

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostic (IVD) immunoassays for therapeutic drug monitoring, pain management, drugs of abuse 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: 2018-11-26

Effective Date: 2018-11-26

Expiry Date: 2019-02-28

Page: 1 of 1



...making excellence a habit.™