



Certificate

No. Q5 083208 0032 Rev. 06

Holder of Certificate: **Fujirebio Inc.**
1-8-1 Akasaka
Minato-ku, Tokyo
107-0052, JAPAN

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Kits and 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.
Provision of antibody, antigen, substrate, magnetic particles, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including design and development, manufacturing)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 083208 0032 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_083208_0032_Rev_06)

Report No.: JN200350002643

Valid from: 2024-09-06
Valid until: 2027-09-05

Date, 2024-08-27



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Fujirebio Inc.**
1-8-1 Akasaka, Minato-ku, Tokyo, 107-0052, JAPAN

Design and Development and Distribution of In-Vitro Diagnostic Kits and 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.
Provision of antibody, antigen, substrate, magnetic particle, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including design and development)

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

Design and Development of In-Vitro Diagnostic Kits and 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;
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Facility(ies):

Fujirebio Inc. Research and Development Center

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

Design and Development of In-Vitro Diagnostic Kits and 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;

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Provision of antibody, antigen, substrate, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including design and development)

Fujirebio Inc. Hachioji 3rd Facility

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

Manufacture of In-Vitro Diagnostic Kits and 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.

Fujirebio Inc. Sagamihara Facility

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

Manufacture and Distribution of In-Vitro Diagnostic Kits and 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.

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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 Kits and 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.

Provision of antibody, antigen, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including manufacturing)

Fujirebio Inc. Ube Facility

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

Manufacture of In-Vitro Diagnostic Kits and 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.

Fujirebio Inc. Atsugi-Aikawa Distribution Center

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

Distribution of In-Vitro Diagnostic Kits and 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;

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