SARS-CoV-2 Antigen Rapid Test

(Nasal Swab)

Product Brochure

Hangzhou AllTest Biotech Co.,Ltd.
www.alltests.com.cn

Contents

White List of Validatiion

EU Common List & EU Recommendation List(Health Security Committee)

Ct No.	RAT comm-ercial name	CE marking	Clinical performance Data by manufacturer	Clinical performance Data used in MS	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)10	In FIND database
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test	YES	/	DE:93,40% sensitivity, 99,90% specificity	/	AT, BE, BG, FR, SI, RO	CH	DE	AT	Yes (1257)	Yes

Paul-Ehrlich-Institut

übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend" bewertet wurden

Testname	Hersteller
AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	Hangzhou AllTest Biotech Co.,Ltd.

White Listed in:

1. BFARM: AT766/21 AT1151/21 Germany — Bundesinstitut für Arzneimittel und Medizinprodukte
2. Switzerland — Schweizerische Eidgenossenschaft, Confédération suisse, Confederazione Svizzera, Confederaziun svizra
3. Belgium — fagg
4. France — MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ
5. Slovenia — REPUBLIKA SLOVENIJA GOV.SI
6. Portugal — Infarmed
7. Italy — Ministero della Salute
8. Austria — Austrian Federal Office for Safety in Health Care BASG
9. Croatia — HALMED
10. U.K. — MHRA
11. Brazil — ANVISA
12. Singapore — HSA
13. Philippines — FDA Philippines
14. Malaysia — Medical Device Authority
15. Myanmar
16. Japan : — Pmda Pharmaceuticals and Medical Devices Agency
17. India
18. Turkey
19. Chile

In addition, we have registered in more than 20 other countries, including, Hungary, Spain, Ukraine, Argentina, Indonesia, Serbia, Peru, Russia, Ecuador, Bulgaria, Guatemala, etc.

ALLTEST COVID-19 Rapid Tests Offer:

- ✓ **Reliable & High Accuracy :** Validated in many reputable laboratories from different countries with high sensitivity and specificity
- ✓ **Global Certification:** White listed (Professional Use) in many countries.
- ✓ **Multiple formats for different requirements.**
- ✓ **Simple operation, no equipment required**
- ✓ **Easy visually interpretation**
- ✓ **Fast results in 15 minutes assay time**

White list of Validation

Hangzhou AllTest Biotech Co.,Ltd.

Self Test Listing

CE1434	CERTIFICATE	BFARM: AT1172/21 Germany	Bundesinstitut für Arzneimittel und Medizinprodukte
Czech Republic	MINISTERSTVO ZDRAVOTNICTVÍ	Austria	Austrian Federal Office for Safety in Health Care BASG
France	MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ	Sweden	LÄKEMEDELSVERKET
Switzerland	Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra	U.K.	MHRA
Malaysia	Medical Device Authority		

Validated In:

Germany:

1. **The test has been evaluated and approved by a reputable laboratory from Germany:**
Clinical Study Results (>100 positive samples; > 100 negative samples):

1. Analytical Results with correlation to Ct-values of the positive samples:

Ct value	No. of Samples	No. of true positive Rapid Test Samples	No. of false negative Rapid Test Samples	Sensitivity of SARS-CoV-2 Antigen Rapid Test (CI)
≤30	82	81	1	98.8% (93-100)
≤32	106	101	5	95.3% (89-98)

2. Analytical Results with correlation to Ct-values of the negative samples:

No. of Samples	No. of true neg. Rapid Test Samples	No. of false positive Rapid Test Samples	Specificity of SARS-CoV-2 Antigen Rapid Test (CI)
100	100	0	100% (96-100), Wilson 95% CI: 96-100%

2. **France:**
SPIRAL Evaluation with good results: Sensitivity 97.1%, Specificity 100%

3. **Malaysia:**
IMR(Institute for Medical Research) Evaluation with good results: Sensitivity 96.0%, Specificity 100%

INSTITUTE FOR MEDICAL RESEARCH

4. **Japan :**
PMDA Evaluation with good results:
Sensitivity 100%, Specificity 100%

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

5. **Switzerland:**
BAG Evaluation with good results:
Sensitivity 95.1%, Specificity 100%

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

WHO

SARS-CoV Rapid Antigen Tests:
progress of the applications in the emergency use listing assessment pipeline

World Health Organization

Manufacturer name	Product name	Product code(s)	Dossier review	QMS Desk Assessment	EUL application number
Hangzhou AllTest Biotech Co	SARS-CoV-2 Antigen Rapid Test	INCP-502-N			0631-111-00

