6 February 2022 5 February 2025 10425433

Original approval(s): ISO 13485 - 4 May 2001

## **Certificate of Approval**

This is to certify that the Management System of:

## Fujirebio Diagnostics, Inc.

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

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 0014049

## 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.

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**Cliff Muckleroy** 

Area Operations Manager Americas

Issued by: LRQA Inc.

for and on behalf of: LRQA Limited



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