Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD 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

Digitally signed by Monastîrschii Viorica
Date: 2022.09.03 12:24:52 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD 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

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

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

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

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,

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®

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

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

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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

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®

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
Mission® Cholesterol Meter	C111-2021
Mission® Cholesterol CTRL Control Device	C121-2021
Mission® Cholesterol Control Solution	C121-2011
Mission® Cholesterol TRIG Triglyceride Test Device	C131-2021, C131-2071
Mission® Cholesterol HDL High Density Lipoprotein Test Device	C131-2031, C131-2081
Mission® Cholesterol CHOL Total Cholesterol Test Device	C131-2011, C131-2061
Mission® Cholesterol 3-in-1 Lipid Panel Test Device	C131-2041, C131-2051

classified for S*elf-testing* 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 24 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

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

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

ACON LABORATORIES, INC. S.A.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc.
jalvarenga@aconlabs.com
+1 858 875 8085

STATEMENT

We, ACON Laboratories, Inc. having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* assign SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*, as authorized representative in correspondence with the conditions of directive 98/79/EC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This authorization will be valid for one year after the date of this statement.

Date: June 1, 2021

Signature: 

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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:

tuv-sud.com/ps-cert

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

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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 ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

TÜV®

On·Call® Plus

Blood Glucose Monitoring System

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 √ †	1 Meter, 10 Test Strips, 1 Control Solution 1, 1 Lancing Device, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 1 Warranty Card, 10 Lancets, 1 Code Chip, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Meter	G113-211 √ †	1 Meter, 1 Control Solution 1, 1 Carrying Case, 1 Manual, 1 Warranty Card, 1 Quick Reference Guide
	G113-214 √	1 Meter, 1 Lancing Device, 1 Control Solution 1, 1 Manual, 1 Carrying Case, 1 Quick Reference Guide, 10 Lancets, 1 Warranty Card, 1 Clear Cap (for testing on forearm and palm)
On Call® Plus Blood Glucose Test Strips	G133-111 √ †	50 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	50 Test Strips (50/vial), 1 Code Chip, 1 Package Insert	
	G133-112 √	100 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
	G133-114 √	10 Test Strips (10/vial), 1 Code Chip, 1 Package Insert
	G133-115 √	25 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-117 √	50 Test Strips (Individually Foil Wrapped), 1 Code Chip, 1 Package Insert
	G133-118 √	25 Test Strips (25/vial), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Test Strips and Lancets	G133-211 √	50 Test Strips (25/vial), 50 Lancets (25/bag), 1 Code Chip, 1 Package Insert
On Call® Plus Blood Glucose Control Solution	G123-311 √†	1 Control Solution 0, 1 Control Solution 1, 1 Control Solution 2, 1 Package Insert
On Call® Lancets	G124-10A √†	100 Lancets (25/bag)
On Call® Lancing Device	G124-11A√	1 Lancing Device, 1 Package Insert
On Call® Diabetes Management Software Kit	G124-13A†	1 USB Data Transfer Cable, 1 Installation Disk

