



## STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: January 3, 2023

Signature:

A handwritten signature in black ink, appearing to read "Xie", is written over a horizontal line.

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



# Certificate

No. Q5 104507 0001 Rev. 03

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_104507_0001_Rev._03)

**Report No.:** SH22743A01

**Valid from:** 2022-09-15  
**Valid until:** 2025-09-06

**Date,** 2022-09-15



Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 104507 0001 Rev. 03

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):**

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

Address holder for registration only

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

Manufacture and distribution of  
In Vitro Diagnostic Test Kits and Reagents for the Determination of  
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,  
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose  
Monitoring System, Lancing Devices and Lancets

**ACON Laboratories, Inc.**  
**6865 Flanders Dr., Suite B, San Diego CA 92121, USA**

Storage of  
In Vitro Diagnostic Test Kits and Reagents for the Determination of  
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,  
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose  
Monitoring System, Lancing Devices and Lancets

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

Design and Development of  
In Vitro Diagnostic Test Kits and Reagents for the Determination of  
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,  
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose  
Monitoring System, Lancing Devices and Lancets

**Acon Laboratories Inc.**  
**Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644**  
**Tijuana B.C. CP, MEXICO**

Manufacture of  
blood glucose test strips, antigen rapid test and IgG/IgM antibody  
rapid test for infectious disease.



# 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. 06**

**Manufacturer:**

**ACON Laboratories, Inc.**

5850 Oberlin Drive, #340  
San Diego CA 92121  
USA

**Product Category(ies): Blood glucose measuring systems for self testing  
and 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1\\_104507\\_0003\\_Rev.06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

**Report no.:** SH22743EXT01

**Valid from:** 2022-05-04

**Valid until:** 2025-05-26

**Date,** 2022-05-04

Christoph Dicks  
Head of Certification/Notified Body



# 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. 06**

## Model(s):

On Call Plus Blood Glucose Monitoring System,  
On Call Plus Blood Glucose Test Strips,  
On Call EZ II Blood Glucose Monitoring System,  
On Call Advanced Blood Glucose Monitoring System,  
On Call Advanced Blood Glucose Test Strips,  
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 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),  
Urinalysis Reagent Strips (Urine),  
UTI Urinary Tract Infection Test Strips,  
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),  
GIMA Blood Glucose Monitoring System,  
GIMA Bluetooth Blood Glucose Monitoring System,  
GIMA Blood Glucose Test Strips,  
On Call GU Dual Blood Glucose & Uric Acid Monitoring



# 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. 06**

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,  
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-  
161),  
Go-Keto Blood Ketone Test Strips (OGS-161),  
Go-Keto Blood Glucose Test Strips,  
On Call Extra GM Blood Glucose Monitoring System(OGM-  
191),  
On Call Extra GM Blood Glucose Test Strips (OGS-191),  
On Call Plus GM Blood Glucose Monitoring System,  
On Call Plus GM Blood Glucose Test Strips,  
Go-Keto Urinalysis Reagent Strips

## 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

Acon Laboratories Inc.  
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana  
B.C. CP, MEXICO

# 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  
in vitro diagnostic device:**

| Device Name                                   | REF Number                                                                     |
|-----------------------------------------------|--------------------------------------------------------------------------------|
| On Call® Plus Blood Glucose Monitoring System | G113-111                                                                       |
| On Call® Plus Blood Glucose Meter             | G113-211, G113-214                                                             |
| On Call® Plus Blood Glucose Test Strips       | G133-111, G133-112, G133-114, G133-115, G133-117, G133-118, G133-119, G133-211 |
| On Call® Plus Glucose Control Solution        | G123-311                                                                       |

**classified for Annex II List B of the directive 98/79/EC,  
meets all the provisions of the directive 98/79/EC on *in vitro*  
diagnostic medical devices which apply to it**

