



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 104507 0001 Rev. 05

**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, Instruments, and Reagents for the Determination of the following: Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Allergen, Fertility/Pregnancy, and Blood Glucose.

Design and Development, Manufacture and Distribution of Lancets.

Manufacture and Distribution of Lancing Device

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, Certification, Validation and Verification Regulations 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 05)

**Report No.:** 72198930, 72198930-CN

**Valid from:** 2024-12-18  
**Valid until:** 2027-12-17

**Date,** 2024-12-18

Christoph Dicks  
Head of Certification/Notified Body



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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **ACON Laboratories, Inc.**  
5850 Oberlin Drive, #340, San Diego CA 92121, USA  
  
Representative company address for Acon Laboratories, Inc

**AZURE Institute, Inc.**  
9440 Carroll Park Dr, San Diego CA 92121, USA

Design and Development of In Vitro Diagnostic Test Kits,  
Instruments and Reagents for the Determination of the following:  
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,  
Tumor/Cardiac Marker, Allergen, Fertility/Pregnancy, and Blood  
Glucose.

Design and Development of Lancets.

**Acon Laboratories Inc.**  
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana  
B.C. CP, MEXICO

Manufacture of Blood Glucose Test Strips and Rapid Tests for  
detection of infectious diseases

**Acon Laboratories, Inc.**  
9440 Carroll Park Dr, San Diego CA 92121, USA

Design and Development, Manufacture and Distribution of In Vitro  
Diagnostic Test Kits, Instruments and Reagents for the  
Determination of the following: Infectious Diseases, Clinical  
Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Allergen,  
Fertility/Pregnancy, and Blood Glucose.

Design and Development, Manufacture and Distribution of Lancets  
and Lancing Device.