

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Exact Diagnostics**
100 South Jones Street
Suite 100
Fort Worth
Texas
76104
USA

Facility ID Number: F005849

Holds Certificate No: **MDSAP 758987**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of in-vitro diagnostic control materials for nucleic acid tests including infectious diseases testing.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-10-24

Effective Date: 2025-05-27

Expiry Date: 2028-05-26



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

...making excellence a habit.™