



Product Service

# CERTIFICATE

No. Q1N 17 05 83208 029

**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, Distribution, Installation and Servicing of Instruments for Immunoassay and Accessories

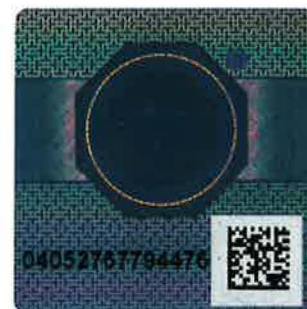
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** JNQ235029667

**Valid from:** 2017-11-01  
**Valid until:** 2020-10-31

**Date,** 2017-10-05

Stefan Preiß



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**DAKkS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



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**CERTIFICATE****No. Q1N 17 05 83208 029****Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2003 + Cor. 1:2009)  
 DIN EN ISO 13485:2012

**Facility(ies):**

**Fujirebio Inc.**  
**2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo, 163-0410 JAPAN**

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

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

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

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

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

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

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

**Fujirebio Inc. Shinagawa Facility**  
**4-1-8, Kounan, Minato-ku, Tokyo, 108-0075 JAPAN**

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

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**Facility(ies):**

**Fujirebio Inc. Tohoku Branch**  
2-8-10, Ichiban-cho, Aoba-ku, Sendai-shi, Miyagi  
980-0811 JAPAN

**Fujirebio Inc. Kita Kanto Branch**  
2-81, Miya-cho, Omiya-ku, Saitama-shi, Saitama  
330-0802 JAPAN

**Fujirebio Inc. Chubu Branch**  
1-21-19, Meiekiminami, Nakamura-ku,  
Nagoya-shi, Aichi 450-0003 JAPAN

**Fujirebio Inc. Osaka Branch**  
3-9-14, Niitaka, Yodogawa-ku, Osaka-shi, Osaka  
532-0033 JAPAN

**Fujirebio Inc. Chushikoku Branch**  
1-10-19, Hikari-machi, Higashi-ku, Hiroshima-shi,  
Hiroshima 732-0052 JAPAN

**Fujirebio Inc. Kyushu Branch**  
2-10-1, Hakataeki-Higashi, Hakata-ku, Fukuoka-shi,  
Fukuoka 812-0013 JAPAN