Web links: https://extranet.who.int/pqweb/sites/default/files/documents/210504_EUL_SARS-CoV-2_product_list.pdf

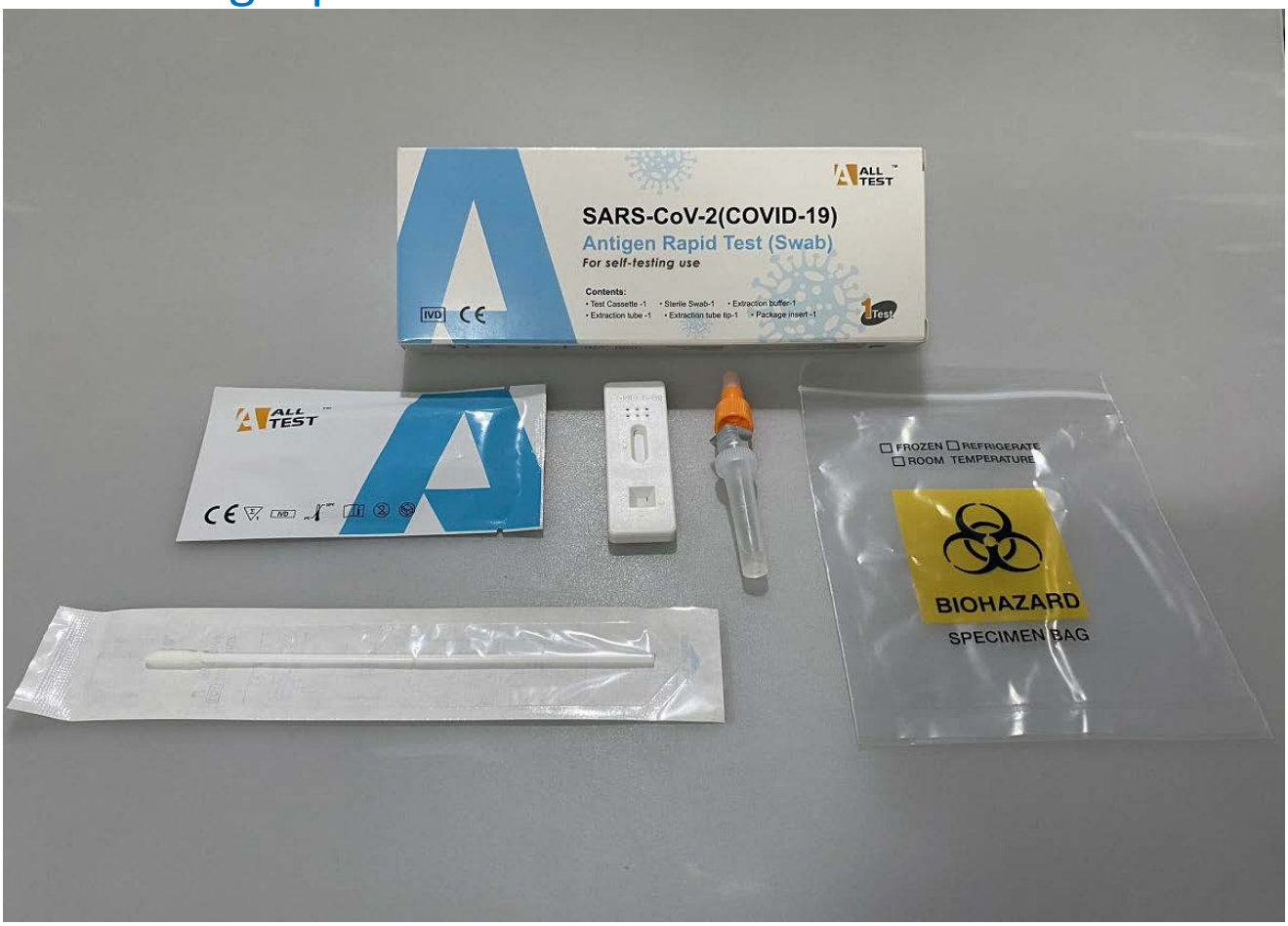
Published Articles in Health Science Journal

Web links: https://www.hsj.gr/medicine/different-methods-of-covid19-detection.pdf
Web links: https://www.hsj.gr/medicine/a-reallife-approach-for-evaluation-of-rapid-ag-testing-in-sarscov2-infection.pdf

