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

A. 510(k) Number:

k111371

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

On Call® Chosen 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 – Quality Control material	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® Chosen 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. Alternate testing sites (forearm and palm) should be used only when glucose is not changing rapidly. The On Call® Chosen 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® Chosen Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for use with neonates

   The On Call® Chosen Test Strips are used with the On Call® Chosen Blood Glucose Meter in the quantitative measurement of glucose in fresh capillary blood from the fingertip, forearm and palm.

   The On Call® Chosen Control Solution is for use with the On Call® Chosen Blood Glucose Meter and Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

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) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.
   AST testing should only be done during steady-state times (when glucose is not changing rapidly).
   For single-patient use only and should not be shared

4. Special instrument requirements:

   On Call Chosen blood glucose meter and On Call Chosen Glucose Test Strips

I. Device Description:

The On-Call Chosen Blood Glucose Monitoring System contains the following:

1. On-Call Chosen Blood Glucose Meter
2. On-Call Chosen Control Solution level 1
3. On-Call Chosen Test Strips with code chip
4. 3-Volt Lithium Coin Battery
5. User's Manual
6. Quick Reference Guide
7. Instructions for use (test strip, control solution)
8. Log book
9. Lancets, lancet device and clear cap
10. Carrying Case

A starter kit including the above component, with a Quick Start Guide and one control solution (level 1) is available for the customer to purchase.

Each box of test strips contains one vial of 25 test strips. Each test strip contains the following reagent compositions: glucose oxidase <25 IU, mediator <300µg, buffer, and other non-reactive ingredients.

Each box of control solutions contain two vials of aqueous control solutions with preservatives (2 mL each): Level 1: Normal level contains 0.2% concentrations of glucose (approximately 100 mg/dL) and Level 2: High level contains 0.4% concentrations of glucose (approximately 350 mg/dL).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch Ultra Blood Glucose Monitoring System

   OneTouch Select control solutions

2. Predicate K number(s):

   k002134

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	OneTouch Ultra meter (predicate device), k002134	On Call® Chosen meter (candidate device)
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Setting	at home and in a clinical settings	Only for single patient use at home
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	User sets calibration code	No coding by user
Power supply	One battery (CR2032)	Two batteries (CR2031X2)
Memory	150 control and glucose	300 records
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 55%	20- 70%
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm	Fingertip, forearm, palm
Sample volume	1.0 µL	0.8µL
Sample test time	5 seconds	Same

Similarities and Differences of the control solution		
Item	OneTouch Select Control Solutions (predicated device),	On-call Chosen Control Solutions (candidate device)
Intended 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 levels	Same

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

1. ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
2. FDA Draft Guidance Document-Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems; October 24, 2006.
3. CLSI Guideline, EP6-A Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline
4. CLSI Guideline, EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline- Second edition

L. Test Principle:

The On Call® Chosen Blood Glucose Monitoring System employs 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 from the redox reaction as the measurable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Within-run precision was measured by using heparinized anti-coagulated whole blood at five different glucose concentrations. Each sample was tested on 3 lots of test strips on 30 meters (10 meters per test strip lot). Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per test strip). Results are summarized below:

   Within-run precision for glucose:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
40	1	42.0	1.48	3.5
	2	41.3	1.49	3.6
	3	38.8	1.48	3.8
75	1	76.4	2.78	3.6
	2	72.2	2.11	2.9
	3	74.9	2.03	2.7
130	1	130.9	3.89	3.6
	2	123.4	3.77	3.1
	3	124.8	3.20	2.6
190	1	186.8	5.07	2.7
	2	191.2	5.37	2.8
	3	193.8	4.94	2.5
310	1	302.4	8.55	2.8
	2	320.5	10.19	3.2
	3	315.7	8.87	2.8

Between-day precision was measured by reading three different control materials on 3 lots of test strips, 10 replicates per day for 10 days, (N = 100). Results are summarized below:

