

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: F003527

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

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

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820

Approval number: MDSAP – 0078138

The scope of this approval is applicable to:

Contract Design and Manufacture of In Vitro Diagnostic Test Kits and Reagents. Design and Manufacture of In Vitro Diagnostic Tumour Marker Tests for the Monitoring of Specific Disease Conditions.



Cliff Muckleroy

Area Operations Manager Americas

Issued by: LRQA Limited

for and on behalf of: LRQA Inc.



LRQA Limited is an MDSAP authorised auditing organization.

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

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.

Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom for and on behalf of: LRQA Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States