

Certificate of Approval

This is to certify that the Management System of:

Fujirebio Diagnostics, Inc.

201 Great Valley Parkway, Malvern, PA, 19355, United States

MDSAP Facility Identifier: 04-852-4263

has been audited by LRQA and found to conform to the following audit 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 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



Cliff Muckleroy - Area Operations Manager Americas
Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 0112325

Effective Date: 2019 February 6

Expiry Date: 2022 February 5

Certificate Identity Number: 10171952

Original approval(s):

MDSAP / ISO 13485 – 2001 May 4

Approval number(s): MDSAP – 0078138

The scope of this approval is applicable to:

Design and Manufacture of Quantitative In Vitro Diagnostic Tumor Marker Kits for Monitoring of Specific Disease Conditions.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>