On·Call® Extra

Blood Glucose Monitoring System

Evaluation Report

October 2014

ACON® Diabetes Care

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Table of Contents

On·Call® Extra

Blood Glucose Monitoring System

1. Introduction

The *On Call® Extra* Blood Glucose Monitoring System (BGMS) is manufactured by ACON Laboratories, Inc.

The system includes a hand-held, battery-operated meter with test strips, glucose control solutions, a lancing device and sterile lancets to measure the glucose concentration in whole capillary blood.

The *On Call® Extra* Blood Glucose Monitoring System is intended for use by patients with diabetes to perform self-monitoring at home.

2. Measurement Principle

The *On Call® Extra* BGMS uses an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood. The blood sample is automatically drawn into the test strip by capillary action where it mixes with chemical reagents initiating a reaction catalyzed by the enzyme Glucose Oxidase. A transient electrical current is generated during the reaction which is detected by the meter and directly related to the blood glucose concentration in the sample.

3. *On Call® Extra* Blood Glucose Monitoring System Specifications

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose oxidase (GOD)
Test Time	4 seconds
Sample Size	0.4 µL
Result Calibration	Plasma-equivalent (Complied with IFCC)
Sample Application	Wicking action, End-fill
Sample Type	Fresh whole blood (Capillary)
Primary Sites	Fingertips
Alternate Sites	Forearm & Palm
Hematocrit Range	25 - 60%
Operating Temp Range	41 – 113 °F (5 – 45 °C)
Operating Humidity Range	10 - 90%
Battery	One (1) 3.0V CR 2032 Lithium coin cell battery
Battery Life	1,000 measurements
Calibration Method	Auto coding
Glucose Test Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Strip Shelf Life	24 months
Open Vial Expiry	6 months
Memory Storage	300 results with time and date
Test Averaging	7, 14, 30, 60, 90-day averages
Data transfer	USB
Control Solution	3 levels
Audio Feature	Optional beep for sample detection, error messages
Automatic Shutoff	2 minutes after last action
Other Functions	Insufficient sample volume detection
	2nd sample application allowed
	Temperature detection
	Meal markers – before & after meals
	Hypo and hyper warnings
	Ketone alert
	Five (5) customizable test reminders
	Test strip ejector on the meter

4. Accuracy Evaluation - Performed By Trained Technicians

4.1. Capillary Whole Blood from Fingertip

4.1.1. Purpose

Studies were conducted to asses the accuracy of the *On Call*® *Extra* Blood Glucose Monitoring System with capillary blood samples.

4.1.2. Procedure

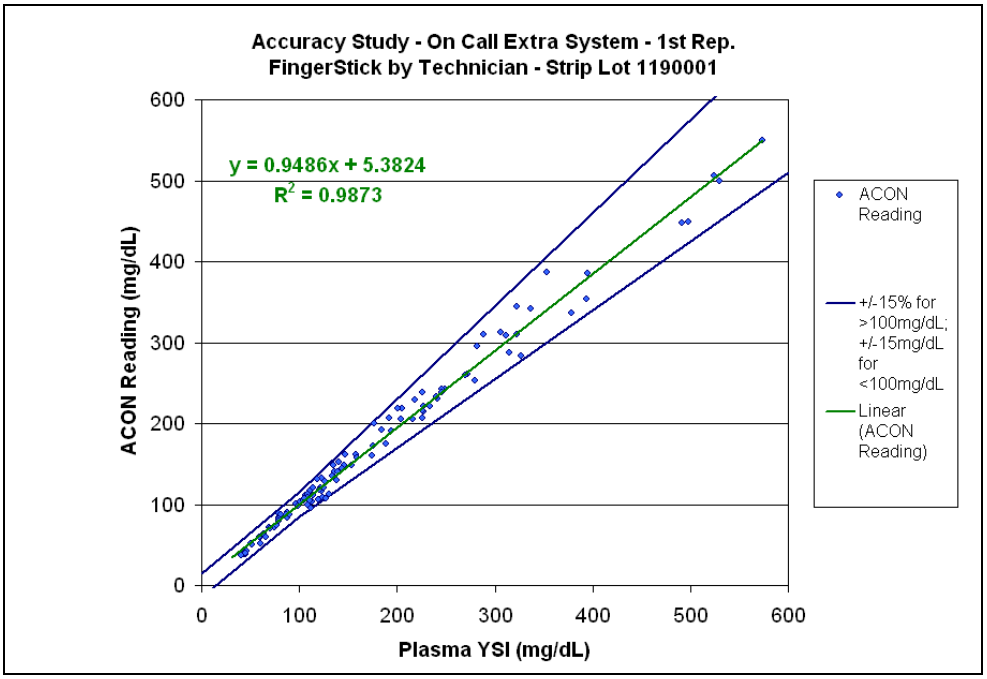
Trained technicians performed capillary fingersticks on study subjects and dosed the test strips. 111 data points from 103 subjects were collected in the study. The tested range of glucose was from 40.9 to 574 mg/dL. Some of the blood samples with very low and very high levels of blood glucose were adjusted by technicians.

