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

A. 510(k) Number:
k090057

B. Purpose for Submission:
New device

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:
Acon Laboratories Co.

F. Proprietary and Established Names:
On-Call Plus Blood Glucose Monitoring System

G. Regulatory Information:
1. Regulation section:
   21CFR Sec.- 862.1345-Glucose test system.
   21CFR Sec.-862.1660 Quality control material (assayed and unassayed).

2. Classification:
   2, 2, 1 (reserved)

3. Product code:
   NBW - System, Test, Blood Glucose, Over the Counter

   CGA - Glucose Oxidase, Glucose

   JJX - Quality Control Material (Assayed and Unassayed)

4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See indication(s) for use below

2. Indication(s) for use:

The On-Call® Plus Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in capillary whole blood from the fingertip, forearm, and/or palm by people with diabetes at home and by healthcare professionals as an aid in the monitoring the effectiveness of diabetes control programs.

The On-Call® Plus 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® Plus Blood Glucose control solution is for use with the On-Call® Plus 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):

- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Alternative site testing is for use at times of steady state only
- For Over-the-Counter use
- Not for use in patients who are dehydrated, in shock, critically ill, or in hyperosmolar state

4. Special instrument requirements:
On-Call® Plus Blood Glucose Meter

I. Device Description:
The On-Call® Plus Blood Glucose Monitoring System consists of glucose meter, blood glucose test strips and two levels of control solution.

J. Substantial Equivalence Information:
1. Predicate device name(s):
One Touch Ultra Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
k002134

3. Comparison with predicate:

Features	On-Call® Plus Blood Glucose Monitoring System	One Touch Ultra Blood Glucose Monitoring System (K002134)
Similarities		
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)	Same
Result Calibration	Plasma-equivalent	Same
Sample	Fresh capillary whole blood	Same
Minimum Sample Size	1 μL	Same
Assay Method	Glucose oxidase biosensor	Same
Power Source	One (1) CR 2032 3.0V coin cell battery	Same
Battery Life	12 months or approximately 1,000 tests	Same
Glucose Units of Measure	mg/dL	Same
Hematocrit Range	30-55%	Same
Automatic Shutoff	Two minutes after last user action	Same
Differences		
Test Time	10 seconds	5 seconds
Memory	Up to 300 records with time and date	150 blood glucose and control solution tests
Meter Size	85 mm x 54 mm x 20.5 mm	3.12" x 2.25" x 0.85"
Weight	Approximately 49.5 g (with battery installed)	1.5 ounces with battery (Approximately 42 g)
Operating Temperature	5-45°C (41 - 113°F)	6-44°C (43 - 111°F)
Operating Relative Humidity	20-90% (non-condensing)	10-90%
Sample Site	Fingertip, palm and forearm	Fingertip and forearm

K. Standard/Guidance Document Referenced (if applicable):
- EN 61010-2-101 - Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment. 12/31/2002
- IEC 60068-2-64 - Environmental Testing. Test Methods. Test Fh: Vibration, broad-band random (digital control) and guidance 04//30/2009

- CLSI EP7-A2 - Interference testing in Clinical Chemistry; Approved Guideline - second edition 11/23/2005
- CLSI EP6-A - Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. 04/01/2003
- ISO 15197: In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus - 2003
- Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems - Issue Date: 10/24/2006

L. Test Principle:

The On-Call® Plus Blood Glucose Test Strips are thin strips with a chemical reagent system using glucose oxidase. They work with the On-Call® Plus Blood Glucose Meter to measure the glucose concentration in capillary whole blood. Blood is applied to the end tip of the test strip. The blood is then automatically absorbed into the reaction cell. The reaction takes place in the reaction cell. A transient electrical current is formed during the reaction which is detected by the meter. The blood glucose concentration is then calculated based on the electrical current. The result is then shown on the meter display. The meters are calibrated to display plasma equivalent results.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      The repeatability precision of the On-Call® Plus Blood Glucose Monitoring System was evaluated according to EN ISO 15197:2003, Section 7.2.2 Repeatability evaluation, with three test strip lots using blood samples at five glucose concentrations measured 10 times on 10 glucose meters each.

