Certificate approval number:	UQA0112325	Original approval:
Effective date:	2022 February 6	MDSAP/ISO 13485 - 2001 May 4
Expiry date:	2025 February 5	
Certificate issue number:	10425432	

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.

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

LRQA Limited is an MDSAP authorised auditing organization.