The ages of the study subjects ranged from 22 to 85 years old. All the study subjects were well informed about the study and learned instructions for proper of use of the system. Capillary blood samples from all study subjects' fingertips were collected into a microtainer tube (with heparin anticoagulant) and then both whole blood and plasma from each sample were tested in duplicate on the YSI reference instrument (YSI Model 2300 STAT PLUS Glucose Analyzer). The plasma YSI value from fingertip capillary blood sample for each study subject was used for comparison.

4.1.3. Results

Linear regression and system accuracy results for capillary whole blood testing from fingertips are as follows:

Figure 1



Fingertip Sample Meter Result (vs. Plasma YSI with Fingertip sample) - 1st Replicate			
Strip Lot: **1190001**			
System Accuracy Results for Glucose Concentration ≥100 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
42 / 82 (51.2%)	72 / 82 (87.8%)	81 / 82 (98.8%)	82 / 82 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
22 / 29 (75.9%)	29 / 29 (100.0%)	29 / 29 (100.0%)	
System Accuracy Results for both Glucose Concentration ≥100 mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
110 / 111 (99.1%)			

4.1.4. Conclusions

The data displayed above shows equivalent correlation to the reference method, demonstrating that the *On Call*® *Extra* Blood Glucose Monitoring System provides highly accurate results with capillary blood samples from fingertip.

4.2. Alternative Site Testing (AST)

4.2.1. Purpose

To test the results of testing samples from alternative sites using the *On Call® Extra* Blood Glucose Monitoring System

4.2.2. Procedure

There are 103 participants whose forearm blood sample and palm blood sample were tested with the *On Call® Extra* Blood Glucose Monitoring System by technicians. At the same time, the blood samples from the fingertips of the same participants were tested on YSI Model 2300 STAT Plus Glucose Analyzer and converted to the IFCC plasma-like reference values.

