ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Digitally signed by Monastîrschii Viorica
Date: 2023.09.25 12:36:48 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

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

**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


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. 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

.


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 |
|---|---|
| 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.

5850 Oberlin Drive #340·San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

# 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

**Report No.:** SH22743A01

**Valid from:** 2022-09-15
**Valid until:** 2025-09-06

**Date,** 2022-09-15

Christoph Dicks
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. 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.

.


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

TÜV®

# Letter of Declaration

To whom it may concern:

We ***Acon Laboratories,Inc.***, who is the legal manufacturer of Blood Glucose Monitoring System (Including Glucose Meter, Glucose test strip, Control Solution, Lancet and lancing device etc, to test the glucose level of human blood),have registered office at 10125 Mesa Rim Road, San Diego, CA 92121 USA, here to declare that:

- ***On Call® Plus Strips*** correspond with ***On Call® Plus*** Blood Glucose Monitoring System.

- We currently have in stock the tender required quantity of Meters, Strips and Lancets (1000/50000/50000).

This clarification letter will only be used for product registration, tender submission, sales and marketing of ***On Call® Plus*** Blood Glucose Monitoring System in **Moldova** it should not be used for any other business or non-business purposes.

Sincerely yours,

Eddie.Shi
International Sales & Marketing Sales Manager
Diabetes Care
***Acon Laboratories,Inc.***

# 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: January 3, 2023

Signature: 

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

# 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

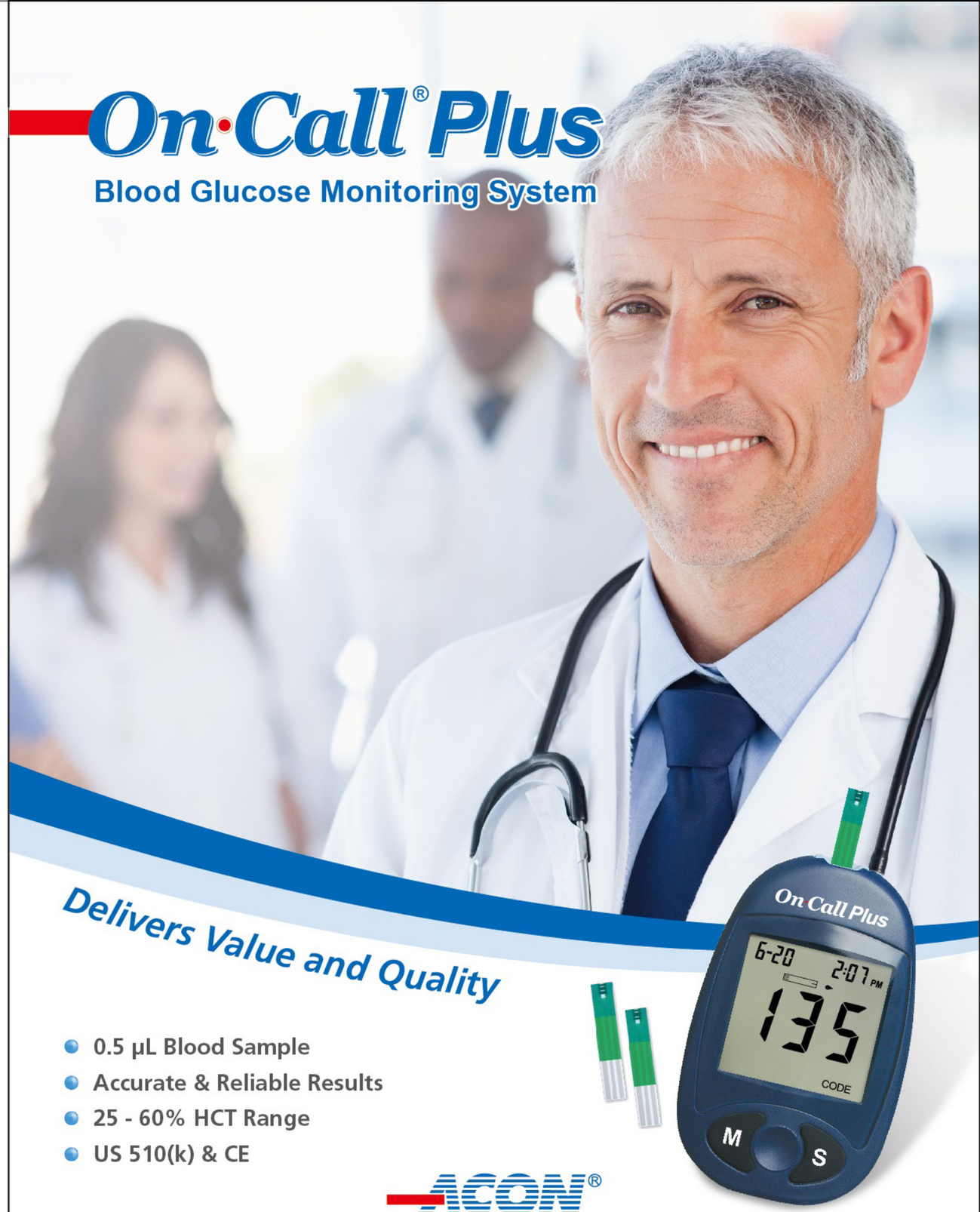
Please visit our website for details: www.acondiabetescare.com

