

Certificate

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

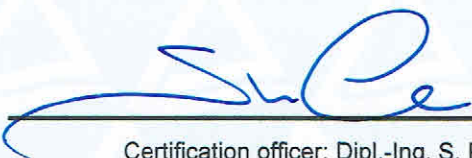
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject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

Project No.: 21249753 009

Issue Date: 2018-10-11

Effective Date: 2018-10-11

Expiry Date: 2021-07-12



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.

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Manufacturer: **QIAGEN Sciences LLC**
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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.

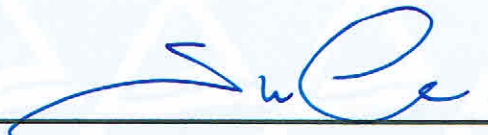
Design, development and manufacture of In Vitro Diagnostic lateral flow testing for detection of Placental Alpha Microglobulin-1 (PAMG-1).

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