



# 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 095123 0008 Rev. 03**

**Manufacturer:**

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

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

**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. 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:V1\\_095123\\_0008\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:V1_095123_0008_Rev.03)

**Report no.:** SH211064EXT01

**Valid from:** 2021-06-15

**Valid until:** 2024-05-26

**Date,** 2021-05-21

Christoph Dicks  
Head of Certification/Notified Body



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## Model(s):

**Toxo IgG/IgM Rapid Test,  
Rubella IgM Rapid Test,  
CMV IgM Rapid Test,  
ToRCH IgM Combo Rapid Test,  
PSA Rapid Test,  
PSA Qualitative Rapid Test,  
Chlamydia Rapid Test,  
Sperm Concentration Rapid Test,  
SP-10 Male Fertility Rapid Test,  
hCG Rapid Test,  
Digital hCG Pregnancy Test  
LH Rapid Test,  
FSH Rapid Test,  
Vaginal pH Rapid Test,  
Ferritin Rapid Test,  
TSH Rapid Test,  
H.pylori Rapid Test,  
Urinary Tract Infections Test,  
FOB Rapid Test,  
Vitamin D Rapid Test**

## Facility(ies):

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