

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **ARK Diagnostics, Inc.**
48089 Fremont Blvd
Fremont
California
94538
USA

Facility ID Number: F000047

Holds Certificate No: **MDSAP 683666**

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture and distribution of in vitro diagnostic (IVD) immunoassays for therapeutic drug monitoring, urine drug testing and other small molecules.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-02-12

Effective Date: 2022-02-12

Expiry Date: 2023-02-11



BSI Group America Inc. is an MDSAP authorized auditing organization

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