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

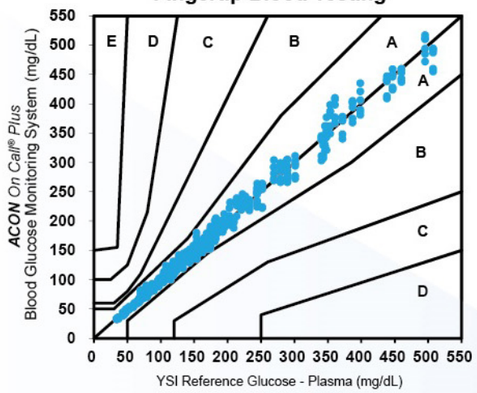
# On·Call® Plus

Blood Glucose Monitoring System

## Accurate and Reliable

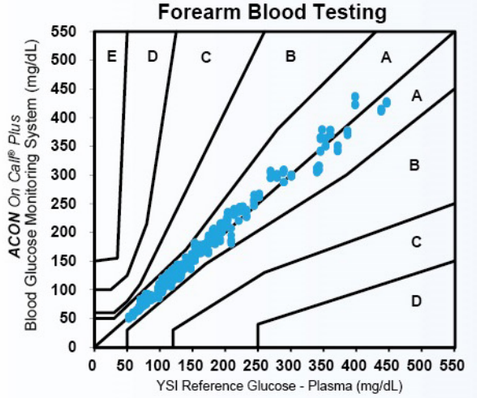
Extensive clinical studies proved the accuracy of *On Call® Plus* Blood Glucose Monitoring System with fresh capillary blood samples, which can comply with **EN ISO 15197: 2015**.

### Fingertip Blood Testing



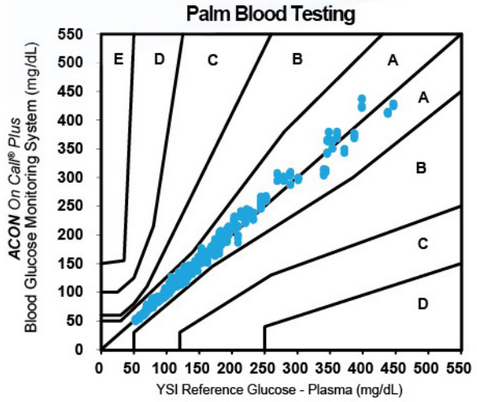

| Consensus Error Grid Analysis<br>Clinical Trial - Fingertip Capillary Blood, by Technican<br>*ACON On Call® Plus* Blood Glucose Monitoring System vs. YSI | | |
|---|---|---|
| **System Accuracy Results for Glucose Concentration ≥ 100 mg/dL** | | |
| Within ±5% | Within ±10% | Within ±15% |
| 290 / 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<br>Clinical Trial - Forearm Capillary Blood, by Technican<br>*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<br>Clinical Trial - Palm Capillary Blood, by Technican<br>*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

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG001
Version 7.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

