



# Certificate

No. Q5 083208 0032 Rev. 03

**Holder of Certificate:** **Fujirebio Inc.**  
2-1-1 Nishishinjuku  
Shinjuku-ku, Tokyo  
163-0410 JAPAN

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of Immunoassay Reagent Kits, Reagent Kits for Biochemistry, Substrate Solution, Wash Solution, Specimen Diluent and Control**  
**Design and Development, Production and Distribution of Instruments for Immunoassay, Sampling Tips and Specimen Container**  
**Installation and Servicing of Instruments for Immunoassay**

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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_083208_0032_Rev_03)

**Report No.:** JN1667218

**Valid from:** 2021-09-06

**Valid until:** 2024-09-05

**Date,** 2021-09-02



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **Fujirebio Inc.**  
**2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN**

Design and Development, Production and Distribution of  
Immunoassay Reagent Kits, Reagent Kits for Biochemistry,  
Substrate Solution, Wash Solution, Specimen Diluent and Control  
Distribution of Instruments for Immunoassay, Sampling Tips and  
Specimen Container

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

Design and Development, Production and Distribution of  
Immunoassay Reagent Kits, Reagent Kits for Biochemistry,  
Substrate Solution, Wash Solution, Specimen Diluent and Control  
Design and Development, Production and Distribution of  
Instruments for Immunoassay, Sampling Tips and Specimen  
Container  
Installation and Servicing of Instruments for Immunoassay

**Fujirebio Inc. Hachioji 2nd Facility**  
**153, Komiya-machi, Hachioji-shi, Tokyo, 192-0031 JAPAN**

Production and Distribution of Immunoassay Reagent Kits,  
Substrate Solution, Wash Solution, Specimen Diluent and Control

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

Production and Distribution of Immunoassay Reagent Kits,  
Reagent Kits for Biochemistry, Substrate Solution, Wash Solution,  
Specimen Diluent and Control

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

Production and Distribution of Immunoassay Reagent Kits,  
Substrate Solution, Wash Solution, Specimen Diluent and Control

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## Facility(ies):

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

Production and Distribution of Immunoassay Reagent Kits,  
Substrate Solution, Wash Solution, Specimen Diluent and Control

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

Production and Distribution of Immunoassay Reagent Kits,  
Substrate Solution, Wash Solution, Specimen Diluent and Control

**Fujirebio Inc. Distribution Center**  
1-17-19, Haijima-cho, Akishima-shi, Tokyo, 196-0002 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for  
Biochemistry, Substrate Solution, Wash Solution, Specimen  
Diluent and Control  
Distribution of Instruments for Immunoassay, Sampling Tips and  
Specimen Container

**Fujirebio Inc. Kuki Distribution Center**  
1662, Shimohayami, Kuki-shi, Saitama, 346-0022 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for  
Biochemistry, Substrate Solution, Wash Solution, Specimen  
Diluent and Control  
Distribution of Instruments for Immunoassay, Sampling Tips and  
Specimen Container

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

Production and Distribution of Immunoassay Reagent Kits,  
Substrate Solution, Wash Solution, Specimen Diluent and Control

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