



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

No. V1 17 06 95123 008

### Manufacturer:

**Hangzhou AllTest Biotech Co., Ltd.**

550#, Yinhai Street  
Hangzhou Economic and Technological Development Area  
310018 Hangzhou  
PEOPLE'S REPUBLIC OF CHINA



### EC-Representative:

**MedNet GmbH**

Borkstrasse 10  
48163 Muenster  
GERMANY

### Product

### Category(ies):

**Products for determination of infection markers  
tumor markers and products for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

### Report No.:

SH17106403

### Valid from:

2017-09-12

### Valid until:

2021-06-14

Date, 2017-09-12

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Model(s):**

**Toxo IgG/IgM Rapid Test,  
CMV IgM Rapid Test,  
PSA Rapid Test,  
PSA Qualitative Rapid Test,  
Rubella IgM Rapid Test,  
Chlamydia Rapid Test,  
ToRCH IgM Combo Rapid Test,  
Sperm Concentration Rapid Test,  
hCG Rapid Tests, LH Rapid Tests,  
FSH Rapid Test, Ferritin Rapid Test,  
TSH Rapid Test, H.pylori Rapid Test,  
Urinary Tract Infection Test,  
FOB Rapid Test,  
Vaginal pH Rapid Test**

**Facility(ies):**

**Hangzhou AllTest Biotech Co., Ltd.  
550#, Yinhai Street, Hangzhou Economic and  
Technological Development Area, 310018  
Hangzhou, PEOPLE'S REPUBLIC OF CHINA**