



## Test Strep A

Cassetta Per Test Rapido Strep A  
(Tampone Faringeo)

- ✓ Accurato
- ✓ Facile da usare
- ✓ Risultato rapido

contiene 1 test

**RISULTATO IN 5 MINUTI**

Solo per uso diagnostico professionale in vitro

## *EC Declaration of Conformity*

**Manufacturer:**

Name: HANGZHOU ALLTEST BIOTECH CO.,LTD.

Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area,  
Hangzhou -310018, P.R. China

**European Representative:**

Name: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Strep A Rapid Test Cassette

Analyte: Strep A antigens in human throat swab.

Cat. No.: IST-502

Model: Cassette

Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)

EDMA Code: 15 70 01 03 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

**General applicable directives:**

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27  
October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO  
18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN  
ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of First Issue of DOC in Hangzhou on 18/12/2019

Place, Date of Issue: in Hangzhou on 30/04/2022

Signature: 

Name: GAO FEI (Position: General Manager)





Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-245.10.07



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 095123 0008 Rev. 04**

**Manufacturer:**

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

550#, Yinhai 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. 04](http://www.tuvsud.com/ps-cert?q=cert:V1 095123 0008 Rev. 04)

**Report no.:**

SH221064A02

**Valid from:**

2022-04-05

**Valid until:**

2025-05-26

**Date,**

2022-04-05

Christoph Dicks

Head of Certification/Notified Body



# 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. 04**

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

杭州奥泰生物技术股份有限公司 Hangzhou AllTest Biotech Co.,Ltd	文件号 Document No.: ZTC-QC-005-R-003
传染病、心肌、肿瘤类 COA The Infectious Disease、Cardiology、Tumor COA	生效日期 Effective Date: 2018 年 07 月 02 日

## Certificate of Analysis

**Product Name: Strep A Rapid Test Cassette (Throat Swab)**

**Catalog No.: IST-502**

**Batch No.: STA25020019**

**Quantity:1000PCS**

**Expiry Date:2027-01**

**Date of Sampling:2025-03-04**

**Date of Analysis:2025-03-04**

**Other information:**

**Extraction reagent 1 Lot: 25025299, EXP: 2027-01**

**Extraction reagent 2 Lot: 25025300, EXP: 2027-01**

QC Item		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	1E+07CFU/ml	Positive	100% Positive	Pass
	2.5E+07CFU/ml	Positive	100% Positive	Pass
	Positive Control	Positive	100% Positive	Pass
	0.5%BSA-PBS	Negative	100% Negative	Pass
	Negative Control	Negative	100% Negative	Pass

<b>Others</b>	/
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<b>Final QC Conclusion:</b>	This batch of product met the QC Criteria.
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传染病、心肌、肿瘤类 COA The Infectious Disease、Cardiology、Tumor COA	生效日期 Effective Date: 2018 年 07 月 02 日

QC supervisor: *Freeman.zheng*

Date: 2025.03.04



Control