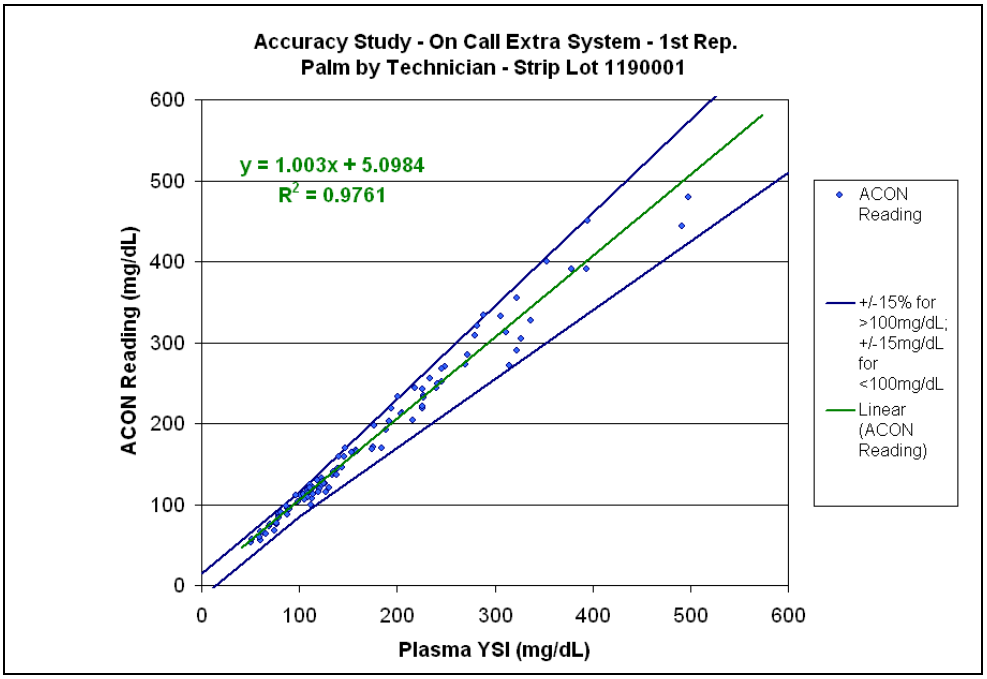
The blood glucose range from fingerstick plasma YSI value ranges from 50.4 to 498 mg/dL.

Patient selection criteria insured that subjects were tested at least 2 hours after or before a meal. All the study subjects were well informed about the study and learned the instructions for proper use of the system.

4.2.3. Results

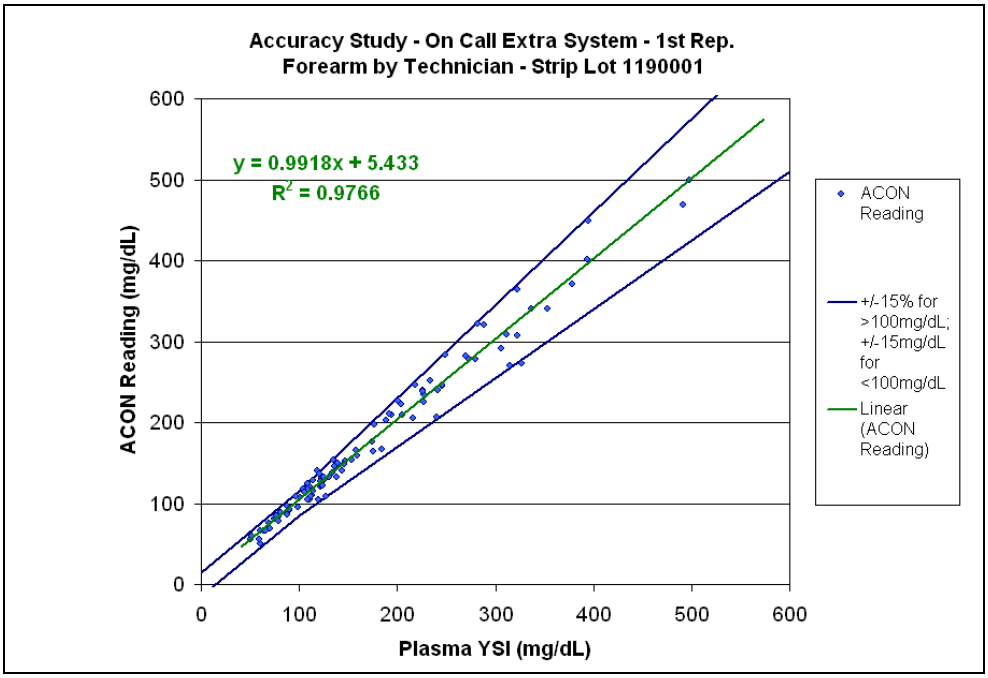
Linear regression and system accuracy results for alternative site tests are as follows:

Figure 2



Palm Sample Meter Result (vs. Plasma YSI with Fingertip sample) - 1st Replicate			
Strip Lot: **1190001**			
System Accuracy Results for Glucose Concentration ≥100 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
38 / 79 (48.1%)	62 / 79 (78.5%)	77 / 79 (97.5%)	79 / 79 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
11 / 24 (45.8%)	22 / 24 (91.7%)	24 / 24 (100.0%)	
System Accuracy Results for both Glucose Concentration ≥100 mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
101 / 103 (98.1%)			

Figure 3



Forearm Sample Meter Result (vs. Plasma YSI with Fingertip sample) - 1st Replicate			
Strip Lot: **1190001**			
System Accuracy Results for Glucose Concentration ≥100 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
39 / 79 (49.4%)	60 / 79 (75.9%)	77 / 79 (97.5%)	79 / 79 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
13 / 24 (54.2%)	23 / 24 (95.8%)	24 / 24 (100.0%)	
System Accuracy Results for both Glucose Concentration ≥100 mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
101 / 103 (98.1%)			

4.2.4. Conclusions

The data above indicates equivalent correlation to the reference method, demonstrating that the *On Call® Extra* Blood Glucose Monitoring System provides highly accurate results with capillary whole blood samples from alternate sites such as the palm and forearm.

5. Accuracy Evaluation for Capillary Whole Blood - Performed by Patients

5.1. Purpose

To test the results from capillary whole blood performed by patients with the *On Call® Extra* Blood Glucose Monitoring System.

5.2. Procedure

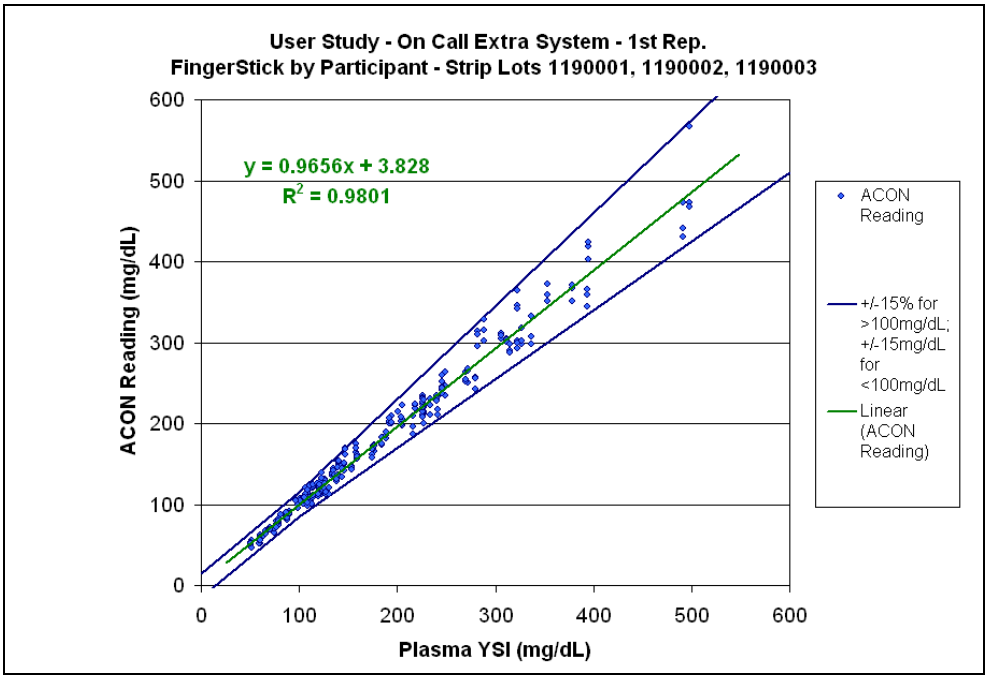
Capillary blood samples from 103 subjects were tested by each subject and also by trained technicians with the *On Call® Extra* Blood Glucose Monitoring System. All the study subjects were well informed about the study and learned the instructions for proper use of the system. The user study included the testing of capillary blood samples from fingertip, palm and forearm sites from each study subject.