***See attachment***

Classification: *Self-testing*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

**Notified Body' Name:** TÜV SÜD Product Service GmbH
**Notified Body Address:** Ridlerstraße 65 80339 München Germany
**Notified Body ID: 0123**
**EC Certificate Registration number:**V1 092305 0002 Rev.01
**Expiry date of EC certificate:** 2025-04-07

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint

**EC Representative's Name:** QARAD BV

**EC Representative's Address:** Cipalstraat 3, 2440 Geel BELGIUM

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: May 12, 2022

Joyce Pang

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

Attachment to CE-DOC-OG001 Version 7.0

| **Product Name** | **Catalog Number** |
|---|---|
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103a-1T |
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103a-2T |
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103b-1T |
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103b-2T |
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103d-1T |
| Orient Gene HCG Pregnancy Rapid Test-Midstream | GAHCG-103d-2T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102a-1T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102a-25T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102b-1T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102b-25T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102d-1T |
| Orient Gene HCG Pregnancy Rapid Test-Cassette | GAHCG-102d-25T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101a-1T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101a-2T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101a-25T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101b-1T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101b-2T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101b-25T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101d-1T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101d-2T |
| Orient Gene HCG Pregnancy Rapid Test-Strip | GAHCG-101d-25T |

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

# Certificate

## No. Q5 092305 0001 Rev. 01

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**


**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

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 092305 0001 Rev. 01

**Report No.:** SH2198802

**Valid from:** 2022-04-11
**Valid until:** 2024-03-16

**Date,** 2022-04-11

Christoph Dicks
Head of Certification/Notified Body


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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service

# Certificate

## No. Q5 092305 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):**

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.


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

TÜV®

# STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

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 Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

# HCG Pregnancy Rapid Test

CE 0123

*English*

*For Self-testing*

REF GAHCG-101b-1T/GAHCG-101b-2T/GAHCG-101b-25T

***Please read all the information in the leaflet before performing the test.***

## INTENDED USE

The HCG Pregnancy Rapid Test is an immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is used to obtain a visual qualitative result. For *in vitro* self-testing use only.

## PRINCIPLE

Human chorionic gonadotropin (hCG) is a hormone, produced by the developing placenta shortly after the conception and secreted into the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When the strip is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane.

When hCG in the sample reaches the Test Zone region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result.

To serve as a procedure control, a colored line will appear at the control zone region, if the test has been performed properly.

## REAGENTS

Coated Antibodies

Control region: Goat anti-mouse (IgG) polyclonal antibody

Test region: Mouse monoclonal anti-hCG antibody A

Labeled Antibodies:

Colloidal gold conjugate of monoclonal anti-hCG antibody B

## MATERIALS SUPPLIED

**GAHCG-101b-1T/ GAHCG-101b-2T/GAHCG-101b-25T**

1. 1/2/25 Test strip(s) (individually pouched) A desiccant is included in each pouch. The desiccant is for storage purposes only and is not used in the test procedures.
2. 1 Instruction for use.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

## PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or is not well sealed.
5. Keep out of the reach of children.
6. Urine specimens may be infectious; Insure proper handing and discard all used devices according to the local regulations.

## STORAGE AND STABILITY

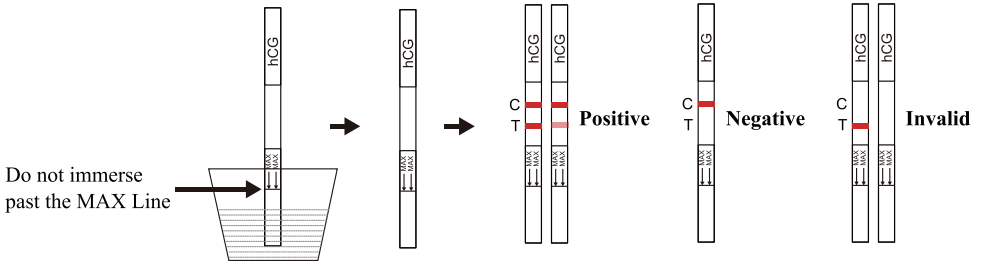
1. Store at 2°C to 30°C in the sealed pouch up to the expiration date.
2. DO NOT FREEZE.
3. The test device must remain in the sealed pouch until use.

