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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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(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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(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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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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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



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 ◆ CERTIFICAT

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

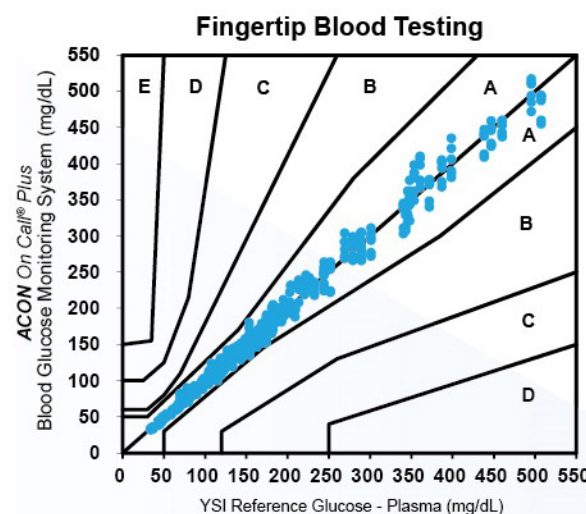
- 0.5 µL Blood Sample
- Accurate & Reliable Results
- 25 - 60% HCT Range
- US 510(k) & CE

ACON®
Diabetes Care

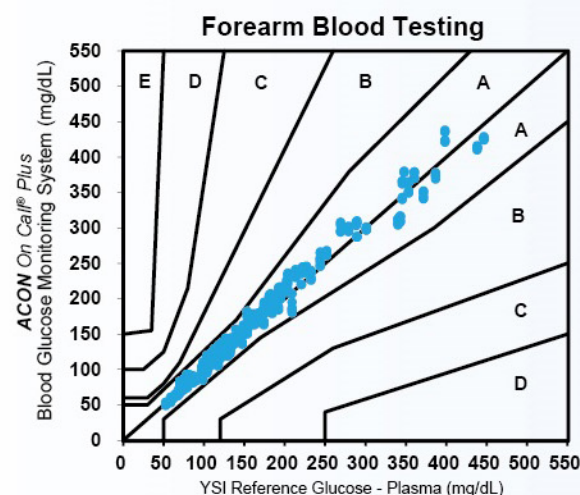


Accurate and Reliable

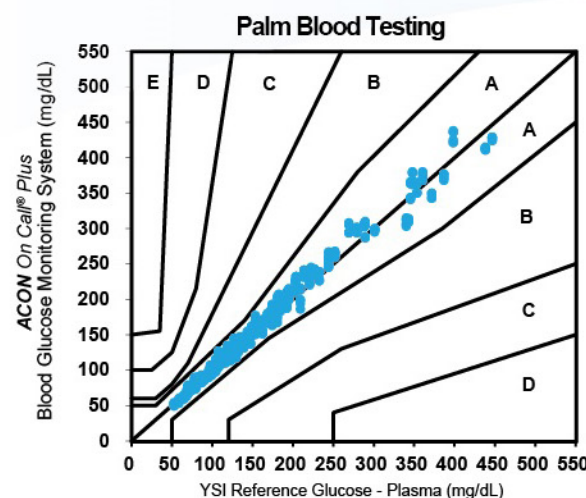
Extensive clinical studies proved the accuracy of *On-Call[®] Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with EN ISO 15197: 2015.



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