Fingertip capillary blood samples from each subject were also collected and tested on the YSI reference instrument (YSI Model 2300 STAT Plus Glucose Analyzer) and later converted to the IFCC plasma-like reference values by technicians for comparison. Three different test strip lots were used during the study. Figure 4 shows the combined test results from all three strip lots for the capillary blood samples collected from the fingertips and tested by the subjects. Figure 5 shows the combined test results from all three strip lots for the capillary blood samples collected from the fingertips and tested by trained technicians.

5.3. Results

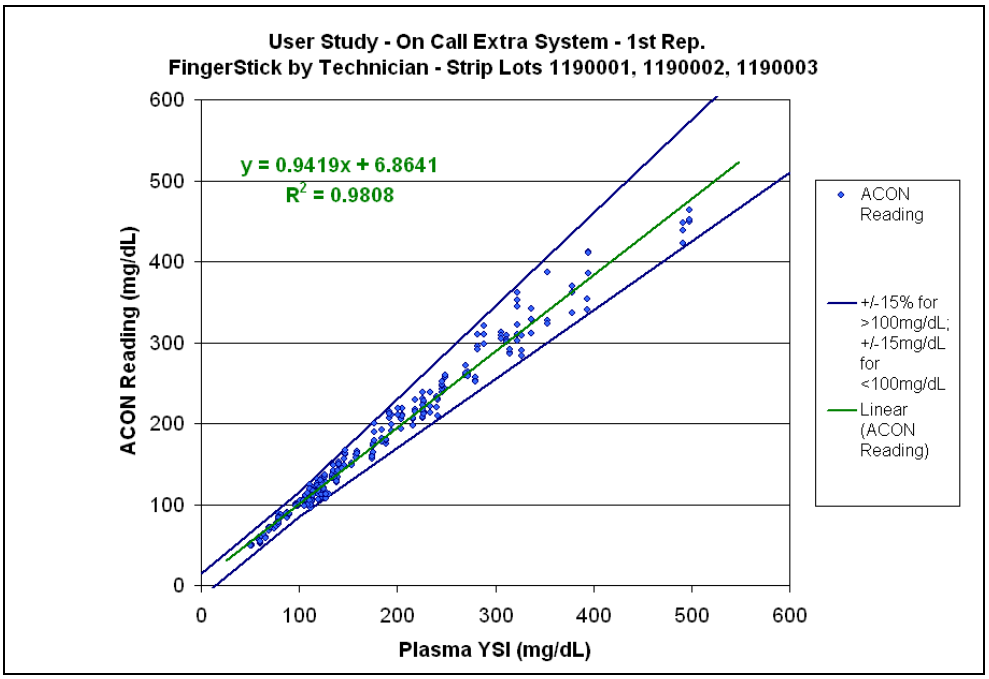
System accuracy results for fingertip capillary whole blood tests performed by patients and technicians are as follows:

Figure 4



Fingertip Sample Site Tested by **Layperson** - 1st Replicate			
Strip Lots: **1190001, 1190002, 1190003**			
System Accuracy Results for Glucose Concentration ≥100 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
120 / 237 (50.6%)	210 / 237 (88.6%)	237 / 237 (100.0%)	237 / 237 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
58 / 72 (80.6%)	71 / 72 (98.6%)	72 / 72 (100.0%)	
System Accuracy Results for both Glucose Concentration ≥100 mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
309 / 309 (100.0%)			

Figure 5



Fingertip Sample Site Tested by **Technician** - 1st Replicate			
Strip Lots: **1190001, 1190002, 1190003**			
System Accuracy Results for Glucose Concentration ≥100 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
126 / 237 (53.2%)	207 / 237 (87.3%)	236 / 237 (99.6%)	237 / 237 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
59 / 72 (81.9%)	72 / 72 (100.0%)	72 / 72 (100.0%)	
System Accuracy Results for both Glucose Concentration ≥100 mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
308 / 309 (99.7%)			

5.4. Conclusions

The results indicate that a layperson can obtain accurate results when testing with capillary whole blood.

