Certificate

Certificate No.:	MD 1180721-1-1
Manufacturer:	**Fujirebio Diagnostics, Inc.** 940 Crossroads Blvd. Seguin TX 78155 USA
REPs Facility ID:	F001107
Certification criteria:	ISO 13485:2016 Canada Medical Devices Regulations – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and Development, Manufacture and Distribution of calibrators, controls and in vitro diagnostic reagents used in the monitoring and/or detection of blood analytes, infectious diseases and fertility testing.

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.:	234210788-11
Issue Date:	2024-09-09
Effective Date:	2024-09-09
Expiry Date:	2026-06-02

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Michiaki Aihara

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.

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