



America

# CERTIFICATE

No. QS6 083208 0037 Rev. 03

**Certificate Holder:**

**Fujirebio Inc.**  
2-1-1 Nishishinjuku  
Shinjuku-ku, Tokyo  
163-0410 JAPAN

**Certification Mark:**



**Scope of Certificate:**

**See Page 2 for Overall Scope Statement.**

**Standard(s):**

**ISO 13485:2016**

**Regulatory Authority(ies):**

**Australia TGA, Health Canada, USA FDA, MHLW / PMDA.**  
**See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:**

**F001669**

**Effective Date:**

**2022-12-20**

**Expiry Date:**

**2025-03-04**

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**Date of Issue:** 2023-01-06

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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act

### United States

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

## Overall Scope Statement:

**Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Design and Development, Distribution, Installation, and Servicing of In-Vitro Diagnostic Instruments, Sampling Tips and Specimen Container used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents**

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**Facility(ies):**

Fujirebio Inc.  
2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN

Fujirebio Inc. Hachioji Facility  
51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Fujirebio Inc. Hachioji 3rd Facility  
935, Ishikawa-machi, Hachioji-shi, Tokyo, 192-0032 JAPAN

Fujirebio Inc. Tokachi Obihiro Facility  
8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun,  
Hokkaido, 080-0341 JAPAN

Fujirebio Inc. Ube Facility  
203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi,  
759-0134 JAPAN

Fujirebio Inc. Sagamihara Facility  
1-3-14, Tanashioda, Chuo-ku, Sagamihara-shi, Kanagawa, 252-  
0245 JAPAN

Fujirebio Inc. Atsugi-Aikawa Distribution Center  
4036-1, Nakatsu, Aikawa-cho, Aiko-gun, Kanagawa, 243-0303,  
JAPAN

Fujirebio Inc. Asahikawa Facility  
23-1975-167, Minamiyonjodori, Asahikawashi, Hokkaido, 078-  
8334 JAPAN

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## Facility Scopes:

### **Fujirebio Inc.**

2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN

Design and Development, and Distribution of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Distribution of In-Vitro Diagnostic Instruments, Sampling Tips and Specimen Container used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents

REPs Facility ID: F001669

### **Fujirebio Inc. Hachioji Facility**

51, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Design and Development, and Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Design and Development, Installation and Servicing of In-Vitro Diagnostic Instruments, Sampling Tips and Specimen Container used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, and Protein Metabolism

REPs Facility ID: F002354

### **Fujirebio Inc. Hachioji 3rd Facility**

935, Ishikawa-machi, Hachioji-shi, Tokyo, 192-0032 JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Coagulation, Endocrine Disorders, Immune Status, and Transmissible Agents

REPs Facility ID: F002356

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**Fujirebio Inc. Tokachi Obihiro Facility**

8-36, Nishi-3-sen, Aza-Otofuke, Otofuke-cho, Katou-gun, Hokkaido,  
080-0341 JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution,  
Wash Solution, Specimen Diluent and Control used in the Diagnosis,  
Management, and Detection of Blood Components, Cancer, Cardiac  
Markers, Disease Status, Endocrine Disorders, Fertility Testing,  
Immune Status, and Protein Metabolism  
REPs Facility ID: F002358

**Fujirebio Inc. Ube Facility**

203-152, Aza-Ushiake, Oaza-Yoshiwa, Ube-shi, Yamaguchi, 759-0134  
JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution,  
Wash Solution, Specimen Diluent and Control used in the Diagnosis,  
Management, and Detection of Blood Components, Cancer, Cardiac  
Markers, Disease Status, Endocrine Disorders, Fertility Testing,  
Immune Status, and Protein Metabolism  
REPs Facility ID: F002359

**Fujirebio Inc. Sagamihara Facility**

1-3-14, Tanashioda, Chuo-ku, Sagamihara-shi, Kanagawa, 252-0245  
JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution,  
Wash Solution, Specimen Diluent and Control used in the Diagnosis,  
Management, and Detection of Blood Components, Cancer, Cardiac  
Markers, Disease Status, Endocrine Disorders, Fertility Testing,  
Immune Status, and Protein Metabolism  
REPs Facility ID: F002357

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**Fujirebio Inc. Atsugi-Aikawa Distribution Center**

4036-1, Nakatsu, Aikawa-cho, Aiko-gum, Kanagawa, 243-0303,  
JAPAN

Distribution of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents; Distribution of In-Vitro Diagnostic Instruments, Sampling Tips and Specimen Container used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents  
REPs Facility ID: F002355

**Fujirebio Inc. Asahikawa Facility**

23-1975-167, Minamiyonjodori, Asahikawashi, Hokkaido, 078-8334  
JAPAN

Manufacture of In-Vitro Diagnostic Reagents, Substrate Solution, Wash Solution, Specimen Diluent and Control used in the Diagnosis, Management, and Detection of Blood Components, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, and Protein Metabolism  
REPs Facility ID: F005697

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