6. Repeatability Precision

6.1. Purpose

The purpose of this study is to validate the repeatability precision for the *On Call® Extra* Blood Glucose Monitoring System.

6.2. Procedure

For this study, technicians obtained venous whole blood samples in vacutainer tubes containing heparin anticoagulant. The blood sample hematocrit level was prepared to 42% ± 2%. Generally, a minimum of 3 lots containing 10 meters and 500 test strips each are needed for repeatability precision evaluations, which was also used in this evaluation. Blood samples are then tested using 10 test strips on 10 separate meters (10 strips per meter) at each glucose concentration level.

6.3. Results

6.3.1. The table below indicates the 5 levels of venous blood glucose concentration used for the study.

Glucose Concentration Levels for Repeatability Precision Evaluation

Level	Glucose Concentration Level (mg/dL)
1	30 – 50 mg/dL
2	51 – 110 mg/dL
3	111 – 150 mg/dL
4	151 – 250 mg/dL
5	251 – 400 mg/dL

6.3.2. The table below shows the results of precision testing of venous blood. Results having values lower than 100 mg/dL must have standard deviations (SD) ≤ 5 mg/dL per glucose concentration level. For results greater than 100 mg/dL, accepted values must have a coefficient of variance (CV) less than 5%.

Repeatability Precision with Whole Blood

Mean (mg/dL)	43.7	85.9	130	189	312
SD or CV	1.49 mg/dL	2.60 mg/dL	2.9%	2.4%	3.2%

6.4. Conclusions

The study results obtained indicate that the precision estimates fall within the accepted criteria specifications. In fact, the CV was calculated to be ≤ 3.2%, sustaining that the *On Call® Extra* Blood Glucose Monitoring System provides precise results with whole blood.

7. Intermediate Precision

7.1. Purpose

The purpose of this study is to validate the intermediate precision for the *On Call*® *Extra* Blood Glucose Monitoring System.

7.2. Procedure

For this study, ten replicate assays drawn from 3 test strip lots were performed on 10 *On Call*® *Extra* blood glucose meters each day, for a total of 10 days. Control solutions at 3 concentration levels were used in the study.

7.3. Results

The results indicate the following intermediate precision:

Intermediate Precision with Control Solution

#	Mean (mg/dL)	SD (mg/dL) or CV
Test Strip lot #1	41.8	1.52 (SD)
	122	2.7%
	332	3.9%
Test Strip lot #2	41.0	1.31 (SD)
	118	2.8%
	332	2.2%
Test Strip lot #3	40.0	1.26 (SD)
	116	2.4%
	332	3.5%

7.4. Conclusions

The accepted performance for glucose results lower than 100 mg/dL is a standard deviation (SD) of ≤ 5 mg/dL per glucose concentration level. For glucose results greater than 100 mg/dL a coefficient of variance (CV) ≤ 5% is required. The study results indicated that the precision meets the criteria specifications. In fact, the CV is less than or equal to 3.9%, suggesting that the *On Call*® *Extra* Blood Glucose Monitoring System provides precise results with control solutions.

8. Effect of Hematocrit

8.1. Purpose

Hematrocrit influence was assessed through testing of venous blood samples with heparin anticoagulant.

8.2. Procedure

Samples were tested at 4 levels of glucose concentrations (45 mg/dL, 110 mg/dL, 290 mg/dL and 525 mg/dL) with hematocrit contrived to 25%, 30%, 35%, 42%, 50%, 55% and 60%. Ten tests were done on meters at each hematocrit level and for each glucose concentration, using 3 test strip lots. The average reading was then compared with the converted plasma-like value from YSI Model 2300 STAT Plus Glucose Analyzer.

