Certificate

TÜVRheinland®

Certificate No.:	MD 3319091 3251698-90
Manufacturer:	**QIAGEN Sciences LLC** 19300 Germantown Road Germantown MD 20874 USA
D-U-N-S No.:	197294564
Certification criteria	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable) United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	21249753 009
Issue Date:	2018-10-11
Effective Date:	2018-10-11
Expiry Date:	2021-07-12

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

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Certificate No.: MD 3319091 3251698-90

Manufacturer: **QIAGEN Sciences LLC**
19300 Germantown Road
Germantown MD 20874
USA

Scope: Design and Manufacture of ELISA-based In Vitro Diagnostic Kits used in the Detection of Transmissible Agents, Sexually Transmissible Agents, the Determination of Disease Status and in the Detection of Immune Responses to Infectious Diseases.

Design and Manufacture of the Cervical Specimen Collection Kits.

Design and Manufacture of Laboratory Equipment and Instrumentation to automate In Vitro Diagnostic Devices used in the Detection of Transmissible Agents and Sexually Transmissible Agents and the Determination of Disease Status.

Design, development and manufacture of In Vitro Diagnostic lateral flow testing for detection of Placental Alpha Microglobulin-1 (PAMG-1).

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