

TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ 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



Product Service

# 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 SUD TÜV SÜD  
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFIKAT ♦