8.3. Results

The table below shows the average bias of results from one test strip lot at 4 blood glucose concentrations, and 7 differing hematocrit levels.

Bias at different level of blood glucose concentrations with different Hematocrit (Hct)

Test Strip lot #1

Glucose level (mg/dL)	45	110	290	525
Bias with Hct 25%	-0.9 mg/dL	6.1%	7.9%	7.8%
Bias with Hct 30%	-0.4 mg/dL	4.5%	6.9%	6.1%
Bias with Hct 35%	-2.3 mg/dL	1.5%	4.5%	4.5%
Bias with Hct 42%	0.0 mg/dL	-1.7%	2.9%	3.1%
Bias with Hct 50%	1.3 mg/dL	-4.5%	-1.4%	-2.6%
Bias with Hct 55%	-2.3 mg/dL	-5.4%	-3.9%	-4.0%
Bias with Hct 60%	-1.8 mg/dL	-6.0%	-5.3%	-4.4%

8.4. Conclusions

8.4.1. Acceptance criteria require the Average % Bias (average strip reading vs. plasma YSI value) be within ± 10% for all glucose concentrations, and the % Bias (individual strip reading vs Plasma YSI value) for each individual data point to be within ± 15%.

8.4.2. The study results indicated that there is very little effect on reported results or precision over the claimed hematocrit range of 25 – 60%. This suggests that accurate readings can be obtained from the *On Call*® *Extra* Blood Glucose Monitoring System when testing blood samples within the hematocrit range of 25 – 60%.

9. Effect of Interfering Substances

9.1. Purpose

The purpose of this study is to validate the interference effect of various substances for the *On Call® Extra* Blood Glucose Monitoring System.

9.2. Procedure

For this study, technicians obtained venous whole blood samples in vacutainer tubes containing heparin anticoagulant. The blood sample hematocrit level was prepared to 42% ± 2%, and then the three blood glucose concentrations shown in the table below were prepared and tested by YSI..

Glucose Concentration Levels for Interference Effect Validation

Level	Glucose Concentration Level (mg/dL)
1	50 – 60 mg/dL
2	100 – 120 mg/dL
3	300 – 350 mg/dL

Blood samples containing each interfering substance from the table below were prepared at the low test concentration and high test concentration for each glucose concentration level above. Control samples were prepared using the same solvent without the substance.

Ten test strips from each of 3 strip lots were tested on meters for each interfering substance test level at each glucose concentration level.

9.3. Results

Summary Table

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Extra* System
		Low	High	
Acetaminophen	1.0-3.0 mg/dL	4 mg/dL	20 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
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
Cholesterol	114-300 mg/dL	250 mg/dL	500 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call*® *Extra* System
		Low	High	
Conjugated Bilirubin	<0.4 mg/dL	34 mg/dL	50 mg/dL	NO INTERFERENCE at 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
Ethanol	100-200 mg/dL	200 mg/dL	400 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Fructose	1-6 mg/dL	30 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Galactose	4-80 mg/dL	78 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Hemoglobin	100-200 mg/dL	200 mg/dL	500 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
Lactose	0.5 mg/dL	5 mg/dL	25 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
L-Dopa (Levo-Dopa)	0.02-0.3 mg/dL	0.3 mg/dL	3 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Maltose	100 mg/dL	40 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Mannitol	0.0128 mg/dL	300 mg/dL	600 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

