STATEMENT

We, ACON Laboratories, Inc. having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* assign SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*, as authorized representative in correspondence with the conditions of directive 98/79/EC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This authorization will be valid for one year after the date of this statement.

Date: June 1, 2021

Signature: 

Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

Digitally signed by Monastîrschii Viorica
Date: 2022.09.09 09:59:21 EEST
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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 104507 0003 Rev. 01

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

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.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-12

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
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TÜV SÜD 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 104507 0003 Rev. 01

Model(s): **For Detail Models see attachment**

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

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

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

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Product Service

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(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

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

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
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,

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TÜV®

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Product Service

EC Certificate

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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 104507 0003 Rev. 01

CMV IgM EIA Test Kit,

Total PSA EIA Test Kit,

PT Coagulation Monitoring System (CCM-121),

PT Coagulation Test Strips (CCS-121),

Cholesterol Monitoring System (CCM-111),

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,

Cholesterol Monitoring System (CCM-101),

CHOL Total Cholesterol Test Strips (CCS-101),

PT/INR Monitoring System (CCM-151),

PT/INR Test Strips (CCS-151),

Hemoglobin Testing System (CCM-141),

Hemoglobin Test Strips (CCS-141),

hCG Pregnancy Rapid Test Cassette (Urine),

Pregnancy Rapid Test Midstream,

On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)

On Call Sure Blood Glucose Monitoring System (OGM-211)

On Call Sure Sync Blood Glucose Monitoring System (OGM-212)

On Call Sure Blood Glucose Test Strips (OGS-211)

On Call GU Dual Blood Glucose & Uric Acid Monitoring System (OGM-201)

On Call Blood Uric Acid Test Strips (OGS-201)

LH Ovulation Rapid Test Cassette (Urine)

Ovulation Rapid Test Midstream

Ovulation & Pregnancy Test Combo Pack

On Call Extra Voice Blood Glucose Monitoring System (OGM-291)

Early Detection Pregnancy Test

Digital Pregnancy Test

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ACON Laboratories, Inc.
10125 Mesa Rim Road. · San Diego, CA 92121 · USA
Tel: (858) 875-8000 · Fax: (858) 875-8099 · E-mail: info@aconlabs.com

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
jalvarenga@aconlabs.com
+1 858 875 8085

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121 USA

We, the manufacturer, declare under our sole responsibility that the medical device:

Mission® Lancets (C121-3041)
On Call® Lancets (G124-10A)
Insight® Lancets (C121-3045)
Swiss Point of Care Lancets (G124-90AA)

of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,

meets all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC concerning medical devices which apply to it.

This declaration is according to Annex II of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. G1 104507 0002 Rev. 01
Expiration Date: 2023-09-06

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 17 day of August, 2021
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

We, the manufacturer, under compliance to Article 19 of EU MDR 2017/745, declare under our sole responsibility that the medical device:

Mission® Lancing Device (C121-3051)
Insight® Lancing Device (C121-3055)
On Call® Lancing Device (G124-11A)
On Call® GenTouch Lancing Device (G124-17A)
Swiss Point of Care Lancing Device (G124-91AA)
GIMA Lancing Device (G124-91AC)
Go-Keto Lancing Device (G124-97AA)

of class I according to Rule 13 of Annex VIII of regulation (EU) 2017/745,

is in conformity with EU MDR 2017/745.

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 8260799999900013V

Intended Purpose of device: The device is intended for injuring the fingertip in combination with a disposable lancet for obtaining a small amount of blood sample.

Signed this 18 day of May 2022
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Letter of Declaration

To whom it may concern:

We ***Acon Laboratories,Inc.***, who is the legal manufacturer of Blood Glucose Monitoring System (Including Glucose Meter, Glucose test strip, Control Solution, Lancet and lancing device etc, to test the glucose level of human blood),have registered office at 10125 Mesa Rim Road, San Diego, CA 92121 USA, here to declare that:

- ***On Call® Plus Strips*** correspond with ***On Call® Plus*** Blood Glucose Monitoring System.

- We currently have in stock the tender required quantity of Meters, Strips and Lancets (1000/50000/50000).

This clarification letter will only be used for product registration, tender submission, sales and marketing of ***On Call® Plus*** Blood Glucose Monitoring System in **Moldova** it should not be used for any other business or non-business purposes.

Sincerely yours,

Eddie.Shi
International Sales & Marketing Sales Manager
Diabetes Care
Acon Laboratories,Inc.