Between-day precision for glucose:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	% CV
40	1	41.3	1.05	2.5
	2	41.0	1.15	2.8
	3	40.7	1.00	2.5
110	1	114.4	3.06	2.7
	2	113.5	2.62	2.3
	3	113.6	2.86	2.5
310	1	314.3	6.58	2.1
	2	317.2	7.08	2.2
	3	310.8	6.55	2.1

b. *Linearity/assay reportable range:*

Linearity study was designed based on CLSI EP6-A guideline. Eleven human whole blood samples were drawn into heparinized tubes and spiked to the target analyte levels. 11 target levels were prepared with glucose concentrations ranging from 20 to 650 mg/dL (20, 30, 50, 80, 100, 170, 220, 330, 450, 550, and 650 mg/dL). All samples were tested on 3 lots of test strips in replicates of four on two different On Call Chosen meters. All samples were also tested on the YSI 2300 analyzer to generate the expected values. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Strip Lot	Slope	Intercept	R	R^2	Samples range tested
1	1.0167	-0.3519	0.9988	0.9976	14.8-673.8 mg/dL
2	1.0283	-4.4780	0.9984	0.9969	13.5-677.8 mg/dL
3	1.0196	-1.4033	0.9988	0.9977	14.5-671.8 mg/dL

The results of the study support the sponsor's claim that the glucose assay is linear from 20-600 mg/dL.

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

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

Value assignment:

The value assignment of the On Call Chosen 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	350 ± 20% (280-420 mg/dL)

Control ranges are lot specific and are provided on the test strip vial.

Stability:

Accelerated stability study was 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. Stability studies protocol and acceptance criteria were provided and found to be adequate. Unopened control solutions have a 24 month shelf life and are stable for 6 months after first use when stored at 2-30^{o}C (36-86 ^{o}F) . The sponsor claimed that the unopened test strips have a 24 month shelf-life and are stable for 6 months after first use when stored at 2-30^{o}C (36-86 ^{o}F). This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline. 25 common endogenous and exogenous interfering substances were evaluated by spiking venous blood with three levels of glucose concentrations (60, 100 and 300 mg/dL). The glucose samples were spiked with the potentially interfering compounds and tested on 3 lots of test strips using 2 different meters. Each sample is tested in replicates of four and a total of 1008 test strips were used. Bias was calculated as the mean percent difference in glucose reading

between the test and control concentration groups. The sponsor claims no significant interference if bias between the tested and the control sample is <10% difference. A summary of the concentrations of the potential interfering substances tested is summarized in the table below:

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration	
		Low	High
Acetaminophen	1.0-3.0 mg/dL	4 mg/dL	20 mg/dL
Ascorbic Acid	0.4-2.0 mg/dL	3 mg/dL	6 mg/dL
Conjugated-Bilirubin	<0.4 mg/dL	34 mg/dL	50 mg/dL
Unconjugated-Bilirubin	0.3-1.3 mg/dL	20 mg/dL	40 mg/dL
Creatinine	0.6-1.3 mg/dL	1.5 mg/dL	5 mg/dL
Dopamine	0.03 mg/dL	0.03 mg/dL	0.09 mg/dL
L-Dopa (Levo-Dopa)	0.02-0.3 mg/dL	0.3 mg/dL	3 mg/dL
Methyl Dopa	0.1-0.75 mg/dL	0.75 mg/dL	1.5 mg/dL
Ethanol	100-200 mg/dL	200 mg/dL	400 mg/dL
Hemoglobin	100-200 mg/dL	200 mg/dL	500 mg/dL
Ibuprofen	1.0-7.0 mg/dL	7 mg/dL	50 mg/dL
Mannitol	0.0128 mg/dL	300 mg/dL	600 mg/dL
Salicylic Acid	10-30 mg/dL	30 mg/dL	60 mg/dL
Sorbitol	0.044mg/dL	30 mg/dL	70 mg/dL
Tetracycline	0.2-0.5 mg/dL	0.5 mg/dL	1.5 mg/dL
Tolazamide	2.0-2.5 mg/dL	5.0 mg/dL	10 mg/dL
Tolbutamide	5.4-10.8 mg/dL	11 mg/dL	64 mg/dL
Uric Acid	2.5-8.0 mg/dL	8 mg/dL	23.5 mg/dL
Galactose	4-80 mg/dL	78 mg/dL	100 mg/dL
Maltose	100 mg/dL	40 mg/dL	100 mg/dL
Xylose	20-40 mg/dL	90 mg/dL	200 mg/dL
Fructose	1-6 mg/dL	30 mg/dL	100 mg/dL
Lactose	0.5 mg/dL	5 mg/dL	25 mg/dL
Cholesterol	114-300 mg/dL	250 mg/dL	500 mg/dL
Triglycerides	150-500 mg/dL	1500 mg/dL	3000 mg/dL

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."

