Certificate

Certificate No.:	MD 3329934-200
Manufacturer:	**Fujirebio Diagnostics AB** Elof Lindälvs gata 13 SE-414 58 Göteborg Sweden
D-U-N-S No.:	357159631
Certification criteria:	ISO 13485:2016 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
Scope:	Design and Development, Manufacture and Distribution of in-vitro diagnostic test kits and reagents used for the determination of cancer and other disease state biomarkers for diagnosis and management of patients with cancer and other disease states

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.:	3329934-110
Issue Date:	2020-10-07
Effective Date:	2020-11-28
Expiry Date:	2023-10-07

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Daniele Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000058941?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124