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call*® *Extra* System
		Low	High	
Salicylic Acid	10-30 mg/dL	30 mg/dL	60 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Sorbitol	0.044mg/dL	30 mg/dL	70 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
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
Tolbutamide	5.4-10.8 mg/dL	11 mg/dL	64 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Triglycerides	150-500 mg/dL	1500 mg/dL	3000 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Unconjugated Bilirubin	0.3-1.3 mg/dL	20 mg/dL	40 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Uric Acid	2.5-8.0 mg/dL	8 mg/dL	23.5 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Xylose	20-40 mg/dL	90 mg/dL	200 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Urea	6.6-85.8 mg/dL	260 mg/dL	600 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Ephedrine	0.001 mg/dL	0.1 mg/dL	0.5 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Gentisic acid	0.2-0.6 mg/dL	6 mg/dL	10 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Glutathione	47-100 mg/dL (Intracellular)	0.1 mg/dL	0.5 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Extra* System
		Low	High	
Heparin Sodium	350-1000 u/L	3000 u/L	80000 u/L	NO INTERFERENCE at therapeutic levels up to high test concentration
EDTA	180 mg/dL	180 mg/dL	360 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration

9.4. Conclusions

The results show that there is no significant interference effect for these substances on the *On Call® Extra* Blood Glucose Monitoring System except at abnormally high concentrations of Ascorbic Acid (Vitamin C).

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 14 06 80997 008

Manufacturer:
ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego CA 92121
USA

EC-Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies):
In Vitro diagnostic for self testing and List B products as specified in the attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1474304

Valid from: 2014-08-26
Valid until: 2017-09-12

636158

Date, 2014-08-27

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 14 06 80997 008

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call EZ Blood Glucose Monitoring System,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call XP Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Monitoring System,
On Call Resolve Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Monitoring System,
On Call Simple Blood Glucose Monitoring System (OGM-111),
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Pal Blood Glucose
Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call GK Dual Blood Glucose &
Ketone Monitoring System (OGM-161),
TESTAmed GlucoCheckPlus
Blood Glucose Monitoring System,
D-ONE Blood Glucose Monitoring System
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit, Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit, Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit, CMV IgM EIA Test Kit,
Total PSA EIA Test Kit,
PT Coagulation Monitoring System (CCM-121),
Cholesterol Monitoring System (CCM-111),
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices

Facility(ies):

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 14 06 80997 008

Supplement 001 dated 2014-08-26

Product Service

For the product(s)/product category (ies):

List B Product:

Human infections: cytomegalovirus, Rubella, Toxoplasma

Tumoral marker: PSA

Blood glucose measuring system for self testing

Device for self testing - Clinical chemistry

Device for self testing - Haematology

Munich, CRT2, 2014-08-27

Hans-Heiner Junker
Certification Medical Technology

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

September 25, 2014

Acon Laboratories, Inc.
c/o Saurabh Jamkhindikar, Regulatory Affairs Specialist
10125 Mesa Rim Road
San Diego, CA 92121 US

Document No: CR140306
Parent(s): k132086
Received: August 6, 2014

Categorization Notification (Waived)

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your companyï¿½s name or if a distributorï¿½s name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you have any questions regarding this complexity categorization, please contact Katherine Serrano at 301-796-6652.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

ATTACHMENT

Parent Number : k132086

Test System : ACON Laboratories, Inc., On Call Extra Blood Glucose Monitoring System
Analyte : Glucose monitoring devices (FDA cleared/home use)
Complexity : WAIVED

Product Service

Choose certainty.
Add value.

To whom it may concern

TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich hereby states that the

On Call® Extra Blood Glucose Monitoring System
(including meter, strips and control solutions)

marketed by the legal manufacturer

Acon Laboratories, Inc.
10125 Mesa Rim Road
San Diego CA 92121
USA

fulfils the requirements of ISO 15197:2013 (subclause 6.3 System Accuracy). All other parts of the standard were not subject to the assessment. The evaluation is based on documents provided by the manufacturer for assessment.

The results of the review are summarized in the corresponding Assessment Result Report (Order No. 713048038-04).

Munich, 2014-12-04

MÜNCHEN TÜV SÜD PRODUCT SERVICE

Dr. Ulrich Aldinger
Product Specialist In-vitro Diagnostics
PS-IVD-MUC

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Product Specialist In-vitro Diagnostics
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