

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

A. 510(k) Number:

k130284

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric (FAD- Glucose Dehydrogenase)

E. Applicant:

Acon Laboratories Inc.

F. Proprietary and Established Names:

On Call Sharp Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR§ 862.1345, Glucose Test System	Clinical Chemistry (75)
LFR	Class II	21 CFR§ 862.1345, Glucose Test System	Clinical Chemistry (75)
JJX	Class I, reserved	21 CFR § 862.1660, Quality control material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The On Call Sharp Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternative site testing should be done only during steady-state times (when blood glucose level is not changing rapidly). The On Call Sharp 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 Sharp Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates.

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

The On Call Sharp Blood Glucose Control Solutions are for use with the On Call Sharp Blood Glucose Meter and On Call Sharp Blood Glucose Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

3. Special conditions for use statement(s):

For In Vitro Diagnostic use

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

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).

Single-patient use only system; should not be shared

4. Special instrument requirements:

On Call Sharp Blood Glucose Meter

I. Device Description:

The On Call Sharp Blood Glucose Monitoring System consists of the On Call Sharp Blood Glucose Meter, On Call Sharp Blood Glucose Test Strips and On Call Sharp Blood Glucose Control Solutions, a lancing device and sterile lancets. The blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

The On Call Sharp Blood Glucose Control Solutions are used to confirm that the meter and strips are working properly. The solutions contain known concentrations of glucose, and preservatives in an aqueous based mixture bottled into dropper bottles with caps. Three solution levels are available (Levels 0, 1, and 2). Level 1 is provided with the system. Levels 0 and 2 are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

On Call Vivid Blood Glucose Monitoring System

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

k112653

3. Comparison with predicate:

Similarities		
Item	On Call Sharp Blood Glucose Monitoring System (Candidate Device)	On Call Vivid BGMS (Predicate Device, k112653)
Indication For Use	The On Call Sharp Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood as an aid in monitoring the effectiveness of diabetes control programs.	Same
Assay Method	Electrochemical	Same
Detection method	Amperometry	Same
Measuring	20 – 600 mg/dL	Same

Range		
Test Time	5 seconds	Same
Memory capacity	up to 500 with time and date	Same
Power source	Two CR2032 3.0 V coin cell batteries	Same
Operating humidity	10 - 90 %	Same
Sample	Fresh capillary whole blood	Same
Weight	Approx. 60g (including batteries)	Same

Differences		
Item	On Call Sharp Blood Glucose Monitoring System (Candidate Device)	On Call Vivid BGMS (Predicate Device, k112653)
Test Strip Enzyme	FDA- dependent Glucose Dehydrogenase Biosensor	Glucose Oxidase biosensor
Battery Life	IGM-0028A: Running 5,000 Tests IGM-0028B(Back Light LCD): Running 1,000 Tests	Running 5,000 Tests N/A
Operating temperature	10 - 45 °C (50 - 113 °F)	5 - 45 °C (41 - 113 °F)
Hematocrit range (%)	25-70%	20-70%

Items	On Call Sharp Blood Glucose Control Solution (Candidate Device)	On Call Vivid Blood Glucose Control Solution (Predicate Device, k112653)
IFU	To confirm that your Test Strips and Blood Glucose Meter are working together properly and that you are performing the test correctly.	Same
Number of Controls	Three levels of control solution are available. They are Control Solution 0, 1, and Control Solution 2.	Two levels of control solution are available. They are Control Solution 1 and Control Solution 2.

Composition	<p>1) Control Solution 0 contains less than 0.1% glucose (active ingredient).</p> <p>2) Control Solution 1 contains less than 0.2% glucose (active ingredient).</p> <p>3) Control Solution 2 contains less than 0.4% glucose (active ingredient).</p> <p>All have preservatives in an aqueous based mixture.</p>	<p>1) Control solution 1 contains less than 0.2% glucose (active ingredient).</p> <p>2) Control Solution 2 contains less than 0.4% glucose (active ingredient).</p> <p>Both have preservatives in an aqueous based mixture.</p>
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K. Standard/Guidance Document Referenced (if applicable):

ISO 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

ISO 13640:2002 Stability and testing of in vitro diagnostic reagents

ISO 14791:2009 Medical Devices – Application of risk management to medical devices.