Avg	SD	CV
Level 1 - 30 to 50 mg/dL		
43.4	2.47	5.70%
Level 2 - 51 to 110 mg/dL		
75.7	2.63	3.47%
Level 3 - 111 to 150 mg/dL		
143.3	4.39	3.07%
Level 4 - 151 to 250 mg/dL		
238.0	7.05	2.97%
Level 5 - 251 to 500 mg/dL		
377.9	12.03	3.17%

The intermediate precision of the On-Call® Plus Blood Glucose Monitoring System was evaluated according to EN ISO 15197, Section 7.2.3 Intermediate

precision evaluation, with three test strip lots using control solution at three glucose concentrations over 10 days on 10 glucose meters each.

Avg	SD	CV
Level 1: 30 to 50 mg/dL		
39.5	1.98	5.0%
Level 2: 96 to 144 mg/dL		
132.1	5.12	3.9%
Level 3: 280 to 420 mg/dL		
360.6	11.92	3.3%

b. *Linearity/assay reportable range:*
The linearity of the On-Call® Plus Blood Glucose Monitoring System was evaluated with three test strip lots using blood samples at 11 glucose concentrations. The 11 levels of glucose concentrations were prepared from venous blood samples containing heparin anticoagulant at approximately 42% hematocrit level. The range of glucose concentrations used (2 to 667 mg/dL) is representative of the measuring range of the meter. The results of meter readings vs. YSI Plasma Values were compared using linear regression analysis.

Strip Lot	Slope	Intercept	R	R^2
1	0.9966	0.9355	0.9983	0.9966
2	0.9971	0.7032	0.9985	0.9970
3	0.9959	1.1810	0.9982	0.9965

The claimed range of measurement is 20 to 600 mg/dL.

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

System traceability and validation of calibration and control materials are traceable to NIST standard reference material (SRM) 917b, D-glucose (dextrose) which was used for calibration.

A real time stability study of the control solution with cap closed was conducted and found to support the 24 month shelf life of the control solution.

In addition, an open and closed stability study of the control solution was also done to mimic the actual use condition. The study results confirm the 3-month use life of the control solution.

d. *Detection limit:*
20 mg/dL based on the above linearity study.

e. Analytical specificity:

The effect of interference on the On-Call® Plus Blood Glucose Monitoring System was evaluated with two test strip lots using venous blood samples containing heparin anticoagulant at approximately 42% hematocrit level at three glucose concentrations (approximately <60 mg/dL, 100–150 mg/dL and 350-450 mg/dL). The blood samples were then used to prepare the test pool at low and high concentrations of the interfering substances and control pool.

The acceptance criteria were as follows:
    Glucose concentration < 75 mg/dL:
        Average absolute bias for each interfering substance compared with control pool must be ≤ ± 15 mg/dL
    Glucose concentration ≥ 75 mg/dL:
        Average % Bias for each interfering substance compared with control pool must be ≤ ±15%

Interfering Substances	Therapeutic/ Physiological Levels	Test Concentration – Low	Test Concentration – High	On-Call® Plus
Acetaminophen	1.0-3.0 mg/dL	4 mg/dL	20 mg/dL	No interference at therapeutic levels and levels ≤4 mg/dL; interference only at super therapeutic levels
Ascorbic Acid	0.4-2.0 mg/dL	3 mg/dL	6 mg/dL	No interference at therapeutic levels and levels ≤3 mg/dL; interference only at super therapeutic levels
Bilirubin	0.3-1.2 mg/dL	20 mg/dL	40 mg/dL	No interference at

Interfering Substances	Therapeutic/ Physiological Levels	Test Concentration – Low	Test Concentration – High	On-Call® Plus
				physiological levels up to high test concentration
Creatinine	0.6-1.3 mg/dL	1.5 mg/dL	5 mg/dL	No interference at physiological levels up to high test concentration
Dopamine	0.03 mg/dL	0.03 mg/dL	0.09 mg/dL	No interference at therapeutic levels up to high test concentration
L-Dopa	0.02-0.3 mg/dL	0.3 mg/dL	3 mg/dL	No interference at therapeutic levels up to high test concentration
Methyl-Dopa	0.1-0.75 mg/dL	0.75 mg/dL	1.5 mg/dL	No interference at therapeutic levels up to high test concentration
Ibuprofen	1.0-7.0 mg/dL	7 mg/dL	50 mg/dL	No interference at therapeutic levels up to high test concentration
Salicylate Acid	10-30 mg/dL	30 mg/dL	60 mg/dL	No interference at therapeutic levels up to high test concentration

