CERTIFICATE OF REGISTRATION

Abbott Laboratories Diagnostic Division

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 United States

D-U-N-S ID No. 001307602

UL Medical Regulatory Services of UL LLC® (UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design, development and manufacture of diagnostic test kits and reagents.

The design and manufacture of in-vitro diagnostic medical devices, used in the screening of blood donor units for transmissible diseases. The design and manufacture of in-vitro diagnostic medical devices used in the diagnosis, management and detection of cancer, autoimmune status, cardiac markers, endocrine disorders, and for therapeutic drug monitoring.

With additional locations listed on Addendum 1 of 1

File Number A18075
Certificate No. 11957207.AZBA

Cycle Start Date December 1, 2017
Effective Date December 1, 2017
Expiry Date November 30, 2020

Authorized by

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Medical and Regulatory Services
UL LLC

Validate Certificate:
here

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services of UL LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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Addendum 1of 1

Off Site 1 located at:

K Complex
Rt. 41 & Martin Luther King Drive
North Chicago, IL 60064 United States

D-U-N-S ID No. 001307602

Performing: QC inspection of incoming materials and products. The storage and distribution of in vitro diagnostic reagents, test kits and accessories.

Manufacturing Site 1 located at:

Long Grove Farm Site
6131 RFD Oakwood Road
Long Grove, IL 60047 United States

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Performing: Antibody production

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Additional Regulatory Requirements

Australia:
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [if design controls are part of the certification];

Brazil:
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

Japan:
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

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