
Acetaminophen	1.0 – 3.0	4	20
Dopamine	0.03	0.03	0.09
Ephedrine	0.001	0.1	0.5
Ethanol	100 – 200	200	400
Gentisic Acid	0.2 – 0.6	6	10
Ibuprofen	1.0 – 7.0	7	50
Levo dopa	0.02 – 0.3	0.3	3
Methyl dopa	0.1 – 0.75	0.75	1.5
Salicylic Acid	10 - 30	30	60
Tetracycline	0.2 – 0.5	0.5	1.5
Tolazamide	2.0 – 2.5	5.0	10
Tolbutamide	5.4 – 10.8	11	64

		Test Concentration	
Sugar Alcohols	Therapeutic Level (mg/dL)	Low Concentration (mg/dL)	High Concentration (mg/dL)
Lactose	0.5	5	25
Fructose	1 - 6	30	100
Galactose	4 - 80	78	100
Maltose	100	40	100
Mannitol	0.0128	300	600
Sorbitol	0.044	30	70
Xylose	20 - 40	90	200

Based on the study data, all the substances and levels tested above have <10% bias except for ascorbic acid > 3 mg/dL (above therapeutic levels). Ascorbic acid levels > 3 mg/dL will interfere with the glucose reading; therefore, the sponsor has the following limitation in their labeling.

"Ascorbic acid (vitamin C) ≤3 mg/dL does not significantly affect results.

However, abnormally high concentration (> 3mg/dL) in blood may cause inaccurately high glucose results."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study:

This study was conducted following guidance from the ISO Standard 15197:2003(E). This study was designed using 105 participants. A trained technician collected fingersticks, palm, and forearm sticks on each participant. Capillary samples were collected and measured on the YSI 2300 analyzer (reference method) and from the same fingersticks, the On Call Vivid BGMS was tested in duplicate (using the first result obtained for analysis) using three different test strip lots. Samples containing <50 mg/dL of glucose were allowed to glycolyze and to obtain sample values >400 mg/dL, samples were spiked with a glucose stock solution. The range of samples tested was 40.0 to 562.5 mg/dL for fingertip samples and 48.1 to 444.0 mg/dL (according to YSI) for palm and forearm samples. Regression analysis is summarized below:

Fingertip Samples (1st replicate):

Linear Regression: On Call Vivid vs. YSI Reference			
Strip Lot	Linear regression equation	R^2	N
1	y=1.0265x – 1.8674	0.9895	113
2	y=1.0018x + 1.2672	0.9885	113
3	y=1.0083x – 1.903	0.9895	113

Palm Samples (1st replicate):

Linear Regression: On Call Vivid vs. YSI Reference			
Strip Lot	Linear regression equation	R^2	N
1	y=0.9956x – 0.5644	0.9895	105
2	y=0.9795x + 0.7935	0.9889	105
3	y=1.0222x – 7.4802	0.989	105

Forearm Samples (1st replicate):

Linear Regression: On Call Vivid vs. YSI Reference			
Strip Lot	Linear regression equation	R^2	N

1	y=1.0318x – 1.822	0.9829	105
2	y=1.0078x + 0.3582	0.9842	105
3	y=0.991x – 1.6726	0.9851	105

Based on the ISO Standard 15197 document, how well the On Call® Vivid BGMS when HCP tested the fingersticks and contrived samples as compared with the YSI method is shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	13/17 (76.5%)	17/17 (100%)	17/17 (100%)
2	9/17 (76.5%)	17/17 (100%)	17/17 (100%)
3	12/17 (70.6%)	17/17 (100%)	17/17 (100%)
Combined	34/51 (74.5%)	51/51 (100%)	51/51 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	63/96 (65.6%)	88/96 (91.7 %)	96/96 (100%)	96/96 (100%)
2	62/96 (64.6%)	85/96 (88.5%)	96/96 (100%)	96/96 (100%)
3	57/96 (59.4%)	86/96 (89.6%)	96/96 (100%)	96/96 (100%)
Combined	182/288 (63.2%)	259/288 (89.9%)	288/288 (100%)	288/288 (100%)

Based on the ISO Standard 15197 document, how well the On Call Vivid BGMS when HCP tested the **forearm** as compared with the YSI method is

shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	10/12 (83.3%)	12/12 (100%)	12/12 (100%)
2	7/12 (58.3%)	12/12 (100%)	12/12 (100%)
3	10/12 (83.3%)	12/12 (100%)	12/12 (100%)
Combined	27/36 (75.0%)	36/36 (100%)	36/36 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	52/93 (55.9%)	76/93 (81.7%)	92/93 (98.9%)	93/93 (100%)
2	53/93 (57.0%)	82/93 (88.2%)	93/93 (100%)	93/93 (100%)
3	46/93 (49.5%)	81/93 (87.1%)	93/93 (100%)	93/93 (100%)
Combined	151/279 (54.1%)	239/279 (85.7%)	278/279 (99.6%)	279/279 (100%)