ISO GP14-A:1996 Labeling of Home-Use In Vitro Testing Products; Approved Guideline.

CLSI Guideline, EP6-A: Evaluation of the Linearity of Quantitative measurement procedures: A statistical approach; Approved Guideline.

CLSI Guideline, EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline. Second Edition

EN 61326-1:2006 Class B Electrical equipment for measurement, control and laboratory use – EMC requirements

EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use. Particular requirements. In vitro diagnostic (IVD) medical equipment

EN 62366:2008 Medical devices. Application of usability engineering to medical devices

EN 62304: 2006 Medical device software. Software life-cycle process

EN 10993-5:2009 Biological evaluation of medical devices. Test for irritation and delayed-type hypersensitivity

EN 10993-5:2009 Biological evaluation of medical devices. Test for in vitro cytotoxicity

EN11607-1-2006 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems

EN11137-2:2000 Sterilization of medical devices. Microbiological Methods. Test of sterility performed in the validation of a sterilization process

EN11137:2006 Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices.

EN11137-2:2007 Sterilization of health care products. Radiation. Establishing the sterilization dose.

EN11137-3:2006 Sterilization of health care products. Radiation. Guidance on dosimetric aspects.

EN11137-1:2006 Sterilization of medical devices. Microbiological Methods. Determination of a population of microorganisms on products

EN556-1 2001/AC:2006 Sterilization of health care products. Radiation. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.

IEC 61010-1: 2001 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 61010-2-101: 2002 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.

L. Test Principle:

The On Call Sharp Blood Glucose Monitoring System is an amperometric method that uses flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading is displayed, calibrated to plasma reference.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within run precision was performed using five venous blood samples spiked with glucose to achieve higher glucose concentrations and allowed to equilibrate for at least 2 hours before use). The samples tested ranged from 39 to 328 mg/dL. Each sample was tested 10 times on three test strip lots, using 10 meters per test strip lot for

n = 100 per test strip lot. The mean values, standard deviations and coefficients of variation were calculated for each sample and are summarized below.

Within-day precision (whole blood)					
Lot #	Glucose Concentration (mg/dL)	n	Mean (mg/dL)	SD (mg/dL)	CV (%)
1	43	100	42	1.68	4.0
	79	100	78	3.09	4.0
	125	100	127	4.48	3.5
	199	100	199	7.45	3.7
	319	100	320	12.74	4.0
2	40	100	40	1.56	3.9
	78	100	76	2.96	3.9
	124	100	124	4.58	3.7
	199	100	199	7.22	3.6
	328	100	328	12.49	3.8
3	39	100	39	1.69	4.3
	76	100	75	3.00	4.0
	129	100	131	4.94	3.8
	197	100	197	8.78	4.5
	322	100	324	11.55	3.6

The intermediate precision evaluation was performed using three levels of control solutions. A total of 300 strips each from three lots of test strips were used with a minimum of 10 meters, 10 replicates per day, for 10 days. The glucose concentration of each sample was determined using the YSI Glucose Analyzer. The mean values and coefficients of variation were calculated for each sample and are summarized below.

Day-to-day precision (control materials)				
Lot #	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
1	100	44	1.76	4.0
	100	121	4.93	4.1
	100	358	11.39	3.2
2	100	43	1.59	3.7

	100	122	4.91	4.0
	100	349	12.82	3.7
3	100	46	1.71	3.7
	100	122	5.19	4.2
	100	336	12.33	3.7

b. Linearity/assay reportable range:

A linearity study was performed using eleven different levels (10, 25, 50, 80, 110, 170, 220, 330, 450, 550, and 650 mg/dL) of venous whole blood samples supplemented with a glucose stock solution to cover the claimed measuring range from 20 to 600 mg/dL. Four measurements were taken from each glucose level and measured using 3 lots of test strips on a minimum of 2 meters. Linear regression analysis resulted in the equation $y = 1.0409x - 5.2697$ with an $R^2 = 0.9903$. The claimed measuring range is 20 to 600 mg/dL based on the linearity data.

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

Traceability

The glucose control standards are traceable to a NIST SRM 917b^a glucose standard and are prepared at three target concentrations (Level 0 = 51 mg/dL, Level 1 = 125 mg/dL and Level 2 = 330 mg/dL). The reference instrument used is the YSI 2300 Glucose analyzer.