"Critically ill patients should not be tested with blood glucose meters. Test results can be falsely low if the patients are severely dehydrated, in shock, or in hyper-osmolar state (with or without ketosis)."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study was performed according to the ISO 15197 document using 110 participants from a diabetic clinic. A trained healthcare professional (HCP) collected samples from the fingertip, forearm and palm on each participant. Capillary samples were collected and measured on the YSI 2300 analyzer (reference method) and from the same fingersticks. One patient had a result >700; therefore, was omitted from the data analysis. In order to obtain sufficient samples in the lowest concentration interval (< 50 mg/dL), 5 additional capillary samples from fingertip were altered. Samples that were <50 mg/dL were contrived samples and samples between 50 to 497 mg/dL were natural samples (109 + 5 = 114). The range of glucose values for the fingerstick samples tested was 44.2-497 mg/dL. Forearm and palm samples were all natural patient samples and sample range tested was 52.1 to 497 mg/dL (109). All samples were tested in duplicate using 3 different lots of test strips and a total of 36 meters and only the first replicate was used for data analysis. Regression analysis results are summarized below:

Regressions between On Call® Chosen BGMS results from fingerstick and the YSI method for the fingerstick samples:

Strip Lot	Linear regressions	R	R^2	N
1	Y=1.0519X – 9.7207	0.9936	0.9872	114
2	Y=1.0839X – 13.516	0.9933	0.9867	114
3	Y=1.0779X – 13.926	0.9939	0.9879	114

Regressions between On Call® Chosen BGMS results from palm and the YSI method for the fingerstick samples:

Strip Lot	Linear regressions	R	R^2	N
1	Y=0.9902X – 4.1788	0.9934	0.9868	109
2	Y=0.9910X – 4.3999	0.9923	0.9847	109
3	Y=0.9871X – 5.1873	0.9944	0.9888	109

Regressions between On Call® Chosen BGMS results from forearm and the YSI method for the fingerstick samples:

Strip Lot	Linear regressions	R	R^2	N
1	Y=1.0289X – 5.6928	0.9921	0.9842	109
2	Y=1.0597X – 9.9687	0.9893	0.9788	109
3	Y=1.0546X – 10.539	0.9910	0.9820	109

Based on the ISO Standard 15197 document, how well the On Call® Chosen 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	9/18 (50.0%)	18/18 (100%)	18/18 (100%)
2	11/18 (61.1%)	18/18 (100%)	18/18 (100%)
3	13/18 (72.2%)	18/18 (100%)	18/18 (100%)
Combined	33/54 (61.1%)	54/54 (100%)	54/54 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	49/96 (51.0%)	79/96 (82.3%)	94/96 (97.9%)	96/96 (100%)
2	49/96 (47.9%)	78/96 (81.3%)	95/96 (99.0%)	96/96 (100%)
3	48/96 (50.0%)	80/96 (83.3%)	95/96 (99.0%)	96/96 (100%)
Combined	146/288 (50.7%)	237/288 (82.3%)	284/288 (98.6%)	288/288 (100%)

Based on the ISO Standard 15197 document, how well the On Call® Chosen 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	9/13 (69.2%)	13/13 (100%)	13/13 (100%)
2	8/13 (61.5%)	13/13 (100%)	13/13 (100%)
3	7/13 (53.8%)	13/13 (100%)	13/13 (100%)
Combined	24/39 (61.5%)	39/39 (100%)	39/39 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	52/96 (54.2%)	78/96 (81.3%)	94/96 (97.9%)	96/96 (100%)
2	46/96 (47.9%)	81/96 (84.4%)	95/96 (99.0%)	96/96 (100%)
3	51/96 (53.1%)	81/96 (84.4%)	96/96 (100%)	96/96 (100%)
Combined	149/288 (51.7%)	240/288 (83.3%)	285/288 (99%)	288/288 (100%)

Based on the ISO Standard 15197 document, how well the On Call® Chosen 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	9/13 (69.2%)	13/13 (100%)	13/13 (100%)
2	8/13 (61.5%)	12/13 (92.3%)	13/13 (100%)
3	9/13 (69.2%)	13/13 (100%)	13/13 (100%)
Combined	26/39 (66.7%)	38/39 (97.4%)	39/39 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	46/96 (47.9%)	74/96 (77.1%)	95/96 (99%)	96/96 (100%)
2	39/96 (40.6%)	77/96 (80.2%)	96/96 (100%)	96/96 (100%)
3	36/96 (37.5%)	80/96 (83.3%)	96/96 (100%)	96/96 (100%)
Combined	121/288 (42.0%)	231/288 (80.2%)	287/288 (99.7%)	288/288 (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):

