Certificate

Certificate No.:	MD 1088319-40
Manufacturer:	**QIAGEN Sciences LLC** 19300 Germantown Road Germantown MD 20874 USA
REPs Facility ID:	F001089
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 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.:	1088319-230
Issue Date:	2021-07-08
Effective Date:	2021-07-13
Expiry Date:	2022-07-12

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

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087995?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

TÜV Rheinland®

Certificate No.: MD 1088319-40

Manufacturer: **QIAGEN Sciences LLC**

19300 Germantown Road
Germantown MD 20874
USA

Scope: Design, Development, Manufacture and Distribution of in vitro diagnostic lateral flow devices for detection of Placental Alpha Microglobulin-1 (PAMG-1), 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, Cervical Specimen Collection Kits and in-vitro diagnostic systems used in the Detection of Transmissible Agents and Sexually Transmissible Agents and the Determination of Disease Status.

Installation and Service of in-vitro diagnostic laboratory equipment and instrumentation used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

Distribution of in vitro diagnostic systems used in the diagnosis, management and detection of cancer, compatibility testing, disease status, genetic testing, immune status, prenatal screening, sexually transmissible agents and transmissible agents.

Project No.: 1088319-230

Issue Date: 2021-07-08

Effective Date: 2021-07-13

Expiry Date: 2022-07-12

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
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Certificate

Certificate No.: MD 1088319-40

Manufacturer: **QIAGEN Sciences LLC**

19300 Germantown Road
Germantown MD 20874
USA

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA	Activities associated with design, development and manufacture REPs facility ID: F001089
/02	QIAGEN LLC 19300 Germantown Road Germantwon MD 20874 USA	Activities associated with distribution, installation and service REPs facility ID: F001089

Project No.: 1088319-230

Issue Date: 2021-07-08

Effective Date: 2021-07-13

Expiry Date: 2022-07-12

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
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