Certificate

Certificate No.:	MD 1545122-1-2
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. 665/2022, RDC ANVISA n. 551/2021, 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.:	1159020-230
Issue Date:	2024-07-12
Effective Date:	2024-07-13
Expiry Date:	2027-07-12

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1545122-1-2

Manufacturer:

QIAGEN Sciences LLC

19300 Germantown Road
Germantown MD 20874
USA

Scope:

Design, development and manufacture of in vitro diagnostic lateral flow testing for detection of placental alpha macroglobulin-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 instruments 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, disease status, immune status, sexually transmissible agents and transmissible agents.

Distribution of in-vitro diagnostic instruments, in-vitro diagnostic reagents and in-vitro diagnostic test kits used in the diagnosis, management and detection of cancer, disease status, immune status, sexually transmissible agents, transmissible agents and transmissible agents and detection of placental alpha macroglobulin-1 (PAMG-1).

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19300 Germantown Road
Germantown MD 20874
USA

The scope of certification also covers the following sites:

No.	Location	Scope
/01	QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA	Design, development, administration and manufacture REPs Facility ID: F001089
/02	QIAGEN LLC 19300 Germantown Road Germantwon MD 20874 USA	Distribution, installation and service REPs Facility ID: F001089
/03	QIAGEN LLC 12920 Cloverleaf Center Drive Germantown MD 20874 USA	Service REPs Facility ID: F001089

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