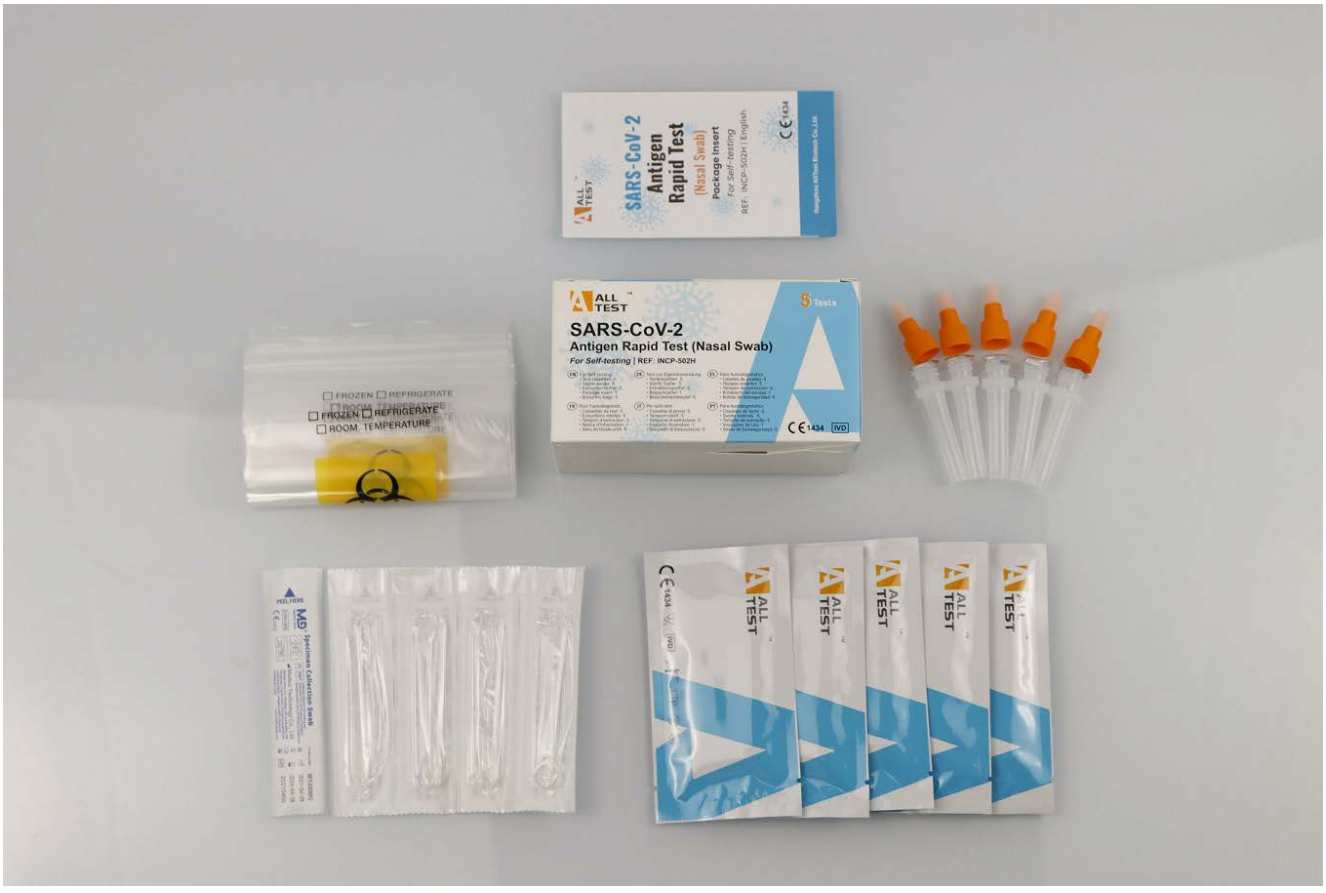
www.alltests.com.cn info@alltests.com.cn No. 550, Yinhai Street, Hangzhou Economy and Technology Development Area, Hangzhou P.R. China

Product Pictures

For single pack



For 5 tests per kit



Packing Information

SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
For self testing use

1T:

480pcs/carton

Size of carton: 55*39.5*46cm

Voulme of carton:0.1cbm ,

Weight of carton:15kgs

5T:

500pcs/carton

Size of carton: 50*34*33cm,

Voulme of carton:0.056cbm,

Weight of carton:15kgs

Declaration of Conformity

ALL TEST™

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 GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
Catalogue No.: INCP-502H
Model: Cassette
Classification: Self-testing of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC, Annex III, section 6
GMDN: 65454

