



America

CERTIFICATE

No. QS6 083208 0037 Rev. 07

Certificate Holder:

Fujirebio Inc.
1-8-1 Akasaka
Minato-ku, Tokyo
107-0052, JAPAN

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 083208 0037 Rev. 07](http://www.tuvsud.com/ps-cert?q=cert:QS6_083208_0037_Rev.07)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F001669

Report No.:

JN200350002643

Effective Date:

2024-09-18

Expiry Date:

2027-09-17

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Regulatory Requirements: Audit/Certification Criteria

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

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, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development, Manufacture, Distribution, Installation, and Servicing of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development and Distribution of In-Vitro Diagnostic Generic use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport and Sample Analyses

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Facility(ies):

Fujirebio Inc.

1-8-1 Akasaka, Minato-ku, Tokyo, 107-0052, JAPAN

Fujirebio Inc. Research and Development Center

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

Fujirebio Inc. Research and Development Center

5-6-50, Shinmachi, Hino-shi, Tokyo, 191-0002 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, Asahikawa-shi, Hokkaido, 078-8334 JAPAN

Facility Scopes:

Fujirebio Inc.

1-8-1 Akasaka, Minato-ku, Tokyo, 107-0052 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,

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Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Distribution of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Distribution of In-Vitro Diagnostic Generic Use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport, and Sample Analyses
REPs Facility ID: F001669

Fujirebio Inc. Research and Development Center
153, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN

Design and Development 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, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development of In-Vitro Diagnostic Generic use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport, and Sample Analyses
REPs Facility ID: F002354

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Fujirebio Inc. Research and Development Center

5-6-50, Shinmachi, Hino-shi, Tokyo, 191-0002 JAPAN

Design and Development 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, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Design and Development of In-Vitro Diagnostic Generic use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport, and Sample Analyses
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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Facility Scopes:

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, Neurodegeneration, 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 and Specimen Diluent) used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents
REPs Facility ID: F002359

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Facility Scopes:

Fujirebio Inc. Sagamihara Facility

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

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, Neurodegeneration, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism and Transmissible Agents;

Manufacture, Distribution, Installation and Servicing of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Distribution of In-Vitro Diagnostic Generic use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport, and Sample Analyses
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Facility Scopes:

Fujirebio Inc. Atsugi-Aikawa Distribution Center

4036-1, Nakatsu, Aikawa-cho, Aiko-gun, 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, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Distribution of In-Vitro Diagnostic Instruments used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Neurodegeneration, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;

Distribution of In-Vitro Diagnostic Generic use Consumables (Sampling Tips and Specimen Container) for Sample Collection, Sample Transport, and Sample Analyses
REPs Facility ID: F002355

Fujirebio Inc. Asahikawa Facility

23-1975-167, Minamiyonjodori, Asahikawa-shi, 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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