Stability

Accelerated stability study was conducted to assess the shelf-life stability of the control solutions and test strips. Real-time stability studies are still on-going. Stability studies protocols and acceptance criteria were provided and found to be adequate.

Unopened control solutions have a 24 month shelf life and are stable for 1 month after first use when stored at 5 - 30°C (35.6 - 86 °F).

Unopened test strips have a 24 month shelf-life and are stable for 1 month after first use when stored at 5 - 30°C (35.6 - 86°F) at a %RH of 10-90%.

Expected values

The controls are prepared at three target concentrations gravimetrically. The solution is then compared to the NIST standard and then the glucose concentrations are verified with the YSI reference method. The expected values are verified for each new lot of strips.

d. *Detection limit:*

See linearity study above in section 1.b.

e. *Analytical specificity:*

The interference study was designed according to CLSI EP7-A2 guideline. 35 common endogenous and exogenous interfering substances were evaluated by spiking venous blood to three levels of glucose concentrations (50, 100, 350 mg/dL). The glucose samples were then spiked with the potentially interfering compounds (2 concentration including normal or therapeutic levels and high or toxic levels). Two meters were used for this study with 4 strips for each meter. Three lots of test strips were tested for a total of 1152 test strips. 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	Maximum Concentration tested at which no interference is observed (mg/dL)
Acetaminophen	20
Ascorbic Acid	3
Cholesterol	500
Conjugated-Bilirubin	50
Creatinine	5
Dopamine	0.09
Ephedrine	0.5
Ethanol	400
Fructose	100
Galactose	30
Gentistic acid	10
Glutathione	1
Hemoglobin	500
Ibuprofen	50
Lactose	25
L-Dopa (Levo-Dopa)	3
Maltose	200
Mannitol	600
Methyl Dopa	1.5
Salicylic Acid	60
Sorbitol	70
Tetracycline	1.5
Tolazamide	10

Tolbutamide	64
Triglycerides	3000
Unconjugated-Bilirubin	40
Uric Acid	23.5
Urea	600
Xylose	4

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) and xylose > 4 mg/dL. Ascorbic acid levels > 3 mg/dL and xylose > 4 mg/dL will interfere with the glucose reading; therefore, the sponsor has the following limitation in their labeling:

“Ascorbic acid (vitamin C) (when occurring in blood at normal or at high therapeutic concentration) do not significantly affect results. However, abnormally high concentration (> 3 mg/dL) in blood may cause inaccurately high results.”

“Do not use during or soon after xylose absorption testing. Xylose (> 4mg/dL) in the blood will cause interference”

Sodium Fluoride interferes with blood glucose testing in the On Call Sharp Blood Glucose Monitoring System. The sponsor has included the following warning “Never test blood that has been placed in test tubes containing fluoride or other anticoagulants. This will cause falsely low results.”

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The accuracy of the ACON On Call Sharp Blood Glucose Monitoring System was assessed by comparing whole blood glucose results to the YSI. Samples were obtained from 103 different subjects over 29 days. 5 of the 103 subjects’ fingertip samples were also aged to obtain glucose concentrations <50 mg/dL and 5 of the 103 subjects’ fingertip samples were also supplemented with additional glucose to obtain glucose concentrations >400 mg/dL. A total of 3 test strip lots and 36 meters were used. The glucose concentration range of the samples tested was 34 to 592 mg/dL. The data is summarized below:

Fingertip Sample:

System Accuracy Results for Glucose concentration <75mg/dL

Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	9/14 (64.3%)	14/14 (100%)	14/14 (100%)
2	10/14 (71.4%)	14/14 (100%)	14/14 (100%)
3	12/14 (85.7%)	14/14 (100%)	14/14 (100%)
Combined	31/42 (73.8%)	42/42 (100.00%)	42/42 (100%)

System Accuracy Results for Glucose concentration ≥75mg/dL

Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	56/99 (56%)	86/99 (86.9%)	99/99 (100%)	99/99 (100%)
2	55/99 (55.6%)	83/99 (83.8%)	98/99 (100%)	99/99 (100%)
3	61/99 (61.6%)	91/99 (91.9%)	98/99 (100%)	99/99 (100%)
Combined	172/297 (57.9%)	260/297 (87.5%)	295/297 (99.3%)	297/297 (100%)

