



# Certificate

No. Q5 083208 0032 Rev. 05

**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, 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 used in the Diagnosis, Management, and Detection of Autoimmune Status, Blood Components, Cancer, Cardiac Makers, 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 particle, 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 and certification regulation of 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 083208 0032 Rev. 05)

**Report No.:** JN2068411\_CN

**Valid from:** 2023-11-21  
**Valid until:** 2024-09-05

**Date,** 2023-11-21



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, 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, 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, magnetic particle, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including design and development)

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

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, 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. 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

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, 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, manufacturing)

### **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, 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)

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## Facility(ies):

### **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, 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  
Provision of antibody, antigen, substrate and magnetic particle, labeled antibody and labeled antigen used in In-Vitro Diagnostic Reagents (including manufacturing)

### **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, Cancer, Cardiac Markers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents;  
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Distribution of In-Vitro Diagnostic generic use consumables (Sampling Tips and Specimen Container) for Sample collection, Sample transport and Sample analyses.

### **Fujirebio Inc. Asahikawa Facility**

23-1975-167, Minamiyonjodori, Asahikawashi, Hokkaido, 078-8334 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, Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, and Protein Metabolism



Product Service

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## Facility(ies):

### **Fujirebio Inc. Shinjuku Facility**

2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 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, 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, Cancer, Cardiac Makers, Coagulation, Disease Status, Endocrine Disorders, Fertility Testing, Immune Status, Protein Metabolism, and Transmissible Agents.

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