A user performance study was conducted in conjunction with the system accuracy study. Lay users self-tested their fingertip glucose results using the labeling provided by the sponsor without any prior training. Lay user self-test results (with fingertip) and the YSI method fingerstick results were compared. Study was performed in one clinical site with 110 subjects, including 45% male and 55% female. 3 lots of test strips were used and each lay user tested two lots of strips randomly. One patient has a result >700; therefore, was omitted from the data analysis. The range of glucose values for the fingerstick samples was 52.2 - 497 mg/dL. Linear regressions analysis results are summarized below:

Regressions between lay user's fingerstick results and the YSI method (fingersticks):

Strip Lot	Linear regressions	R	R^2	N
1	Y=1.0809X – 13.6020	0.9905	0.9811	109
2	Y=1.0725X – 12.760	0.9931	0.9863	109
3	Y=1.0886X – 14.8270	0.9931	0.9863	109

Based on the ISO Standard 15197 document, how well the On Call® Chosen BGMS when lay user 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	7/13 (53.8%)	13/13 (100%)	13/13 (100%)
2	9/13 (69.2%)	13/13 (100%)	13/13 (100%)
3	12/13 (92.3%)	13/13 (100%)	13/13 (100%)
Combined	28/39 (71.8%)	39/39 (100%)	39/39 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	44/96 (45.8%)	78/96 (81.3%)	93/96 (96.9%)	96/96 (100%)
2	46/96 (47.9%)	84/96 (87.5%)	93/96 (96.9%)	96/96 (100%)
3	47/96 (48.9%)	81/96 (84.4%)	94/96 (97.9%)	96/96 (100%)
Combined	137/288 (47.6%)	243/288 (84.4%)	280/288 (97.2%)	288/288 (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.

Alterative testing sites (AST) for blood glucose measurement were evaluated during a user performance study with 110 subjects. Testing was performed by the lay user using the forearm and palm (thenar and hypothenar regions) to show comparable performance at times of steady state conditions with the fingertip glucose results measured with the YSI method. The range of glucose

values for these samples was 52.2 - 497 mg/dL (by YSI). One patient has a result >700; therefore, was omitted from the data analysis. The linear regressions were summarized below:

AST sites	Lot	Linear regressions	R^2	N
Forearm vs. YSI	1	Y=1.0552X - 8.7304	0.9841	109
Forearm vs. YSI	2	Y=1.0330X – 4.8868	0.9829	109
Forearm vs. YSI	3	Y=1.0597X – 9.9687	0.9788	109

AST sites	Lot	Linear regressions	R^2	N
Palm vs. YSI	1	Y=1.0155X – 6.7723	0.9818	109
Palm vs. YSI	2	Y=1.0149X – 7.0104	0.9980	109
Palm vs. YSI	3	Y=0.9910X – 4.3999	0.9847	109

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	8/13 (61.5%)	13/13(100%)	13/13 (100%)
2	10/13 (76.9%)	13/13 (100%)	13/13 (100%)
3	9/13 (69.2%)	13/13 (100%)	13/13 (100%)
Combined	27/39 (69.2%)	39/39 (100%)	39/39 (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	37/96 (38.5%)	77/96 (80.2%)	96/96 (100%)	96/96 (100%)
2	43/96 (44.8%)	75/96 (78.1%)	96/96 (100%)	96/96 (100%)
3	44/96 (45.8%)	75/96 (78.1%)	96/96 (100%)	96/96 (100%)
Combined	124/288 (43.1%)	227/288 (78.8%)	288/288 (100%)	288/288 (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	10/13 (76.9%)	13/13 (100%)	13/13 (100%)
2	10/13 (76.9%)	12/13 (92.3%)	13/13 (100%)
3	9/13 (69.2%)	12/13 (92.3%)	13/13 (100%)
Combined	29/39 (74.4%)	37/39 (94.9%)	39/39 (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	46/96 (47.9%)	79/96 (82.3%)	96/96 (100%)	96/96 (100%)
2	38/96 (39.5%)	70/96 (72.9%)	95/96 (99.0%)	96/96 (100%)
3	46/96 (47.9%)	80/96 (83.3%)	96/96 (100%)	96/96 (100%)
Combined	130/288 (45.1%)	229/288 (79.5%)	287/288 (99.7%)	288/288 (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:

Expected blood glucose results for non-pregnant people without diabetes were cited from the literature[1] and presented in the labeling as follows:

Fasting and before meals: 70 - 100 mg/dL
2 hours after meals: < 140 mg/dL

[1]American Diabetes Association Clinical Practice Recommendations, 2011.