Interfering Substances	Therapeutic/ Physiological Levels	Test Concentration – Low	Test Concentration – High	On-Call® Plus
Tetracycline	0.2-0.5 mg/dL	0.5 mg/dL	1.5 mg/dL	No interference at therapeutic levels up to high test concentration
Tolazamide	2.0-2.5 mg/dL	5.0 mg/dL	10 mg/dL	No interference at therapeutic levels up to high test concentration

Hematocrit study

The effect of different hematocrit levels was evaluated on the On-Call® Plus Blood Glucose Monitoring System with three test strip lots using blood samples at four glucose concentrations (40-60, 80-120, 250-300, and 450-550 mg/dL). The four levels of glucose concentrations were prepared from venous blood samples containing heparin anticoagulant at six different hematocrit levels ranging from 30-55%. Glucose results for each concentration and hematocrit level were compared to the same plasma glucose concentration on the YSI at 40% Hematocrit using the acceptance criteria below.

Glucose concentration ≥75 mg/dL:
Average % Bias (Average strip reading vs. Plasma YSI Value at 40% Hct): within ±15% bias
Individual %Bias (Individual strip reading vs. Plasma YSI Value at 40% Hct): within ±15% bias
Glucose concentration < 75 mg/dL:
Average Bias (Average strip reading vs. Plasma YSI Value at 40% Hct): within ±15 mg/dL bias
Individual Bias (Individual strip reading vs. Plasma YSI Value at 40% Hct): within ±15 mg/dL bias

Results indicate that the On-Call® Plus Blood Glucose Monitoring System can provide accurate results when measuring blood samples having 30–55% hematocrit ranges covering measurement range of the system.

Altitude study

An altitude effect study was performed by testing each of 15 different samples at sea level and at elevated altitude of 8,516 ft. The On-Call® Plus Blood Glucose Monitoring System meets acceptance criteria of having more than 95% of the data points for all three strip lots within ± 20% bias when glucose concentration is ≥ 75 mg/dL, and ± 15 mg/dL when glucose concentration is < 75 mg/dL when compared to plasma YSI values. The results indicate that the On-Call® Plus Blood Glucose Monitoring System meets the accuracy acceptance criteria for testing at both sea level and elevated altitude of 8,516 ft.

Temperature and humidity studies were performed per ISO 15197:2003 and showed that the meter can be used at temperatures from 5-45°C and at a relative humidity from 20-90%

f. *Assay cut-off:*
   Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
      The system accuracy evaluation for the On-Call® Plus Blood Glucose Monitoring System has been performed according to EN ISO 15197:2003, Section 7.3 System accuracy evaluation.

      A trained technician performed testing with each study subject's capillary blood samples from fingertip, palm and forearm sites on the studied system. The testing was performed using the same method provided in the instructions for use for the studied system. Exceptions are allowed for very low (<50 mg/dL) and very high (>400 mg/dL) glucose concentration samples. Per EN ISO 15197:2003, samples with glucose concentration of <50 mg/L and >400 mg/L can be prepared by incubating the samples or by supplementing additional glucose to obtain the samples in these very low and very high glucose concentration levels. For each subject, an additional fingerstick capillary blood sample was also collected into microtainer tubes containing heparin anticoagulant for the YSI reference instrument testing and hematocrit level testing.

      Study Site:
      The tested glucose concentration range was from 43.6 to 473 mg/dL for fingertip capillary blood testing. The tested glucose concentration range was from 47.5 to 399 mg/dL for palm and forearm capillary blood testing. The subject blood hematocrit range is from 32% to 49%.

Linear Regression Summary Table: Meter Reading (y) vs. Plasma YSI Value (x) (YSI using fingertip sample)

Sample Site	Lot	Slope	Intercept	R	R^2	N
Fingertip	1	0.9972	-4.6130	0.9924	0.9849	244
Fingertip	2	0.9649	-0.5640	0.9917	0.9834	244
Fingertip	3	0.9848	3.8831	0.9898	0.9797	244
Palm	1	0.9702	2.8354	0.9821	0.9645	214
Palm	2	0.9614	4.4561	0.9820	0.9642	214
Palm	3	0.9747	9.8885	0.9819	0.9641	214
Forearm	1	0.9419	5.5952	0.9778	0.9560	214
Forearm	2	0.9226	9.0375	0.9814	0.9632	214
Forearm	3	0.9410	12.656	0.9778	0.9561	214

Fingertip Sample On-Call® Plus Result (vs. Plasma YSI with Fingertip sample)

