



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 095123 0007 Rev. 05

Holder of Certificate: **Hangzhou AllTest Biotech Co., Ltd.**
550#, Yin Hai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology), Haemostasis, Infectious Diseases, and Immunohaematology (Blood Grouping), including Professional Laboratory Use, Near Patient and Self Testing**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 095123 0007 Rev. 05

Report No.: SH24106402_CN

Valid from: 2025-04-16

Valid until: 2026-09-24

Date, 2025-04-16

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): **Hangzhou AllTest Biotech Co., Ltd.**
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Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA

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Diagnostic Reagents, Control Material and Instruments for Clinical
Chemistry, Immunochemistry (Immunology), Haemostasis,
Infectious Diseases, and Immunohaematology (Blood Grouping),
including Professional Laboratory Use, Near Patient and Self
Testing

Hangzhou AllTest Biotech Co., Ltd.
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Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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