On·Call® Plus

Blood Glucose Monitoring System

Specification

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose oxidase (GOD)
Result Calibration	Plasma-equivalent
Test Time	10 seconds
Sample Size	0.5 µL
Sample Type	Fresh capillary whole blood
Hematocrit Range	25 - 60%
Glucose Test Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Memory Storage	300 results with date and time
Test Averaging	7, 14, 30-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
Battery	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 measurements
Operating Conditions	41 - 113 °F (5 - 45°C) and 10 - 90% relative humidity
Strip Storage Temperature	2-35°C
Expiration Date	24 months (6 months after first opening)

Catalog

Product Name	Catalog No.	Contents
On Call® Plus Blood Glucose Monitoring System	G113-111 √ †	1 Meter, 10 Test Strips, 1 Control Solution 1, 1 Lancing Device, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 1 Warranty Card, 10 Lancets, 1 Code Chip, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Meter	G113-211 √ †	1 Meter, 1 Control Solution 1, 1 Carrying Case, 1 Manual, 1 Warranty Card, 1 Quick Reference Guide
	G113-214 √	1 Meter, 1 Lancing Device, 1 Control Solution 1, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 10 Lancets, 1 Warranty Card, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Test Strips	G133-111 √ †	50 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	50 Test Strips (50/vial), 1 Code Chip, 1 Package Insert	
	G133-112 √	100 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	G133-114 √	10 Test Strips (10/vial), 1 Code Chip, 1 Package Insert
	G133-115 √	25 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-117 √	50 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-118 √	25 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Test Strips and Lancets	G133-211 √	50 Test Strips (25/vial), 50 Lancets (25/bag), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Control Solution	G123-311 √†	1 Control Solution 0, 1 Control Solution 1, 1 Control Solution 2, 1 Package Insert
On Call® Lancets	G124-10A √†	100 Lancets (25/bag)
On Call® Lancing Device	G124-11A√	1 Lancing Device, 1 Package Insert
On Call® Diabetes Management Software Kit	G124-13A†	1 USB Data Transfer Cable, 1 Installation Disk

√ CE Marked for sale in the European Community CE 0123 † US 510(k) Cleared and CLIA Waived

ACON®

***ACON* Laboratories, Inc.**, 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com

Please visit our website for details: www.acondiabetescare.com

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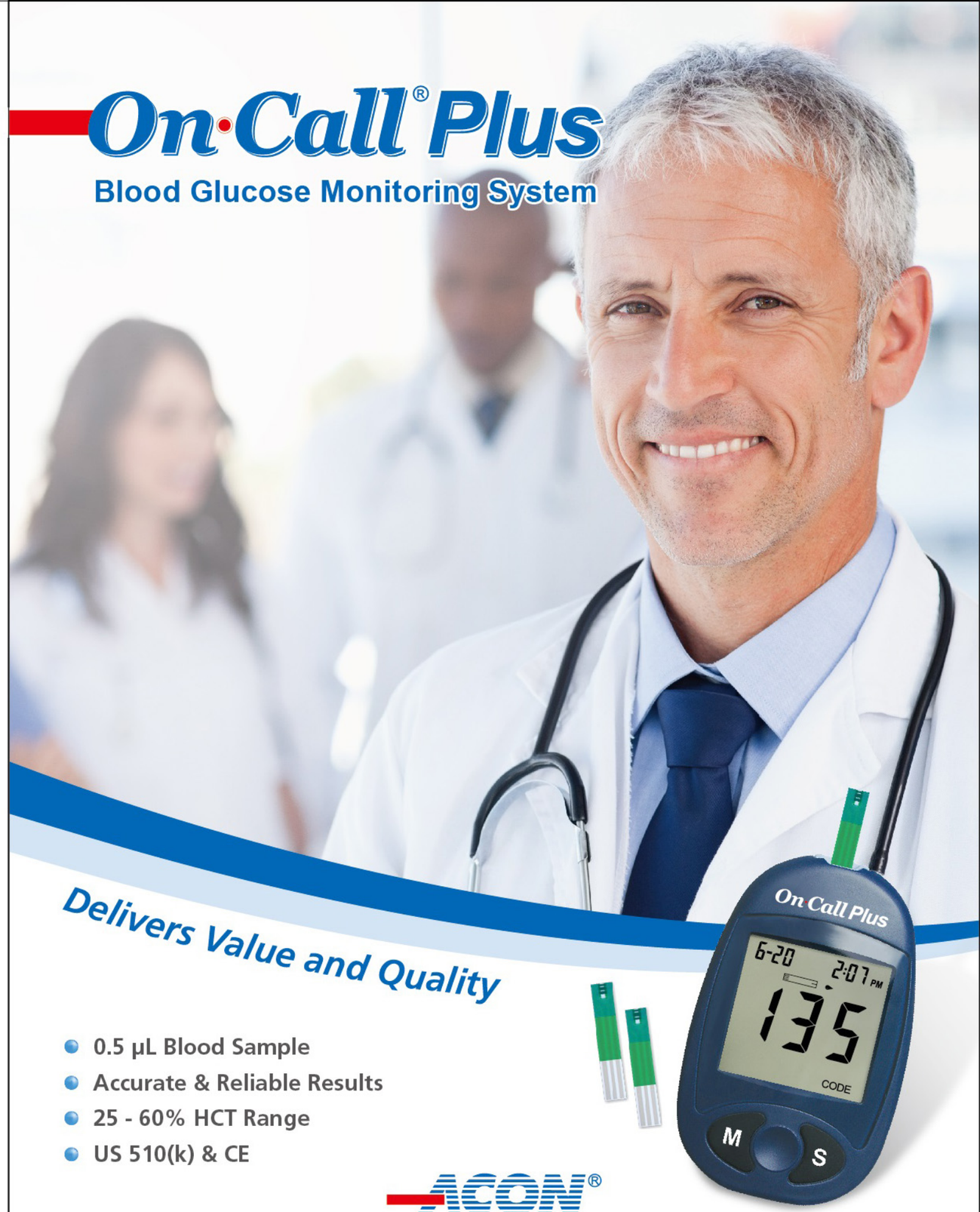
On·Call® Plus

