

# 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 523575**

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:

  
\_\_\_\_\_  
Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 10/25/2007

Effective Date: 09/27/2016

Expiry Date: 02/28/2019



CMDCAS  
Recognized  
Registrar



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