



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

TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE

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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