Based on the ISO Standard 15197 document, how well the On Call Vivid BGMS when HCP tested the **palm** as compared with the YSI method is shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	8/12 (66.7%)	12/12 (100%)	12/12 (100%)
2	10/12 (83.3%)	12/12 (100%)	12/12 (100%)
3	9/12 (75%)	12/12 (100%)	12/12 (100%)
Combined	27/36 (75%)	36/36 (100%)	36/36 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	60/93 (64.5%)	89/93 (95.7%)	93/93 (100%)	93/93 (100%)
2	50/93 (53.8%)	86/93 (92.5%)	93/93 (100%)	93/93 (100%)
3	53/93 (57.0%)	85/93 (91.4%)	93/93 (100%)	93/93 (100%)
Combined	163/279 (58.4%)	260/279 (93.2%)	279/279 (100%)	279/279 (100%)

b. Matrix comparison:

None. Only capillary whole blood samples are acceptable matrix.

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):

Lay user performance study:

The sponsor stated that the study was conducted following the ISO Standard 15197 and compared layuser self-test fingerstick, palm, and forearm measurements to the YSI method. The study was performed at a clinical site with 105 subjects and using sample glucose ranges from 48.1 to 444.0 mg/dL. The results from linear regression analysis are as follows:

Regressions between Lay user's fingerstick results and the YSI method/Technician result and the YSI method (1st replicate):

Strip Lot	Tester	Linear Regression	R^2	N
1	Layperson	y= 1.0496x – 3.7828	0.9859	105
1	Technician	y= 1.0596x – 6.5509	0.9908	105

2	Layperson	y= 1.0433x – 3.8467	0.989	105
2	Technician	y= 1.0365x – 3.5873	0.99	105
3	Layperson	y= 1.0279x – 5.7082	0.9915	105
3	Technician	y= 1.0421x – 6.5499	0.9898	105

Regressions between Lay user's palm results and the YSI method/Technician result and the YSI method (1st replicate):

Strip Lot	Tester	Linear Regression	R^2	N
1	Layperson	y=1.0249x – 0.5752	0.9854	105
1	Technician	y=0.9956x – 0.5644	0.9895	105
2	Layperson	y=0.9958 + 1.4262	0.9845	105
2	Technician	y=0.9795 + 0.7935	0.9889	105
3	Layperson	y=1.0065x – 2.3563	0.9898	105
3	Technician	y=1.0222x – 7.4802	0.989	105

Regressions between Lay user's forearm results and the YSI method/Technician result and the YSI method (1st replicate):

Strip Lot	Tester	Linear Regression	R^2	N
1	Layperson	y=1.0311x – 0.9288	0.9846	105
1	Technician	y=1.0318x – 1.822	0.9829	105
2	Layperson	y=1.0059x + 1.4546	0.9804	105
2	Technician	y=1.0078x + 0.3582	0.9842	105
3	Layperson	y=0.9904x + 0.5226	0.9846	105
3	Technician	y=0.991x – 1.6726	0.9851	105

Based on the ISO Standard 15197 document, how well the On Call® Vivid BGMS when lay users tested themselves (using fingertip) as compared with the YSI method is shown in the tables below:

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	7/12 (58.3%)	12/12 (100%)	12/12 (100%)
2	7/12 (58.3%)	12/12 (100%)	12/12 (100%)
3	4/12 (33.3%)	11/12 (91.7%)	12/12 (100%)
Combined	18/36 (50%)	35/36 (97.2%)	36/36 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	51/93 (58.3%)	83/93 (89.2%)	91/93 (97.8%)	93/93 (100%)
2	62/93 (75%)	85/93 (91.4%)	93/93 (100%)	93/93 (100%)
3	59/93 (58.3%)	86/93 (92.5%)	93/93 (100%)	93/93 (100%)
Combined	172/279 (63.9%)	254/279 (91.0%)	277/279 (99.3%)	279/279 (100%)

Total accuracy agreement: 100% of all the individual glucose results fall within ±15 mg/dL of the YSI results of glucose concentration <75 mg/dL and within ±20% of the YSI results of glucose concentration ≥75 mg/dL.

Based on the ISO Standard 15197 document, how well the alternative testing by lay users compared with the YSI method is shown in the tables below:

1. Lay user test results of the **forearm** when compared to the YSI method (for glucose concentration <75 mg/dL):

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	5/12 (41.7%)	12/12 (100%)	12/12 (100%)
2	6/12 (50%)	12/12 (100%)	12/12 (100%)
3	6/12 (50%)	12/12 (100%)	12/12 (100%)
Combined	17/36 (47.2%)	36/36 (100%)	36/36 (100%)

Lay user test results of the **forearm** when compared to the YSI method (for glucose concentration ≥ 75 mg/dL):

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	54/93 (41.7%)	78/93 (83.9%)	92/93 (98.9%)	93/93 (100%)
2	57/93 (50%)	76/93 (81.7%)	93/93 (100%)	93/93 (100%)
3	49/93 (50%)	74/93 (79.6%)	93/93 (100%)	93/93 (100%)
Combined	160/279 (47.2%)	228/279 (81.7%)	278/279 (99.6%)	279/279 (100%)

