



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

Certificate

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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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