

Certificate of Approval

This is to certify that the Management System of:

Agilent Technologies, Inc. Genomics Solutions Division

1834 State Highway 71 West, Cedar Creek, TX, 78612, United States

MDSAP Facility Identifier: 11-320-9121-002

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

ISO 13485:2016

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 00000881

Effective Date: 2018 November 21

Expiry Date: 2021 November 20

Certificate Issue Number: 10158188

Original Approval:

MDSAP/ ISO 13485 - 2009 November 1

Approval Number: MDSAP – 00017869

The scope of this approval is applicable to:

Design and Development of Microarrays, Reagents and Accessories used in the Diagnosis, Detection and/or Management of Molecular Genetic Testing. Manufacture of Reagents and Accessories used in the Diagnosis, Detection and/or Management of Molecular Genetic Testing.



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>