

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Asuragen, Inc.  
2150 Woodward Street  
Austin  
Texas  
78744  
USA

Facility ID Number: F000057

Holds Certificate No:

**MDSAP 695020**

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; 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; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture, and distribution of in-vitro diagnostic reagents and in-vitro diagnostic test kits and their calibrators and controls, used in clinical research, diagnosis, management and detection of cancer and genetic testing.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-07

Effective Date: 2020-12-15

Expiry Date: 2023-05-06



BSI Group America Inc. is an MDSAP authorized auditing organization

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