Certificate

Certificate No.:	MD 7091956-1
Manufacturer:	**CareDx AB** Franzéngatan 5 SE-112 51 Stockholm Sweden
REPs Facility ID:	F004744
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Canada Medical Device Regulation – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D, 21 CFR 821
Scope:	Design and development, manufacture and distribution of software and in vitro diagnostics based on molecular genetic testing and flow cytometry used in the fields of tissue typing, transplant genetics and crossmatch tests

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.:	1096030-40
Issue Date:	2022-01-28
Effective Date:	2022-02-11
Expiry Date:	2025-02-10

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000015611?locale=en or calling 1-888-743-4652.

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