



Certificate

No. Q5 083208 0032 Rev. 02

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, Nucleic Acid Test Reagent Kits and Accessories**
Design and Development, Distribution, Installation and Servicing of Instruments for Immunoassay and Accessories

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. 02

Report No.: **JN1600018**

Valid from: **2021-04-21**
Valid until: **2021-09-05**

Date, **2021-04-21**

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,
Nucleic Acid Test Reagent Kits and Accessories
Distribution, Installation and Servicing of Instruments for
Immunoassay and Accessories

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,
Nucleic Acid Test Reagent Kits and Accessories
Design and Development and Distribution of Instruments for
Immunoassay and Accessories

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

Production and Distribution of Immunoassay Reagent Kits and
Accessories

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 and Accessories

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

Production and Distribution of Immunoassay Reagent Kits and
Accessories

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

Production and Distribution of Immunoassay Reagent Kits and
Accessories

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Fujirebio Inc. Ube Facility

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

Production and Distribution of Immunoassay Reagent Kits and
Accessories

Fujirebio Inc. Distribution Center

1-17-19, Haijima-cho, Akishima-shi, Tokyo, 196-0002 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Shinagawa Facility

4-1-8, Kounan, Minato-ku, Tokyo, 108-0075 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Hokkaido Branch

**4-1-2, Nishi, Kita-7-jo, Kita-ku, Sapporo-shi, Hokkaido,
060-0807 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Tohoku Branch

**2-8-10, Ichiban-cho, Aoba-ku, Sendai-shi, Miyagi,
980-0811 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Kita Kanto Branch

**4-333-13, Sakuragi-cho, Omiya-ku, Saitama-shi, Saitama,
330-0854 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
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Distribution of Instruments for Immunoassay and Accessories

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Facility(ies):

Fujirebio Inc. Chubu Branch

**1-21-19, Meiekiminami, Nakamura-ku, Nagoya-shi, Aichi,
450-0003 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Osaka Branch

**3-9-14, Niitaka, Yodogawa-ku, Osaka-shi, Osaka, 532-0033
JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Chushikoku Branch

**1-10-19, Hikari-machi, Higashi-ku, Hiroshima-shi, Hiroshima,
732-0052 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Kyushu Branch

**2-10-1, Hakataeki-Higashi, Hakata-ku, Fukuoka-shi, Fukuoka,
812-0013 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Shutoken Branch

2-38-5, Akebono-cho, Tachikawa-shi, Tokyo, 190-0012 JAPAN

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

Fujirebio Inc. Kanagawa Branch

**2-10-27, Kitasaiwai, Nishi-ku, Yokohama-shi, Kanagawa,
220-0004 JAPAN**

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

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Facility(ies):

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

Distribution of Immunoassay Reagent Kits, Reagent Kits for
Biochemistry, Nucleic Acid Test Reagent Kits and Accessories
Distribution of Instruments for Immunoassay and Accessories

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

Production and Distribution of Immunoassay Reagent Kits and
Accessories

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