



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

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



Product Service

Certificate

No. Q5 104507 0001 Rev. 05

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, Instruments, and Reagents for the Determination of the following: Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Allergen, Fertility/Pregnancy, and Blood Glucose.

Design and Development, Manufacture and Distribution of Lancets.

Manufacture and Distribution of Lancing Device

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, Certification, Validation and Verification Regulations 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_104507_0001_Rev.05)

Report No.: 72198930, 72198930-CN

Valid from: 2024-12-18
Valid until: 2027-12-17

Date, 2024-12-18

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 104507 0001 Rev. 05

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Representative company address for Acon Laboratories, Inc

AZURE Institute, Inc.
9440 Carroll Park Dr, San Diego CA 92121, USA

Design and Development of In Vitro Diagnostic Test Kits,
Instruments and Reagents for the Determination of the following:
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Allergen, Fertility/Pregnancy, and Blood
Glucose.

Design and Development of Lancets.

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

Manufacture of Blood Glucose Test Strips and Rapid Tests for
detection of infectious diseases

Acon Laboratories, Inc.
9440 Carroll Park Dr, San Diego CA 92121, USA

Design and Development, Manufacture and Distribution of In Vitro
Diagnostic Test Kits, Instruments and Reagents for the
Determination of the following: Infectious Diseases, Clinical
Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Allergen,
Fertility/Pregnancy, and Blood Glucose.

Design and Development, Manufacture and Distribution of Lancets
and Lancing Device.

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**

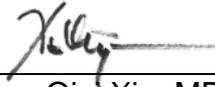
**The declaration according to Annex IV of the Directive
is based on approval by the notified body
TÜV SÜD Product Service GmbH,
Ridlerstraße 65,
80339 MÜNCHEN, Germany,
notified under No. 0123 to the EC Commission**

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.





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

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

+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



On-Call[®] Plus
Blood Glucose Monitoring System



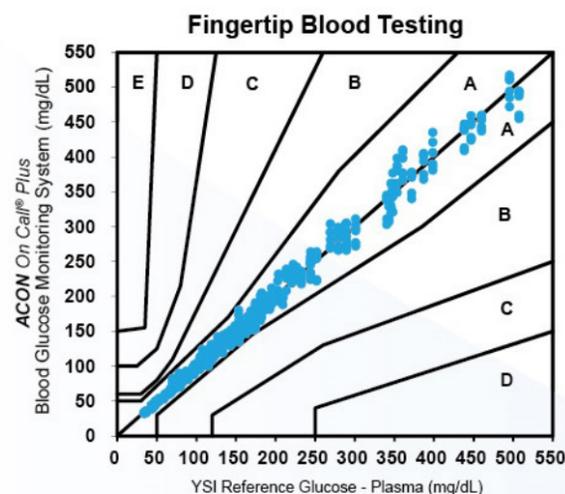
Delivers Value and Quality

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

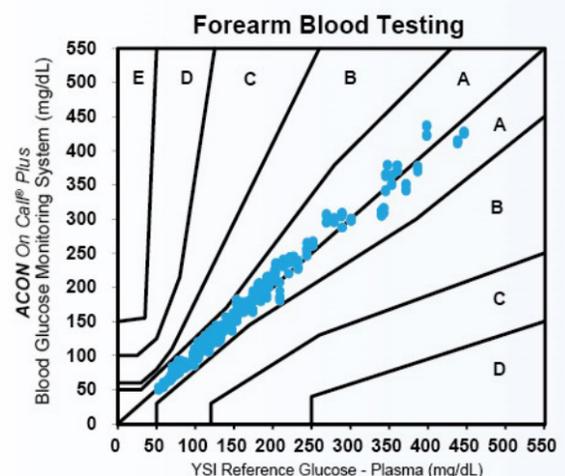


Accurate and Reliable

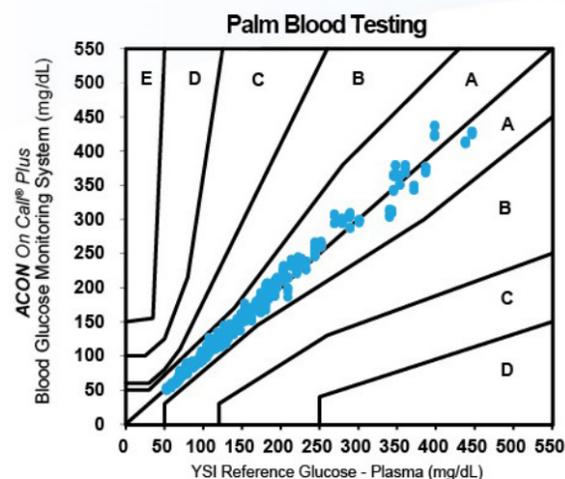
Extensive clinical studies proved the accuracy of *On-Call Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ 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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ 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 $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 15\%$ or ± 15 mg/dL		
609 / 612 (99.5%)		

Key Features

- 0.5 μ 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