N. Instrument Name:

On Call® Chosen 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 ___X_____ or No _____

   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. The On-Call Chosen Blood Glucose Monitoring System's memory will store 300 test results with respective dates and time.

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.

   Testing on Fingertips – Refer to the ON-Call Chosen Blood Glucose Monitoring System User's Manual for detailed meter information prior to testing.

   Testing on palm and forearm- The following important notes are listed in the package insert:

   - Consult your healthcare professional before you begin using the palm or forearm for testing.
   - Under certain conditions, blood glucose test results obtained using samples taken from your palm or forearm may differ significantly from fingertip samples. Do not use palm or forearm testing when your blood glucose is changing rapidly such as following a meal, an insulin dose, or

associated with physical exercise.

- Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

5. Calibration:

   There is no calibration required for the On Call® Chosen meter by the user. The meter is plasma-calibrated. However, there is a code chip that is coded with the calibration information that comes with each test strip vial. The code chip automatically calibrates the meter with the code number when inserted into the meter. The code chip must match the lot number on the test strip before running a glucose test.

6. Quality Control:

   Glucose control solutions at two different concentrations (level 1 and level 2) are available to be run with this device and are sold separately. One level of control solution (level 1) is provided with the kit. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient results. 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. A usability study was performed to assess the readability of the labeling by recruiting 110 lay users (aged 21-82 yrs old) who were provided with the test kit containing labeling for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. These lay users also completed a questionnaire to assess whether the device is easy to use and if the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User's Manual, test strip package insert, control solution package insert, and Quick Guides) were written at $\leq 8^{th}$ grade level.

3. Customer service is available 24/7, 365 days a year. Toll free phone number is 1-800-838-9502 for customer support.

4. A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the On Call® Chosen BGMS. Three lots of test strips were tested using blood from three

donors, each adjusted to a glucose concentration of 60, 100 and 500 mg/dL. Blood at each concentration was applied to strips at five target sample volumes of 0.4, 0.6, 0.7, 0.8 and 1.0 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.8 µL produced accurate results and samples <0.8 µL give an error code ("E5"- insufficient sample).

5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 5°C to 45°C and relative humidity from 10% to 90%. Extreme temperatures and humidity conditions combinations were tested as follows: 10%/5°C, 10%/45°C, 90%/5°C, and 90%/45°C. Protocol and acceptance criteria were provided and found to be acceptable. (% bias for all individual result against YSI results are within ±10% bias).The results supported the Sponsor's claimed operating temperature from 5°C to 45°C (41°F to 113°F) and relative humidity range from 10% to 90%.

6. EMC testing was evaluated by TUV Rheinland Co., Ltd. and test report summary was issued to ACON Laboratories, Inc. on January 31, 2011.

7. The device is intended for single-patient use only. DisCide Ultra Disinfecting Towelette with EPA registration # 10492-4 was validated demonstrating complete inactivation of live hepatitis B virus (HBV) for use with the meter. The towelette is available for purchase through Palmero Health Care Company and user can either call 1-800-344-6424 or visit their website at www.palmerohealth.com. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 1642 cleaning cycles and 1642 disinfection cycles designed to simulate 4.5 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. The optional RS 232 data transmitting port was reviewed and found to be adequate to support the use of transmitting data to a Data Management Software. The Data Management Software has been previously cleared in k101371.

9. Hematocrit Study - The sponsor performed hematocrit studies using eight different hematocrits (Hct) (20, 25, 30, 40, 50, 60, 65 and 70%) levels across the glucose measuring range (20-600 mg/dL). At each hematocrit level, 4 samples at glucose concentration of 50, 100, 250, and 500 mg/dL were tested against the YSI method. 3 lots of test strips were tested on 2 meters, with replicates of three for each concentration tested and the values were compared to the YSI method and the nominal hematocrit level (40%). All results generated from the On Call Chosen glucose meter had a bias of <10% when compared to the YSI method and the nominal hematocrit level. Based on the data, the sponsor claims that hematocrit between 20% to 70% do not significantly affect the glucose results.

10. Altitude Study - A study was conducted to evaluate the effect of altitude on the On Call® Chosen BGMS. 3 lots of test strips were tested on 16 meters using

blood from three donors at three glucose concentrations (70, 240, and 450 mg/dL) at one high altitude level (8,516 feet), and sea level (0 feet) as a control. Testing was performed in a hyperbaric chamber. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. Bias was within ± 10% for all three altitude levels tested. Based on the data, the sponsor claims that the On Call® Chosen BMGS can be used at altitude up to 8,516 feet.

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.