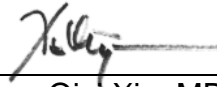
**The declaration according to Annex IV of the Directive  
is based on approval by the notified body  
TÜV SÜD Product Service GmbH,  
Ridlerstraße 65,  
80339 MÜNCHEN, Germany,  
notified under No. 0123 to the EC Commission**

This declaration is valid until expiration of EC Certificate  
No. V1 104507 0003 Rev. 06  
Expiration Date: 2025-05-26

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



Signed this 25 day of May, 2022  
in San Diego, CA USA



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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](mailto:info@aconlabs.com)



**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)              |

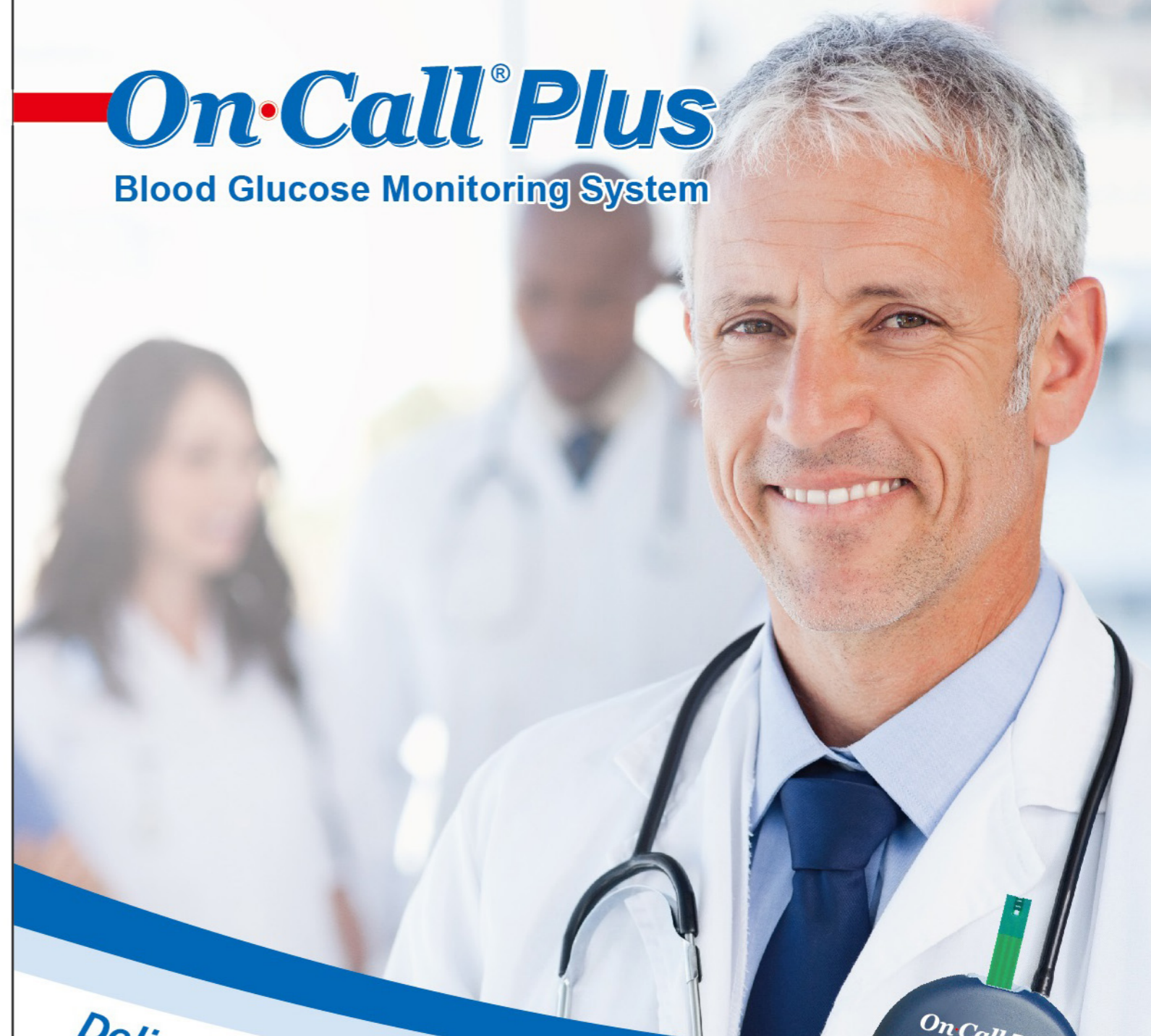
**Catalog**

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

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



**On-Call<sup>®</sup> Plus**  
Blood Glucose Monitoring System



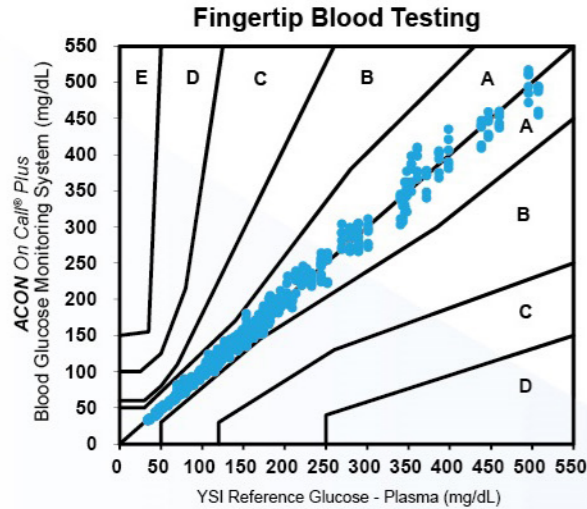
*Delivers Value and Quality*

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

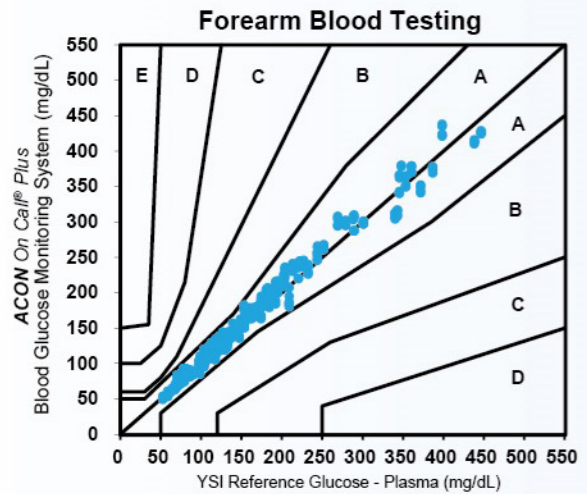


**Accurate and Reliable**

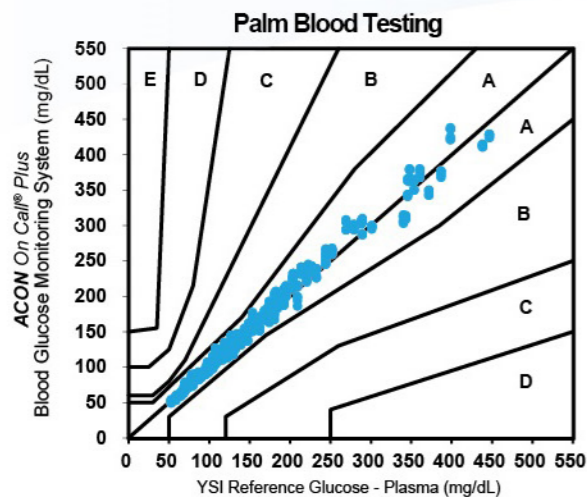
Extensive clinical studies proved the accuracy of *On Call Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



