



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

S. Pennit

Stefan Preiß
Head of Certification/Notified Body





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

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



Page 2 of 4

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

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,



Page 3 of 4

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

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

TUV®



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





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:



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

S. Preiß

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

