



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ARK Diagnostics, Inc.
48089 Fremont Blvd
Fremont
California
94538
USA

Holds Certificate No:

FM 704400

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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: 2007-10-25

Latest Revision Date: 2019-02-12

Effective Date: 2019-02-12

Expiry Date: 2022-02-11

Page: 1 of 1



...making excellence a habit.™