Strip Lot: 390346

System Accuracy Results for Glucose Concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
97/208 (46.6%)	159/208 (76.4%)	194/208 (93.3%)	208/208 (100%)

System Accuracy Results for Glucose Concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
11/36 (30.6%)	29/36 (80.6%)	36/36 (100%)	

Strip Lot: 390350

System Accuracy Results for Glucose Concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
94/208 (45.2%)	159/208 (76.4%)	196/208 (94.2%)	208/208 (100%)

System Accuracy Results for Glucose Concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
16/36 (44.4%)	30/36 (83.3%)	36/36 (100%)	

Strip Lot: 390357

System Accuracy Results for Glucose Concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/208 (48.1%)	164/208 (78.8%)	193/208 (92.8%)	208/208 (100%)

System Accuracy Results for Glucose Concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
16/36 (44.4%)	25/36 (69.4%)	36/36 (100%)	

Palm Sample On-Call® Plus Result (vs. Plasma YSI with Fingertip sample)

Strip Lot: 390346

System Accuracy Results for Glucose Concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
88/198 (44.4%)	144/198 (72.7%)	187/198 (94.4%)	197/198 (99.5%)

System Accuracy Results for Glucose Concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
10/16 (62.5%)	16/16 (100%)	16/16 (100%)	

Strip Lot: 390350			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
85/198 (42.9%)	143/198 (72.2%)	186/198 (93.9%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
7/16 (43.8%)	16/16 (100%)	16/16 (100%)	
Strip Lot: 390357			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
72/198 (36.4%)	127/198 (64.1%)	167/198 (84.3%)	197/198 (99.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±5 mg/dL	Within ±15 mg/dL	
8/16 (50.0%)	15/16 (93.8%)	16/16 (100%)	
Forearm Sample On-Call® Plus Result (vs. Plasma YSI with Fingertip sample)			
Strip Lot: 390346			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
73/198 (36.9%)	131/198 (66.2%)	172/198 (86.9%)	197/198 (99.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
14/16 (87.5%)	16/16 (100%)	16/16 (100%)	
Strip Lot: 390350			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
77/198 (38.9%)	154/198 (77.8%)	185/198 (93.4%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
10/16 (62.5%)	15/16 (93.8%)	16/16 (100%)	
Strip Lot: 390357			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
71/198 (35.9%)	134/198 (67.7%)	169/198 (85.4%)	197/198 (99.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
12/16 (75.0%)	15/16 (93.8%)	16/16 (100%)	

b. *Matrix comparison:*
Not Applicable - capillary whole blood is the only indicated 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):

The objective of the user performance evaluation study was to demonstrate that the intended users are able to operate the On-Call® Plus Blood Glucose Monitoring System (studied system) as well as a trained technician. The user study was performed for fingertip, palm, and forearm sample sites to demonstrate that acceptable user performance can be obtained at palm and forearm alternative sample sites in addition to the fingertip sample site.

The Flesch-Kincaid Grade Level Score of 6.0 to 7.8 was obtained with the User's Manual and the test strip and control Package Inserts of the On-Call® Plus Blood Glucose Monitoring System. In addition, a questionnaire administered to the participating lay persons indicated user satisfaction with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the On-Call® Plus Blood Glucose Monitoring System.

Device labeling was given to each study subject to allow the subject to learn and understand how to run testing for the studied system. After reading the instructions, each study subject performed fingerstick testing on the studied system by themselves. After each study subject tested themselves, a trained technician also ran the same testing with the same subject's fingerstick blood. The same procedure for fingerstick testing was then repeated for palm and forearm alternative sites. In the study for each subject, additional fingerstick capillary blood was also collected into microtainer tubes containing heparin anticoagulant for the YSI reference instrument testing and hematocrit level testing.

A user performance study was performed by testing 107 different subjects over 13 days. Both the layperson and technician performed the testing for each subject sample for the user study. The tested glucose concentration range was from 47.5 to 399 mg/dL.

The user performance on the On-Call® Plus Blood Glucose Monitoring System was evaluated according to EN ISO 15197:2003, Section 8 User performance evaluation. The user study was performed for fingertip, palm, and forearm sample sites to show that acceptable user performance can be obtained at palm and forearm alternative sample sites in addition to the fingertip sample site.

