

TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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

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

TUV SÜD TÜV SÜD  
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT