





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

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT





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**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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