## SPECIMEN COLLECTION

Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG.

## TEST PROCEDURE

1. Remove a strip from the foil pouch by tearing at the notch and use it as soon as possible.
2. Place the stip in urine stream for at least 10 seconds until thoroughly wet. Do not urinate passed the arrow mark.
3. Wait for color bands to appear.
4. Read the result in 5 minutes. **Do not read results after more than 5 minutes.**




## INTERPRETATION OF RESULTS

**Positive**

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). This means you are probably pregnant. One line may be lighter than the other, they do not have to match.

**Negative**

One red line appears in the control region (C).No apparent red or pink line appears in the test region (T).This means you are probably not pregnant.

**Invalid**

The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). You should repeat the test with a new test.

***NOTE:*** *If the test line is weak, it is recommended that the test be repeated in 48 hours.*

## LIMITATIONS

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. If a urine sample is too dilute (ie, low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments, based on hCG, may cause false results. Consult your physician.

## PERFORMANCE CHARACTERISTICS

A layer users evaluation was conducted comparing the results obtained using the HCG Pregnancy Rapid Test

(Urine) to professional users.The study included 60 urine specimens, and layer users and professional users identified 30 negative and 30 positive results. The results demonstrated an identical agreement between layer users and professional users.

Layer users vs professional users

| Tests (tester) | Total Evaluated Samples | Correct Positive Results | Correct Negative Results |
|---|---|---|---|
| **hCG Test by Layer users** | 60 | 30 | 30 |
| Positive Agreement | / | 30/30=100% | / |
| Negative Agreement | / | / | 30/30=100% |
| Total Agreement | (30+30)/60=100% | / | / |
| **hCG Test by Professional users** | 60 | 30 | 30 |
| Positive Agreement | / | 30/30=100% | / |
| Negative Agreement | / | / | 30/30=100% |
| Total Agreement | (30+30)/60=100% | / | / |

Sensitivity

The HCG Pregnancy Rapid Test detects hCG in urine at a concentration of 10 mIU/mL or greater.

Specificity

The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL) and TSH (1,000 μIU/mL) to negative (0 mIU/mL hCG) and positive (10 mIU/mL hCG) specimens showed no cross-reactivity.

## QUESTIONS AND ANSWERS

**1. Q: How soon after I suspect that I am pregnant can I take the test?**

A: You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

**2. Q: Do I have to test with first morning urine?**

A: Although you can test any time of the day your first morning urine specimen is usually the most concentrated of the day and would have the most hCG in it.

**3. Q: How accurate is the test?**

A: A clinical evaluation was conducted comparing the results obtained using the HCG Pregnancy Rapid Test to another commercially available urine membrane hCG test. The consumer clinical trial included 216 urine specimens: both assays identified 76 positive and 140 negative results. The results demonstrated >99% overall accuracy of the HCG Pregnancy Rapid Test when compared to the other urine membrane hCG test.

**4. Q: Which factors may affect the test result?**

A: Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.

**5. Q: What should I do if the result shows that I am pregnant?**

A: It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

**6. Q: Does the result mean anything other than normal pregnancy if it shows that I am pregnant?**

A: A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG.

**7. Q: How do I know that the test was run properly?**

A: The appearance of a red line in the control window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

**8. Q: What should I do if the result shows that I am not pregnant?**

A: It means that no hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

**Please take the following steps to increase your chances for a healthy pregnancy and your baby.**

1. Use the HCG Pregnancy Rapid Test to detect pregnancy when your period is late. You can begin better prenatal care as soon as you learn of your pregnancy.
2. If you get a positive result, it is advisable to visit your doctor immediately.
3. Maintain a well-balanced diet, stop smoking, and reduce your intake of alcohol.

## INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | Σ | Tests per kit | EC REP | Authorized Representative |
| IVD | For *in vitro* diagnostic use only | | Use by | | Do not reuse |
| 2°C 30°C | Store between 2~30°C | LOT | Lot Number | REF | Catalog# |

Zhejiang Orient Gene Biotech Co., Ltd.
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

Effective Date: 2021-06-15
B23053-01