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 corresponding national laws, the provisions of the following EC Council Directives, Standards and Common Technical Specifications. All supporting documentations are retained at 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 ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016,EN 13532:2002

Notified body: Polish Center for Testing and certification (CE1434)
(EC) Certificate(s): 1434-IVDD-438/2021
Expire date of the Certificate: 2024-05-27
Start of CE Marking: 2021-07-05
Place, Date of First Issue: in Hangzhou on 2021-07-05
The Date of Issue of DOC on 2021-10-08

Signature:
Name: Gao Fei (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological
Development Zone,
Hangzhou 310018, P.R.China
杭州奥盛生物技术股份有限公司
地址：杭州经济技术开发区
银海街550号
邮编：310018
TEL：+86 571 5026 7801
EMAIL：info@alltests.com.cn
http://www.alltests.com.cn
电话：+86 571 5026 7801
邮箱：info@alltests.com.cn
网址：www.alltests.com.cn

CE 1434 Certificate

CERTIFICATE

EC Certificate No. 1434-IVDD-438/2021
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou AllTest Biotech Co., Ltd,

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

in vitro diagnostic medical devices
for self-testing

SARS-COV-2 Antigen Rapid Test (Nasal Swab)
The list of medical devices covered by this certificate is provided in the annex 1

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 05.07.2021 to 27.05.2024

The date of issue of the Certificate: 05.07.2021

The date of the first issue of the Certificate: 05.07.2021

CE 1434

Issued under the Contract No. MD-34/2021
Application No: 048/2021
Certificate bears the qualified signature.
Warsaw, 05.07.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.07.05 20:01:31 +02'00'

Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-438/2021

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	REF. No.	Product Name
1	ALLTEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
2	Beright	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
3	JusChek	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
4	Lambra	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
5	SCREEN CHECK TEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
6	Rapid Response	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
7	gruppo Si.Gi.	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
8	AllChek	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
9	NovaTec Immundiagnostica GmbH	CVAG502H05	GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal Swab)
10	Mila	INCP-502H	Mila SARS-CoV-2 SZYBKI TEST ANTYGENOWY (Wymaz z nosa)

CE 1434

Issued under the Contract No. MD-34/2021
Application No: 048/2021
Certificate bears the qualified signature.
Warsaw, 06/10/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Date: 2021.10.06 10:10:02 +02'00'

Vice - President

ISO 13485 Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11371-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095123 0007 Rev. 03

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

Facility(ies): Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai 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 Kit for Obstetrics and Gynecology, Infectious Disease, Drug of Abuse, Vitamin, Special Protein, Oncology, Cardiology and Biochemistry, and Digital test for pregnancy and ovulation. Home use, Clinical Laboratory use and Near Patient In-vitro Diagnostic Devices and the related POCT analyzer.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH20106401

Valid from: 2020-09-25
Valid until: 2023-09-24

Date, 2020-08-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

TÜV®

BfArm List and PEI Approval

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SAR Impressum Administration

Liste der Antigen-Tests zur Eigenanwendung zum direkten Erregernachweis des Coronavirus SARS-CoV-2,

die Gegenstand des Anspruchs nach § 1 Satz 1 der "Verordnung zum Anspruch auf bestimmte Testungen für den Nachweis des Vorliegens einer Infektion mit dem Coronavirus SARS-CoV-2 (Coronavirus-Testverordnung – TestV)" sind.

Allgemeine Hinweise

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen oder deren erstmaliges Inverkehrbringen in Deutschland ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird („Sonderzulassung des BfArM").

Die Liste wird kontinuierlich aktualisiert, sobald seitens des BfArM weitere entsprechende Sonderzulassungen erteilt wurden, diese, z.B. durch Ablauf der Befristung der Sonderzulassung oder Abschluss der regulären Konformitätsbewertung und CE-Kennzeichnung, nicht mehr bestehen oder das Verfahren zur Aufnahme CE-gekennzeichneter Tests zur Eigenanwendung in die Liste erfolgreich abgeschlossen wurde.

Eine entsprechende Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** finden Sie unter folgendem Link.

AT1172/21 Los Aktionen

Nach 'AT1172/21' suchen

			Hersteller		Europäischer Bevollmächtigter	
Test-ID	Name des Tests	Evaluieru... PEI	Name	Land	Name	Land
AT1172/21	SARS-CoV-2 Antigen Schnelltest...	Ja	Hangzhou AllTest Biotech Co., Ltd.	CN	MedNet GmbH	DE

letzte Änderung: 18.11.2021 12:47

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

05.11.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	Hangzhou AllTest Biotech Co.,Ltd.