



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



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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**

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

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

TÜV®





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Product Service

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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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ZLG-BS-244.10.08



Product Service

## EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 104507 0002 Rev. 01**

**Manufacturer:**

**ACON Laboratories, Inc.**

5850 Oberlin Drive, #340

San Diego CA 92121

USA

**Product Category(ies): Lancets, Safety Lancets**

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 categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

SH1974310

**Valid from:**

2019-10-24

**Valid until:**

2023-09-06

**Date,**

2019-10-24

Stefan Preiß

Head of Certification/Notified Body



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Product Service

## EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 104507 0002 Rev. 01**

### 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



# 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.**





Product Service

# Certificate

No. Q5 104507 0001 Rev. 01

**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). See also notes overleaf.

**Report No.:** SH1974310

**Valid from:** 2019-10-24

**Valid until:** 2022-09-06

**Date,** 2019-10-24

Stefan Preiß  
Head of Certification/Notified Body



# Certificate

No. Q5 104507 0001 Rev. 01

**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  
  
ACON Laboratories, Inc.  
10125 Mesa Rim Road, San Diego CA 92121, USA  
  
ACON Laboratories, Inc.  
6865 Flanders Dr., Suite B, San Diego CA 92121, USA  
  
AZURE Institute, Inc.  
10125 Mesa Rim Road, San Diego CA 92121, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICATE



## 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 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® 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® Plus Blood Glucose Test Strips             | G133-111 v † | 50 Test Strips (25/vial)                   | 1 Code Chip                                            | 1 Package Insert                                                                                 |                                     |
|                                                     | G133-112 v   | 50 Test Strips (50/vial)                   | 1 Code Chip                                            | 1 Package Insert                                                                                 |                                     |
|                                                     | G133-114 v   | 100 Test Strips (25/vial)                  | 1 Code Chip                                            | 1 Package Insert                                                                                 |                                     |
|                                                     | G133-115 v   | 10 Test Strips (10/vial)                   | 1 Code Chip                                            | 1 Package Insert                                                                                 |                                     |
|                                                     | G133-117 v   | 25 Test Strips (Individually Foil Wrapped) | 1 Code Chip                                            | 1 Package Insert                                                                                 |                                     |
|                                                     | G133-118 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® 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® 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® Lancets                                    | G124-10A v†  | 100 Lancets (25/bag)                       |                                                        |                                                                                                  |                                     |
| On-Call® Lancing Device                             | G124-11AV    | 1 Lancing Device                           |                                                        | 1 Package Insert                                                                                 |                                     |
| On-Call® 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



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](mailto:info@aconlabs.com)

Please visit our website for details: [www.acondiabetescare.com](http://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

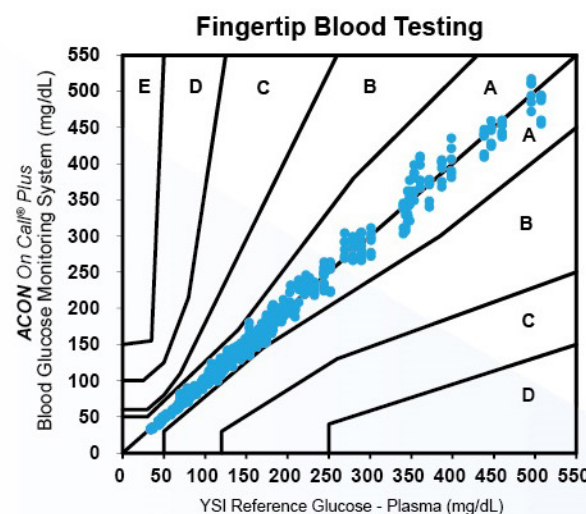
**ACON®**  
Diabetes Care



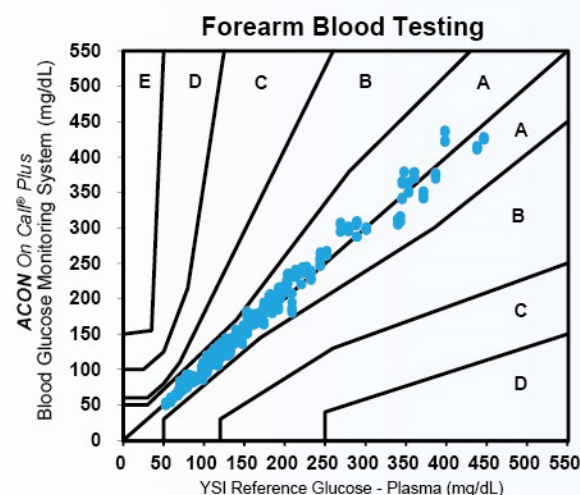


## Accurate and Reliable

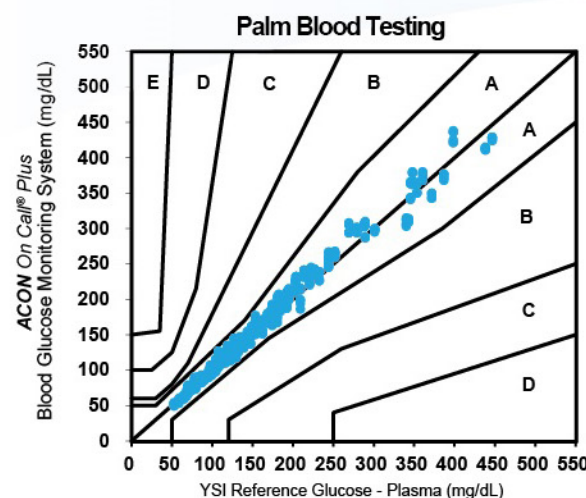
Extensive clinical studies proved the accuracy of *On-Call<sup>®</sup> Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



| Consensus Error Grid Analysis<br>Clinical Trial - Fingertip Capillary Blood, by Technican<br>ACON On Call® Plus Blood Glucose Monitoring System vs. YSI |                   |                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
| 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<br>≥ 100 mg/dL and < 100 mg/dL                                                                   |                   |                    |
| Within ±15% or ±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 |                   |                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
| 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<br>≥ 100 mg/dL and < 100 mg/dL                                                                 |                   |                    |
| Within ±15% or ±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 |                   |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------|
| 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<br>≥ 100 mg/dL and < 100 mg/dL                                                              |                   |                    |
| Within ±15% or ±15 mg/dL                                                                                                                           |                   |                    |
| 609 / 612 (99.5%)                                                                                                                                  |                   |                    |

## Key Features



## Authority Certificate



CE certificate



USFDA CFG certificate



Health Canada certificate