| Consensus Error Grid Analysis<br>Clinical Trial - Fingertip Capillary Blood, by Technican<br>ACON On Call Plus Blood Glucose Monitoring System vs. YSI |                       |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| <b>System Accuracy Results for Glucose Concentration <math>\geq 100</math> mg/dL</b>                                                                   |                       |                       |
| Within $\pm 5\%$                                                                                                                                       | Within $\pm 10\%$     | Within $\pm 15\%$     |
| 290 / 462 (62.8%)                                                                                                                                      | 432 / 462 (93.5%)     | 462 / 462 (100.0%)    |
| <b>System Accuracy Results for Glucose Concentration <math>&lt; 100</math> mg/dL</b>                                                                   |                       |                       |
| Within $\pm 5$ mg/dL                                                                                                                                   | Within $\pm 10$ mg/dL | Within $\pm 15$ mg/dL |
| 145 / 198 (73.2%)                                                                                                                                      | 193 / 198 (97.5%)     | 198 / 198 (100.0%)    |
| <b>System Accuracy Results for both Glucose Concentration <math>\geq 100</math> mg/dL and <math>&lt; 100</math> mg/dL</b>                              |                       |                       |
| Within $\pm 15\%$ or $\pm 15$ mg/dL                                                                                                                    |                       |                       |
| 658 / 660 (99.7%)                                                                                                                                      |                       |                       |



| Consensus Error Grid Analysis<br>Clinical Trial - Forearm Capillary Blood, by Technican<br>ACON On Call Plus Blood Glucose Monitoring System vs. YSI |                       |                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| <b>System Accuracy Results for Glucose Concentration <math>\geq 100</math> mg/dL</b>                                                                 |                       |                       |
| Within $\pm 5\%$                                                                                                                                     | Within $\pm 10\%$     | Within $\pm 15\%$     |
| 202 / 444 (45.5%)                                                                                                                                    | 375 / 444 (84.5%)     | 440 / 444 (99.1%)     |
| <b>System Accuracy Results for Glucose Concentration <math>&lt; 100</math> mg/dL</b>                                                                 |                       |                       |
| Within $\pm 5$ mg/dL                                                                                                                                 | Within $\pm 10$ mg/dL | Within $\pm 15$ mg/dL |
| 110 / 168 (65.5%)                                                                                                                                    | 154 / 168 (91.7%)     | 168 / 168 (100.0%)    |
| <b>System Accuracy Results for both Glucose Concentration <math>\geq 100</math> mg/dL and <math>&lt; 100</math> mg/dL</b>                            |                       |                       |
| Within $\pm 15\%$ or $\pm 15$ mg/dL                                                                                                                  |                       |                       |
| 608 / 612 (99.3%)                                                                                                                                    |                       |                       |



| Consensus Error Grid Analysis<br>Clinical Trial - Palm Capillary Blood, by Technican<br>ACON On Call Plus Blood Glucose Monitoring System vs. YSI |                       |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------|
| <b>System Accuracy Results for Glucose Concentration <math>\geq 100</math> mg/dL</b>                                                              |                       |                       |
| Within $\pm 5\%$                                                                                                                                  | Within $\pm 10\%$     | Within $\pm 15\%$     |
| 219 / 444 (49.3%)                                                                                                                                 | 395 / 444 (89.0%)     | 441 / 444 (99.3%)     |
| <b>System Accuracy Results for Glucose Concentration <math>&lt; 100</math> mg/dL</b>                                                              |                       |                       |
| Within $\pm 5$ mg/dL                                                                                                                              | Within $\pm 10$ mg/dL | Within $\pm 15$ mg/dL |
| 130 / 168 (77.4%)                                                                                                                                 | 166 / 168 (98.8%)     | 168 / 168 (100.0%)    |
| <b>System Accuracy Results for both Glucose Concentration <math>\geq 100</math> mg/dL and <math>&lt; 100</math> mg/dL</b>                         |                       |                       |
| Within $\pm 15\%$ or $\pm 15$ mg/dL                                                                                                               |                       |                       |
| 609 / 612 (99.5%)                                                                                                                                 |                       |                       |

**Key Features**

- 0.5  $\mu$ L 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