



Product Service

Certificate

No. Q5 104507 0001 Rev. 04

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 and certification regulation of 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. 04

Report No.: 72188635

Valid from: 2023-09-14

Valid until: 2025-09-06

Date, 2023-09-14



Christoph Dicks
Head of Certification/Notified Body

Certificate

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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

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture 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. Manufacture of Lancets. Manufacture of Lancing Device

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

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. Distribution of Lancets. Distribution of Lancing Device

AZURE Institute, Inc.
10125 Mesa Rim Road, 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