Palm Sample:

System Accuracy Results for Glucose concentration <75mg/dL

Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	4/9 (44.4%)	8/9 (88.9%)	9/9 (100%)
2	5/9 (55.6%)	9/9 (100%)	9/9 (100%)
3	4/9 (44.4%)	9/9 (100%)	9/9 (100%)
Combined	13/27 (48.1%)	26/27 (96.3%)	27/27 (100%)

System Accuracy Results for Glucose concentration ≥75mg/dL

Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	34/94 (32.2%)	74/94 (78.7%)	94/94 (100%)	94/94 (100%)
2	43/94 (45.7%)	75/94 (79.8%)	93/94 (98.9%)	94/94 (100%)
3	47/94 (50.0%)	79/94 (84.0%)	93/94 (98.9%)	94/94 (100%)
Combined	124/282 (44.0%)	228/282 (80.9%)	280/282 (99.3%)	282/282 (100%)

Forearm Sample:

System Accuracy Results for Glucose concentration <75mg/dL

Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	7/9 (77.8%)	8/9 (88.9%)	9/9 (100%)
2	6/9 (66.7%)	9/9 (100%)	9/9 (100%)
3	8/9 (88.9%)	9/9 (100%)	9/9 (100%)
Combined	21/27 (77.8%)	27/27 (100%)	27/27 (100%)

System Accuracy Results for Glucose concentration ≥75mg/dL

Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	50/94 (53.2%)	82/94 (87.2%)	93/94 (98.9%)	94/94 (100%)
2	39/94 (41.5%)	79/94 (84.0%)	94/94 (100%)	94/94 (100%)
3	45/94 (47.9%)	80/94 (85.1%)	93/94 (98.9%)	94/94 (100%)
Combined	134/282 (47.5%)	241/282 (85.5%)	280/282 (99.3%)	282/282 (100%)

Regression between ACON On Call Sharp Blood Glucose Monitoring System results and the YSI for the capillary blood samples:

Sample Site	Strip Lot	Slope	Intercept	R ²	N
Fingertip	1	1.0265	-4.6214	0.9890	113
Fingertip	2	1.0443	-6.7028	0.9894	113
Fingertip	3	1.0324	-2.5683	0.9933	113
Fingertip	Combined	1.0344	-4.6308	0.9904	
Palm	1	1.0052	-5.7371	0.9784	103
Palm	2	0.9930	-4.2799	0.9795	103
Palm	3	0.9953	-3.2084	0.9821	103
Palm	Combined	0.9978	-4.4084	0.9799	
Forearm	1	1.0613	-8.1484	0.9832	103
Forearm	2	1.0563	-7.8509	0.9817	103
Forearm	3	1.0441	-5.4430	0.9813	103
Forearm	Combined	1.0539	-7.1475	0.982	

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):*

Lay user studies

One hundred and three (103) lay users participated in the study. Three (3) strip lots were tested on 36 meters. Instructions for use were given to each study subject to let the subject 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. 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. Both layperson and technician

performed the testing for each subject sample for the user study. For each study subject, additional fingerstick capillary blood was also collected into microtainer tubes (w/ heparin anticoagulant) for the YSI reference instrument testing and hematocrit level testing. The tested glucose concentration range was from 58 to 392 mg/dL. A questionnaire was given to each study subject for their feedback on the ACON On Call Sharp Blood Glucose Monitoring System.

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	1	1.0407	-6.4065	0.9918	0.9836	103
Layperson	Fingertip	2	1.0208	-4.1204	0.9851	0.9705	103
Layperson	Fingertip	3	1.0623	-6.3760	0.9894	0.9789	103
Layperson	Palm	1	0.9868	-2.8861	0.9899	0.9798	103
Layperson	Palm	2	1.0142	-5.9534	0.9894	0.9788	103
Layperson	Palm	3	0.9957	-1.6720	0.9889	0.9780	103
Layperson	Forearm	1	1.0820	-10.1895	0.9901	0.9803	103
Layperson	Forearm	2	1.0611	-6.8329	0.9906	0.9812	103
Layperson	Forearm	3	1.0648	-5.4734	0.9907	0.9815	103

Combined data from 3 lots for Fingerstick (Layperson vs YSI)