Blood Glucose Monitoring System



Delivers Value and Quality

- 0.5 µL Blood Sample
- Accurate & Reliable Results
- 25 - 60% HCT Range
- US 510(k) & CE

ACON®

Diabetes Care

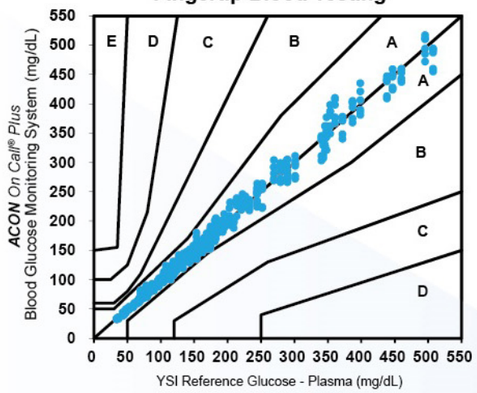
On·Call® Plus

Blood Glucose Monitoring System

Accurate and Reliable

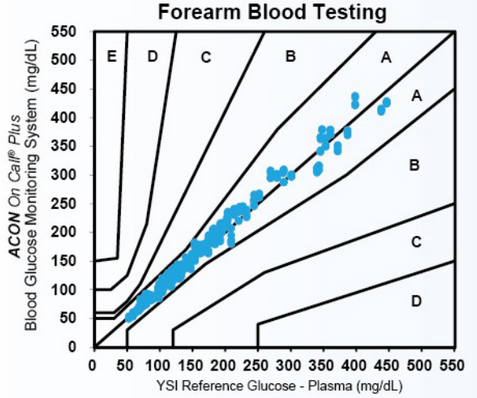
Extensive clinical studies proved the accuracy of *On Call® Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with **EN ISO 15197: 2015**.

Fingertip Blood Testing



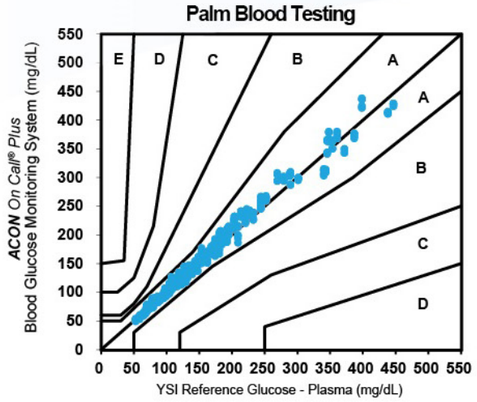
Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
145 / 198 (73.2%)	193 / 198 (97.5%)	198 / 198 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
658 / 660 (99.7%)		

Forearm Blood Testing



Consensus Error Grid Analysis Clinical Trial - Forearm Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ± 5%	Within ± 10%	Within ± 15%
202 / 444 (45.5%)	375 / 444 (84.5%)	440 / 444 (99.1%)
System Accuracy Results for Glucose Concentration <100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
110 / 168 (65.5%)	154 / 168 (91.7%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
608 / 612 (99.3%)		

Palm Blood Testing



Consensus Error Grid Analysis Clinical Trial - Palm Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
219 / 444 (49.3%)	395 / 444 (89.0%)	441 / 444 (99.3%)
System Accuracy Results for Glucose Concentration < 100 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
130 / 168 (77.4%)	166 / 168 (98.8%)	168 / 168 (100.0%)
System Accuracy Results for both Glucose Concentration ≥ 100 mg/dL and < 100 mg/dL		
Within ±15% or ±15 mg/dL		
609 / 612 (99.5%)		

On·Call® Plus

Blood Glucose Monitoring System

Key Features

- 0.5 µL blood sample
- HCT 25 - 60% HCT range
- 2 - 35°C strip storage temperature
- Optional individually packaged test strips available
- Alternative testing sites including fingertip, forearm and palm
- Automatic detection of insufficient sample
- 300 test memory with date and time
- 7, 14, 30 - day averages calculation
- Easy PC data transfer and smart App data analysis

Authority Certificate

CE certificate

USFDA CFG certificate

Health Canada certificate