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

ACON®

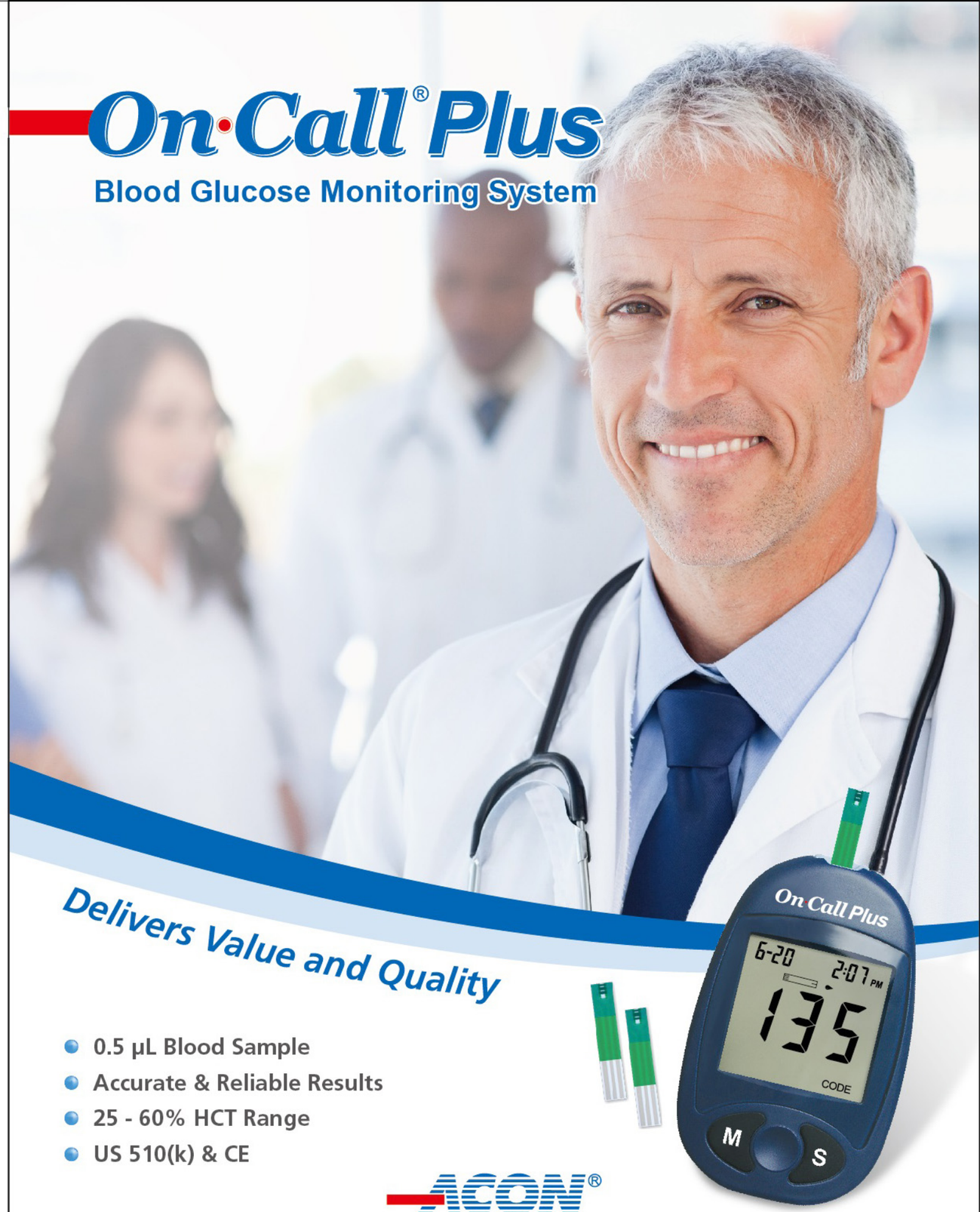
***ACON* Laboratories, Inc.**, 10125 Mesa Rim Road, San Diego, CA 92121, USA • Tel: 1-858-875-8000 • Fax: 1-858-200-0729 • E-mail: info@aconlabs.com

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

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

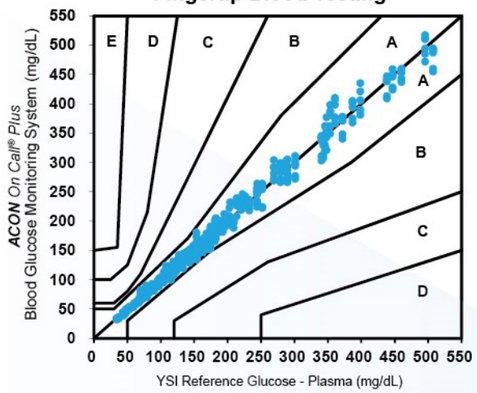
On·Call® Plus

Blood Glucose Monitoring System

Accurate and Reliable

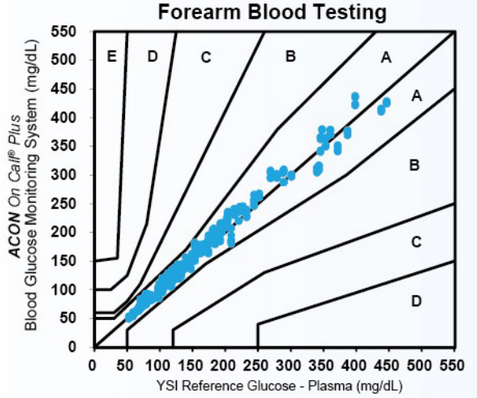
Extensive clinical studies proved the accuracy of *On Call® Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with **EN ISO 15197: 2015**.

