

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 Number:

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 molecules.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2007-10-25

Latest Revision Date: 2025-01-07

Effective Date: 2025-02-12

Expiry Date: 2028-02-11

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

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