Linear Regression	$y = 1.0413x - 5.6343$			
R ²	0.9770			
<75 mg/dL	Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL	
	20/27 (74.1%)	26/27 (96.3%)	27/27 (100.0%)	
≥75 mg/dL	Within ±5%	Within ±10%	Within ±15%	Within ±20%
	135/282 (47.9%)	229/282 (81.2%)	279/282 (98.9%)	282/282 (100%)

Combined data from 3 lots for

Linear Regression	$y = 0.9989x - 3.5038$
R ²	0.9786

Patient Palm vs YSI 2300

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
12/27 (44.4%)	27/27 (100%)	27/27 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
133/282 (47.2%)	224/282 (79.49%)	278/282 (98.6%)	282/282 (100%)

<u>Combined data from 3 lots for Linear Regression</u>	$y = 1.0693 x - 7.4986$
R2	0.9808

Patient Forearm vs YSI

System accuracy results for glucose concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
20/27 (74.1%)	24/27 (88.9%)	27/27 (100%)	

System accuracy results for glucose concentration ≥ 75 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
132/282 (46.8%)	220/282 (78.0%)	277/282 (98.2%)	282/282 (100%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose values for people without diabetes are as below:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70-100	3.9-5.6
2 Hours after Meals	Less than 140	Less than 7.8

ADA Clinical Practice Recommendations, 2013. Diabetes Care, 2013, Vol.36, Supplement 1, S67-S74.

N. Instrument Name:

ACON On Call Sharp 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.

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

Yes or No

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

Yes or No

2. Software:

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

Yes or No

3. Specimen Identification:

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 fingertip, palm or forearm which is directly applied to the test strip.

5. Calibration:

The device must be coded with the code found on the current test strip label. No further calibration is required.

6. Quality Control:

There are three levels of glucose control solution (Level 0, 1 and 2) that can be run with this device. Level 1 is included with the test kit and Levels 0 and 2 can be purchased separately. Recommendations on when to test the control materials are provided in the

labeling. 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. Hematocrit Study: The effect of different hematocrit levels on the performance of the ACON On Call Sharp BGMS was evaluated using venous whole blood samples with hematocrit levels of 20, 25, 30, 40, 50, 60, 65 and 70% and spiked with glucose to achieve 5 concentrations ranging from 50 to 525 mg/dL (50, 100, 275 and 525 mg/dL). Each sample was then tested 4 times on three different test strip lots and the values were compared with those obtained from YSI reference analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 25 to 70%.

2. Altitude study: Fingerstick capillary blood samples from fifteen subjects were tested on 6 test strips (3 strip lots) on 6 On Call Sharp meters. The sample range tested was 33 to 491 mg/dl for sea level and at 8, 516 ft. Blood glucose target concentrations were then verified by the reference YSI glucose analyzer. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 8, 516 feet have no significant effect on blood glucose measurements from the On Call Sharp Blood Glucose Monitoring System.

3. Sample volume study: The sponsor performed a study to verify the minimum test strip sample volume requirement and the test strip fill error requirement established for the On Call Sharp Blood Glucose Monitoring System. Blood samples were tested at six sample volumes (0.4, 0.6, 0.7, 0.8 and 1.0 μ L) and values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.8 μ L and the error code for insufficient sample volume.

4. Temperature and humidity studies: The sponsor performed temperature and humidity studies using venous blood samples in vacutainer tubes with heparin anticoagulant to evaluate temperatures of 10, 21 and 45°C and relative humidity of 10% to 90%. Meter results were compared to YSI reference analyzer. Six temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, average temperature/low humidity, average temperature/high humidity, high temperature/low humidity and high temperature/high humidity. No significant effect (relative to YSI reference analyzer) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 10 to 45°C with relative humidity of 10 to 90%.

5. Infection Control Studies: The On Call Sharp Blood Glucose Monitoring System is intended for single-patient use. DisCide Ultra Disinfecting Towelettes with EPA registration number 10492-4 were validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 3,285 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC testing was evaluated and certified by TUV Rheinland (Shanghai) Co., LTD and Verification of Compliance reports are provided.

7. Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert, control solution package insert and Quick Reference Guide Insert were written at the 7.4 grade level, 7.5 grade level, 7.0 grade level and 7.2 grade level respectively.

Customer service is available 24 hours a day, 7 days a week by calling 1-800-838-9502,

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.