2. Lay user test results of the **palm** when compared to the YSI method (for glucose concentration <75 mg/dL):

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	9/12 (75%)	12/12 (100%)	12/12 (100%)
2	9/12 (75%)	12/12 (100%)	12/12 (100%)
3	10/12 (83.3%)	12/12 (100%)	12/12 (100%)
Combined	28/36 (77.8%)	36/36 (100%)	36/36 (100%)

Lay user test results of the **palm** when compared to the YSI method (for glucose concentration ≥ 75 mg/dL):

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	51/93 (75%)	78/93 (83.9%)	93/93 (100%)	93/93 (100%)
2	55/93 (75%)	81/93 (87.1%)	93/93 (100%)	93/93 (100%)
3	63/93 (83.3%)	88/93 (94.6%)	92/93 (98.9%)	93/93 (100%)
Combined	169/279 (60.6%)	247/279 (88.5%)	278/279 (99.6%)	279/279 (100%)

Total accuracy agreement: 100% of all the individual glucose results fall within ±15 mg/dL of the YSI results of glucose concentration <75 mg/dL and within ±20% of the YSI results of glucose concentration ≥75 mg/dL.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:
   For people without diabetes:
   Fasting and before meals: 70 - 100 mg/dL
   2 hours after meal: < 140 mg/dL

   American Diabetes Association Clinical Practice Recommendation, 2011.

N. Instrument Name:

On Call ® Vivid Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.8 uL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No __X_____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

2. Software:

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

   Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the On Call Vivid meter by the user. The meter is plasma-calibrated.

6. Quality Control:

   Glucose control solutions at two different concentrations can be run with this device. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Altitude Study :

   This study was conducted at a single site to evaluate the effect of altitude on the On Call Vivid BGMS. The tested glucose range (obtained using YSI reference method) was from 41.7 to 567 mg/dL at sea level and 35.7 to 525 mg/dL at 8,516 ft above sea level. Fingerstick blood samples were collected and compared to the YSI analyzer reference value. These blood samples were evaluated using both the On Call Vivid BGMS and a YSI glucose analyzer. Each test strip glucose value was compared to the YSI method and then analyzed as a percent bias. The glucose values obtained using the On Call Vivid blood glucose meter had acceptable biases to support the altitude claim of 8,516 feet.

2. Hematocrit Study –

   The sponsor performed hematocrit studies using 8 different hematocrit (20, 25, 30, 40, 50, 60, 65, and 70%) levels across the glucose measuring range (target glucose concentrations 50, 100, 275, and 500 mg/dL). 3 test strip lots were evaluated and compared to the YSI method. The results support the sponsor's claimed hematocrit range of 20 – 70%.

3. Temperature and Relative Humidity Study:

   Operating Conditions Study:

   In this study, three test strip lots were tested at 7 combined temperature and relative humidity conditions (5ºC/10% RH, 21 ºC/ 10% RH, 45 ºC/10%, 5 ºC/90% RH, 21 ºC/ 90% RH, 45 ºC/ 90% RH, and 21 ºC/ 45% RH). Each sample was also compared to the YSI reference method. Three blood samples were adjusted to the following glucose concentration levels: (40-60 mg/dL, 80-120 mg/dL, 500-550 mg/dL) The results demonstrate that accurate readings can obtained after

exposure to temperatures ranging from 5 - 45ºC and relative humidity conditions ranging from 10 – 90%.

4. EMC Electromagnetic Compatibility and Electrical Safety verification testing of the On Call Vivid Blood Glucose Monitoring System was performed following the requirements of ISO 15197:2003 (E).

   The following consumer cautionary statement is provided in the user's manual:

   "All Glucose Systems Preventive Warnings with Regard to EMC:

   • This instrument complies with the emission and immunity requirements. The requirements are described in EN61326-1 and EN61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation. These may interfere with proper operation of the meter."

5. Sample volume study:

   Acon performed a sample volume study to demonstrate that 0.8µL of whole blood is sufficient volume for the On Call Vivid blood glucose meter system. For this study, sample volumes ranging from 0.4µL – 1.0 µL were evaluated using three different lots of test strips. The blood glucose sample results collected using the On Call Vivid blood glucose meter were compared with glucose values obtained with the YSI reference method and supported the minimum sample volume claim of 0.8 µL.

6. Infection control:

   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, (DisCide Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipe (EPA Reg. No. 10492-4). Robustness studies were also performed by the sponsor demonstrating that there was not change in performance or external materials of the meter and lancing device after 3,285 times of cleaning and disinfection cycles, using (DisCide Wipes) Quaternary Ammonium/Isopropyl Alcohol disinfectant wipes, to simulate 3 years of use by layusers. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Readability:

   The readability of the labeling (user guides, test strip package insert and control

solution package insert) using a Flesch-Kincaid analysis and were found to be written at the 7th grade level.

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.

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