

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

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

DUNS Number: 16-488-0598

Holds certificate No: **MDSAP 683666**

Statement of Conformity: The company listed on this certificate has been audited to 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 [if design controls are part of the certification]; 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 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:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-02-12

Effective Date: 2019-02-12

Expiry date: 2022-02-11

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