



# Certificate

No. Q5 107987 0001 Rev. 01

**Holder of Certificate:** **Ameritech Diagnostic  
Reagent (Jiaxing) Co., Ltd.**

K4-2 Science Technology Garden, Economic Development Zone  
314500 Tongxiang, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution  
of In Vitro Diagnostic Test Kits(Rapid Colloidal Gold  
Method) used in the diagnosis of infectious diseases,  
fertility and pregnancy.  
Production and Distribution of Urinalysis Strip and  
rapid colloidal gold in vitro diagnostic test products.

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 107987 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 107987 0001 Rev. 01)

**Report No.:** SH21163401

**Valid from:** 2021-11-11

**Valid until:** 2024-07-07

**Date,** 2021-11-11

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):**

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K4-2 Science Technology Garden, Economic Development Zone,  
314500 Tongxiang, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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