



# CERTIFICATE OF REGISTRATION

## Agilent Technologies, Inc.

5301 Stevens Creek Boulevard  
Santa Clara, California 95051 UNITED STATES

REPs Facility ID: F005193

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

### ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design, manufacture and service of in-vitro diagnostic test kits, reagents, automated slide stainers and cellular imaging systems used in the diagnosis and/or management of cancer, immune status, disease status, autoimmune status, blood analytes, immunological typing and disease management.

With additional locations listed on Addendum: 1

Authorized by

**Deborah Jennings-Conner**  
Global Regulatory Director  
UL Life and Health Sciences  
UL LLC



Check Certificate  
Status: [here](#)



File Number	A12643	Cycle Start Date	January 28, 2018
Certificate Number	1073.201201	Effective Date	December 1, 2020
Initial Issue Date	January 28, 2018	Expiry Date	January 27, 2021

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory  
Services UL, LLC is an  
MDSAP Recognized  
Auditing Organization**

UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA

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### Addendum 1

#### 2-1

REPs Facility ID: **F001395**

**Agilent Technologies, Inc.**

**6392 Via Real**

**Carpinteria, California 93013 UNITED STATES**

Performing: Corporate, Reagent R&D and PharmDx, sustaining engineering

#### 2-2

REPs Facility ID: **F001395**

**Agilent Technologies, Inc.**

**1170 Mark Ave.**

**Carpinteria, California 93013 UNITED STATES**

Performing: Production & Administrative Sales, Training, TSG, and configuration lab.

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### Additional Regulatory Requirements

#### 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

#### Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act (,as applicable)

#### United States:

- 21 CFR 820  
- 21 CFR 803  
- 21 CFR 806  
- 21 CFR 807 – Subparts A to D  
- 21 CFR 821 (where applicable)

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