Fingertip Blood Testing



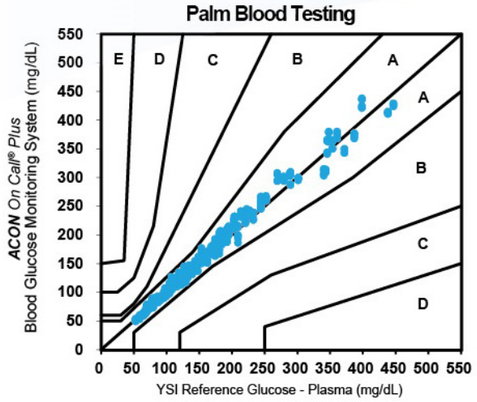
Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technican *ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL		
Within ±5%	Within ±10%	Within ±15%
290 / 462 (62.8%)	432 / 462 (93.5%)	462 / 462 (100.0%)
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%)		

Forearm Blood Testing



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%)		

Palm Blood Testing



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%)		

On·Call® Plus

Blood Glucose Monitoring System

Key Features

- 0.5 µL 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

Mission®

Cholesterol Monitoring System

Provides high quality and reliable results for complete Lipid Panel testing!

- *Efficient*
- *Reliable*
- *Easy to Use*

ACON®

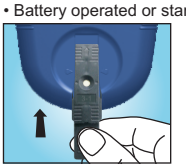
Global Diagnostics for Local Markets™

Mission® Cholesterol Monitoring System

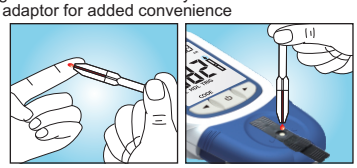
Efficient
- Complete Lipid Panel test in as little as 45 seconds with 3-1 lipid panel, or individual devices
- One 3-1 lipid panel device tests for Total Cholesterol (CHOL), High Density Lipoprotein (HDL), and Triglycerides (TRIG)
- Also includes calculated Low Density Lipoprotein (LDL), CHOL/HDL ratio, and Cardiac Risk Assessment
- Cardiac Risk Assessment evaluates risk of heart attack, stroke, and heart disease

Reliable
- Can test whole blood, serum, or plasma
- Wide hematocrit range of 0-50%
- Small external printer available for quick and immediate printing of results
- Unique device identification to ensure use of proper device to avoid procedural error

Easy to Use
- Large LCD display for easy reading
- Color coded test devices with engraved test name for easy identification
- Battery operated or standard AC adaptor for added convenience



Step 1: Insert device into meter



Step 2: Apply specimen with capillary transfer tube

Step 3: Read result

Specifications

Feature	Technical Specification
Detection Principle	Reflectance Photometry
Wavelengths	635 nm
Time to Results	45 seconds-2 minutes
Memory with Date/Time	200 results
Type of Test	Quantitative
Tests	Total Cholesterol (CHOL); High Density Lipoprotein (HDL); Triglycerides (TRIG); Calculated Low Density Lipoprotein (LDL), CHOL/HDL ratio, Cardiac Risk Assessment
Specimen Volume	3-1 Lipid **Panel** Test Device: 35 µL; Requires 21G/2.8 mm Safety Lancets and 35 µL Plastic Capillary Transfer Tubes
	CHOL, TRIG, HDL **Individual** Test Device: 10 µL; Requires 21G/2.8 mm Safety Lancets or 26G/1.3 mm Lancets using Lancing Device, and 10 µL Plastic Capillary Transfer Tubes
Specimen Type	Capillary or venous whole blood, serum, or plasma
Transfer Tool	Capillary Transfer Tube or Pipette
Operator Training/Maintenance	Minimal
Measurement Units	mg/dL or mmol/L
Measurement Range	CHOL: 100-500 mg/dL (2.59-12.93 mmol/L) HDL: 15-100 mg/dL (0.39-2.59 mmol/L) TRIG: 45-650 mg/dL (0.51-7.34 mmol/L)
HCT	0-50%
Precision (CV%)	CHOL: 100-500 mg/dL (2.59-12.93 mmol/L) (≤ 5.0%) HDL: 30-100 mg/dL (0.78-2.59 mmol/L) (≤ 5.0%) TRIG: 100-650 mg/dL (1.13-7.34 mmol/L) (≤ 5.0%)
Accuracy (Bias%)	CHOL: 100-500 mg/dL (2.59-12.93 mmol/L) (≤ 15%) HDL: 15-30 mg/dL (0.39-0.78 mmol/L) (≤ ± 5mg/dL or ≤ ± 0.13 mmol/L); 30-100 mg/dL (0.78-2.59 mmol/L) (≤ 15%) TRIG: 45-100 mg/dL (0.51-1.13 mmol/L) (≤ ±15mg/dL or ≤ ± 0.17 mmol/L); 100-650 mg/dL (1.13-7.34 mmol/L) (≤ 15%)
PC Interface for Data Transfer to PC	Mini USB Port
Calibration	Code Chip
Available Languages on the Screen	English abbreviations
Operating Conditions	15-40°C (59-104°F); ≤ 90% RH
Test Device Shelf Life	Opened canister: 3 months Unopened canister and pouch: 1 year
Control Device Shelf Life	Opened canister: 1 year; Unopened canister: 2 years
Meter Storage Conditions	0-50°C (32-122°F)
Device Storage Conditions	2~30°C (36-86°F)
Power Source	4 AAA or AC Adaptor (Mini USB, 5V dc, 50 mA)
Battery Life	≥ 1,000 tests
Automatic Shut Off	5 minutes
Meter Dimensions (L x W x H)	137 mm × 79 mm × 26 mm (5.4" x 3.1" x 1.0")
Display Dimensions (L x W)	50 mm × 50 mm (2.0" x 2.0")
Weight Excluding Batteries	145 g (5.11 oz)

