

## 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: March 18, 2024

Signature:



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Qiyi Xie, Md, MPH  
V.P. of Regulatory & 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](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.



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. 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**

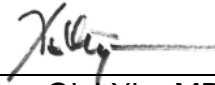
This declaration is valid until expiration of EC Certificate  
No. V1 104507 0003 Rev. 06  
Expiration Date: 2025-05-26

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)



# 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)

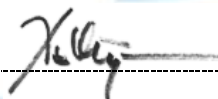
**of class IIA according to Annex IX rule 6 of the directive 93/42/EEC,  
meets all the provisions of the directive 93/42/EEC as amended by directive  
2007/47/EC concerning medical devices which apply to it.**

**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.





**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](mailto:info@aconlabs.com)

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November 11<sup>th</sup> 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

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.

Jassy Alvarenga  
International Account Manager  
ACON Laboratories, Inc. S.A.

[jalvarenga@aconlabs.com](mailto:jalvarenga@aconlabs.com)

+1 858 875 8085



## 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	
		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® 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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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

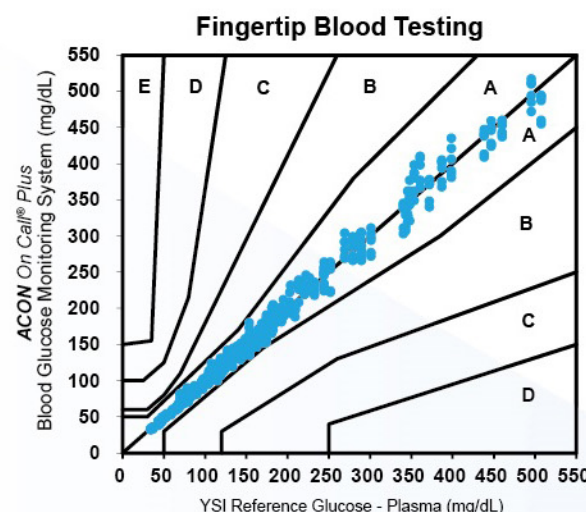
**ACON®**  
Diabetes Care



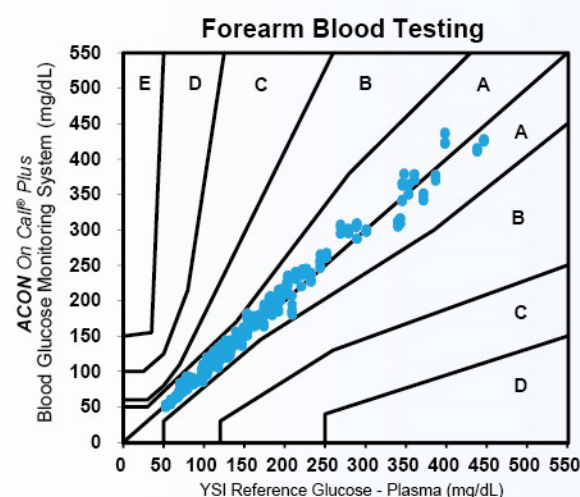


## Accurate and Reliable

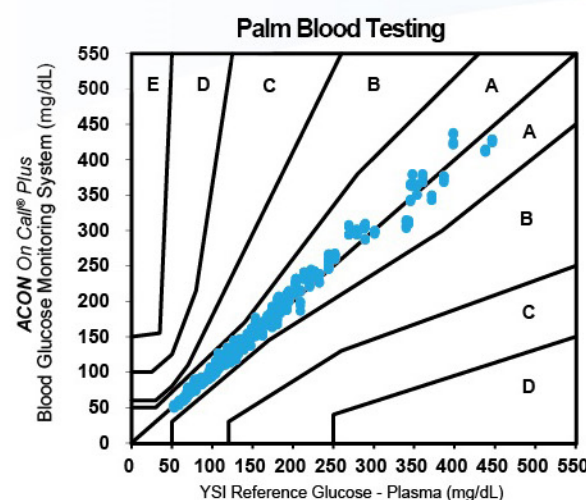
Extensive clinical studies proved the accuracy of *On-Call<sup>®</sup> Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



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 Technician 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 Technician 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