Linear Regression Summary Table: Meter Reading (y) vs. Plasma YSI Value (x)							
Tested By	Sample Site	Strip Lot	Slope	Intercept	R	R^2	N
Layperson	Fingertip	390346	0.9881	-2.3697	0.9862	0.9727	214
Technician	Fingertip	390346	0.9927	-3.6585	0.9857	0.9716	214
Layperson	Fingertip	390350	0.9355	4.5351	0.9867	0.9736	214
Technician	Fingertip	390350	0.9457	2.6854	0.9851	0.9703	214
Layperson	Fingertip	390357	0.9700	5.9324	0.9827	0.9656	214
Technician	Fingertip	390357	0.9931	4.1391	0.9843	0.9688	214
Layperson	Palm	390346	1.0187	-2.1565	0.9863	0.9727	214
Technician	Palm	390346	0.9702	2.8354	0.9821	0.9645	214
Layperson	Palm	390350	0.9733	5.0519	0.9840	0.9683	214
Technician	Palm	390350	0.9614	4.4561	0.9820	0.9642	214
Layperson	Palm	390357	1.0375	2.4647	0.9869	0.974	214
Technician	Palm	390357	0.9747	9.8885	0.9819	0.9641	214
Layperson	Forearm	390346	0.9845	1.0704	0.9825	0.9654	214
Technician	Forearm	390346	0.9419	5.5952	0.9778	0.9560	214
Layperson	Forearm	390350	0.9449	5.9403	0.9809	0.9621	214
Technician	Forearm	390350	0.9226	9.0375	0.9814	0.9632	214
Layperson	Forearm	390357	0.9663	8.9432	0.9784	0.9572	214
Technician	Forearm	390357	0.9410	12.656	0.9778	0.9561	214

Layperson compared to YSI:

Fingertip Sample Site Tested by Layperson			
Strip Lot: 390346			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
89/198 (44.9%)	161/198 (81.3%)	185/198 (93.4%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
11/16 (68.8%)	16/16 (100%)	16/16 (100%)	
Strip Lot: 390350			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
86/198 (43.4%)	156/198 (78.8%)	190/198 (96.0%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
11/16 (68.8%)	16/16 (100%)	16/16 (100%)	

Strip Lot: 390357			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
89/198 (44.9%)	155/198 (78.3%)	183/198 (92.4%)	197/198 (99.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
12/16 (75.0%)	15/16 (93.8%)	16/16 (100%)	
Palm Sample Site Tested by Layperson			
Strip Lot: 390346			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
97/198 (49.0%)	155/198 (78.3%)	185/198 (93.4%)	196/198 (99.0%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
12/16 (75.0%)	15/16 (93.8%)	16/16 (100%)	
Strip Lot: 390350			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
89/198 (44.9%)	163/198 (82.3%)	185/198 (93.4%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
10/16 (62.5%)	15/16 (93.8%)	16/16 (100%)	
Strip Lot: 390357			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
83/198 (41.9%)	135/198 (68.2%)	170/198 (85.9%)	196/198 (99.0%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±5 mg/dL	Within ±15 mg/dL	
9/16 (56.3%)	15/16 (93.8%)	16/16 (100%)	
Forearm Sample Site Tested by Layperson			
Strip Lot: 390346			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
88/198 (44.4%)	149/198 (75.3%)	179/198 (90.4%)	198/198 (100%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
8/16 (50.0%)	16/16 (100%)	16/16 (100%)	
Strip Lot: 390350			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
92/198 (46.5%)	147/198 (74.2%)	180/198 (90.9%)	197/198 (99.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	

7/16 (43.8%)	16/16 (100%)	16/16 (100%)	
Strip Lot: 390357			
System Accuracy Results for Glucose Concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
70/198 (35.4%)	130/198 (65.7%)	167/198 (84.3%)	195/198 (98.5%)
System Accuracy Results for Glucose Concentration <75 mg/dL			
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	
9/16 (56.3%)	14/16 (87.5%)	16/16 (100%)	

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   The sponsor included the following expected values for non-diabetic normal glucose levels in their strip labeling*:

Time	Range, mg/dL
Fasting and Before Meals	70 – 100
2 hours after Meals	Less than 140

   *ADA Clinical Practice Recommendations, 2003

N. Instrument Name:

On-Call® Plus Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

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

   Yes __X_____ or No _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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:

   This device is intended to be used with capillary whole blood from the finger, palm, or forearm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

   A calibration code chip is provided with each vial of test strips.

6. Quality Control:

   The sponsor is providing a one level of glucose control solution with this device Two levels are available for purchase separately, as stated in the labeling. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the user manual and customer support for problems.

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

None

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.