Ordering Information

Product Name	Catalog No.	Components
Mission® Cholesterol Meter	C111-2021 ♦	1 Meter; 1 Carrying Case; 1 Quick Reference Guide; 1 Manual; 4 Batteries; 1 Warranty Card; 2 Control Devices (2/canister); 1 Control Device Insert; 5 Safety Lancets (5/bag)
Mission® Cholesterol Test Devices- 3-1 Lipid Panel	C131-2041 ♦	**Package 1:** 5 Test Devices (Individual Pouch); 5 Capillary Transfer Tubes; 1 Code Chip; 1 Package Insert — or — **Package 2*:** 20 Test Devices (10/canister); 20 Capillary Transfer Tubes; 1 Code Chip; 1 Package Insert — or — **Package 3:** 25 Test Devices (Individual Pouch); 25 Capillary Transfer Tubes; 1 Code Chip; 1 Package Insert
Mission® Cholesterol Test Devices- CHOL Total Cholesterol	C131-2011 ♦	
Mission® Cholesterol Test Devices- HDL High Density Lipoprotein	C131-2031 ♦	
Mission® Cholesterol Test Devices- TRIG Triglycerides	C131-2021 ♦	
Mission® Cholesterol CTRL Control Devices	C121-2021 ♦	2 Control Devices (2/canister); 1 Package Insert
Mission® Cholesterol Control Solution*	C121-2011 ♦	**For 3-1 Lipid Panel:** 1 CHOL Control Solution 1 (Normal level, 2 mL/bottle); 1 CHOL Control Solution 2 (High level, 2 mL/bottle); 1 HDL/TRIG Control Solution 1 (Normal level, 2 mL/bottle); 1 HDL/TRIG Control Solution 2 (High level, 2 mL/bottle); 1 Package Insert **For CHOL/HDL/TRIG Individual Test Devices:** 1 CHOL Control Solution 1 (Normal level, 2 mL/bottle); 1 CHOL Control Solution 2 (High level, 2 mL/bottle); 1 HDL/TRIG Control Solution 1 (Normal level, 2 mL/bottle); 1 HDL/TRIG Control Solution 2 (High level, 2 mL/bottle); 1 Package Insert
Mission® Capillary Transfer Tubes	C121-3081 √	50 Capillary Transfer Tubes (10 µL and 35 µL)
Mission® Lancets	C121-3041 ♦	100 Lancets
Mission® Lancing Devices	C121-3051 √	1 Lancing Device; 1 Lancing Device Insert
Mission® Safety Lancets I	C121-3061 ♦	20 Lancets/Kit (21G/2.8 mm)
		25 Lancets/Kit (21G/2.8 mm)
Mission® Adaptor Kit	C121-3011 √	1 Power Adaptor; 1 Plug
Mission® Printer	C121-1021	1 Printer; 1 Paper Roll; 1 Package Insert; 1 Cable; 1 Adapter

* Coming Soon √CE ♦CE0123

We also offer other rapid diagnostic and medical products:

Blood Glucose Monitoring Systems, Clinical Chemistry including Urinalysis, Immunoassay EIA/ELISA and more

CE Marked for sale in the European Community

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.aconlabs.com

1150653402