



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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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(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

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**

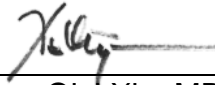
**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission**

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



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

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)

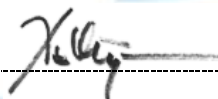
**of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,
meets all the provisions of the directive 93/42/EEC as amended by directive
2007/47/EC concerning medical devices which apply to it.**

**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



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





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

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.

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.



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: June 2, 2022

Signature:



Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@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® Plus Blood Glucose Monitoring System | G113-111 v † | 1 Meter 1 Manual 10 Lancets | 10 Test Strips 1 Carrying Case 1 Code Chip | 1 Control Solution 1 1 Quick Reference Guide 1 Clear Cap (for testing on forearm and palm) | 1 Lancing Device 1 Warranty Card |
| On-Call® Plus Blood Glucose Meter | G113-211 v † | 1 Meter 1 Manual | 1 Control Solution 1 1 Warranty Card | 1 Carrying Case 1 Quick Reference Guide | |
| | G113-214 v | 1 Meter 1 Manual 10 Lancets | 1 Lancing Device 1 Carrying Case 1 Warranty Card | 1 Control Solution 1 1 Quick Reference Guide 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

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

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1150944001

On-Call® Plus

Blood Glucose Monitoring System

Delivers Value and Quality

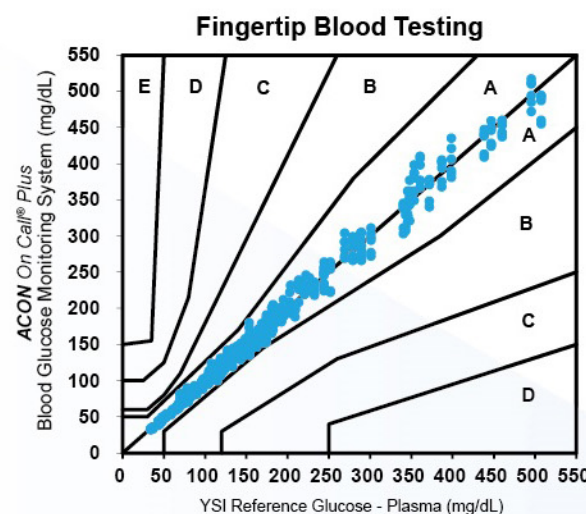
- 0.5 µL Blood Sample
- Accurate & Reliable Results
- 25 - 60% HCT Range
- US 510(k) & CE

ACON®
Diabetes Care

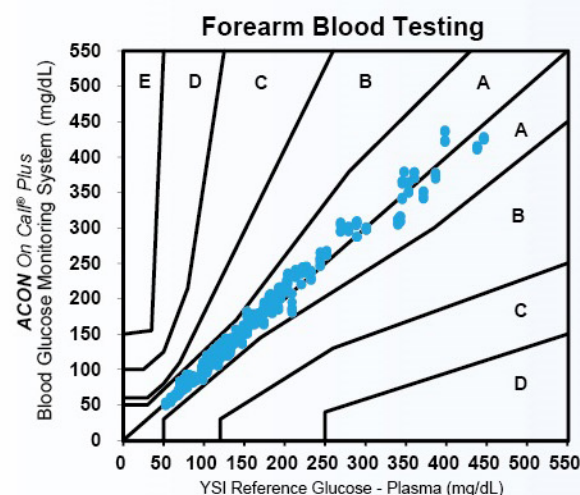


Accurate and Reliable

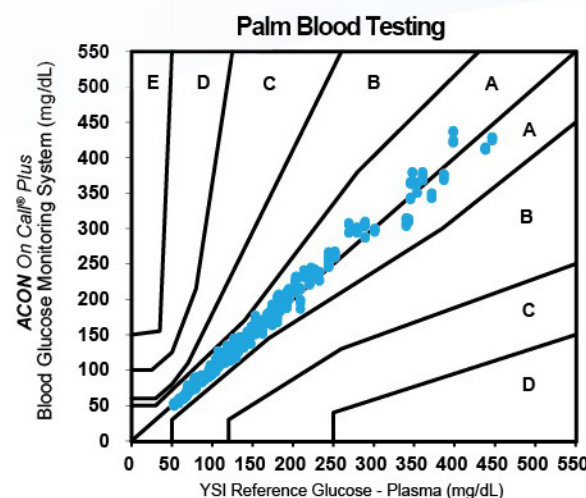
Extensive clinical studies proved the accuracy of *On-Call[®] Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



| 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%) | | |



| 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%) | | |



| 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%) | | |

Key Features



Authority Certificate



CE certificate



USFDA CFG certificate



Health Canada certificate