



SARS-CoV-2 Antigen Rapid Test

(Nasal Swab)

Product Brochure

Hangzhou AllTest Biotech Co.,Ltd.

www.alltests.com.cn

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Sell sheet of Product



Beright™

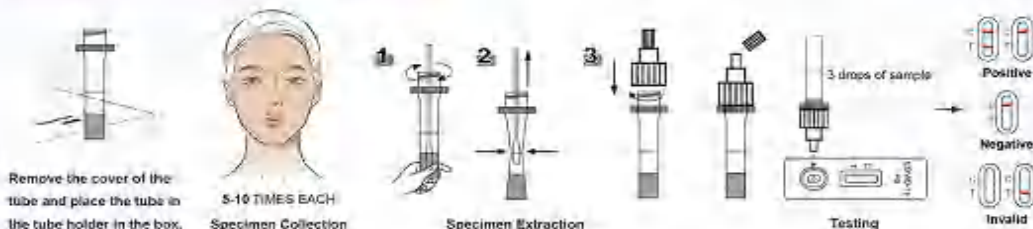
SARS-CoV-2 Antigen Rapid Test

- ✓ Self-testing format for high privacy
- ✓ Easy Nasal Swab specimen collection
- ✓ Fast results in 15 minutes assay time
- ✓ Easy visually interpretation
- ✓ Simple operation, no equipment required
- ✓ High accuracy
(Sensitivity: 95.4% / Specificity: 99.4% / Accuracy: 97.8%)

Easy Nasal Swab
Specimen Collection
Fast Home Testing

Self-Testing

Convenient Operation



Ordering Information

Cat. no.: INCP-502H
Product: SARS-CoV-2 Antigen Rapid Test
Specimen: Nasal Swab
Format: Cassette
Pack: 1T/5 T
CE Status: CE1434



📍 No. 550, Yin Hai Street, Hangzhou Economy and Technology Development Area, Hangzhou P.R. China
🌐 www.alltests.com.cn
✉ info@alltests.com.cn

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.



Beright
COVID-19 Antigen
Rapid Tests (Swab)
 We are now on the
EU Recommendation
and PEI Approval List !



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

| Ct.No. | RAT commercial name | CE marking | Clinical performance Data by manufacturer | Clinical performance Data used in MS | FINO 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 FINO database |
|------------------------------------|-----------------------------|------------|---|---|-------------------------|------------------------------------|-----------------------------------|--|-------------------------|---------------------------------|------------------|
| Hangzhou AllTest Biotech Co., Ltd. | COVID-19 Antigen Rapid Test | YES | | DE:93.40% sensitivity, 99.96% 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 | 11 | Brazil |  |
| 2 | Switzerland |  Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra | 12 | Singapore |  |
| 3 | Belgium |  | 13 | Philippines |  |
| 4 | France |  MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ | 14 | Malaysia |  |
| 5 | Slovenia |  REPUBLIKA SLOVENIJA GOV.SI | 15 | Myanmar |  |
| 6 | Portugal |  | 15 | Japan |  |
| 7 | Italy |  Ministero della Salute | 16 | India |  |
| 8 | Austria |  Austrian Federal Office for Safety in Health Care BASG | 17 | Turkey |  |
| 9 | Croatia |  | 18 | Chile |  |
| 10 | U.K. |  | | | |

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

Self Test Listing

| | | |
|-----------------------|--|---|
| CE1434 |  CERTIFICATE |  BFARM: AT1172/21 Germany |
| Czech Republic |  MINISTERSTVO ZDRAVOTNICTVÍ Palackého náměstí 375/4, 128 01 Praha 2 |  Austria Austrian Federal Office for Safety in Health Care BASG |
| France |  MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ |  Sweden LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY |
| Switzerland |  Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra |  U.K. MHRA |
| Malaysia |  Medical Device Authority Ministry of Health Malaysia | |

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 | 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%



4

Japan :

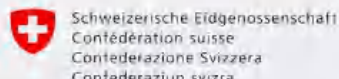
PMDA Evaluation with good results:
Sensitivity 100%, Specificity 100%



5

Switzerland:



BAG Evaluation with good results:
Sensitivity 95.1%, Specificity 100%



WHO

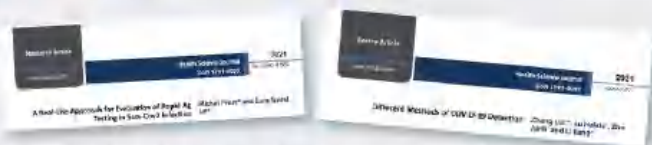
SARS-CoV Rapid Antigen Tests:
progress of the applications in the emergency use listing assessment pipeline



| 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 | INCR-502-N |  |  | 0831-111-00 |

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>

Product Pictures

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

Volume of carton:0.1cbm,

Weight of carton:15kgs

5T:

500pcs/carton

Size of carton: 50*34*33cm,

Volume of carton:0.056cbm,

Weight of carton:15kgs

Declaration of Conformity



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)



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

Vice-President

Elektronicznie
podpisany przez Annę
Małgorzata Wyroba
Data: 2021.07.05
2001:31+02:00



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) |



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 Annę
Małgorzata Wyroba
Data: 2021.10.06
10:10:02 +0200

Vice - President

ISO 13485 Certificate



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

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFIKAT • CERTIFICATE

BfArM List and PEI Approval

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](#).

| <input type="text" value="Q"/> | <input type="text" value="AT1172/21"/> | <input type="button" value="Los"/> | <input type="button" value="Aktionen"/> |
|--------------------------------|--|--|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="button" value="Nach 'AT1172/21' suchen"/> | <input type="button" value="X"/> |
| Test-ID | Name des Tests | Hersteller | Europäischer Bevollmächtigter |
| AT1172/21 | SARS-CoV-2 Antigen Schnelltest... | Hangzhou AllTest Biotech Co., Ltd. | MedNet GmbH |

Evaluiert
PEI
Ja

letzte Änderung: 18.11.2021 12:47

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

AllTest SARS-CoV-2 Antigen Rapid Test
(Nasal Swab)

Hangzhou AllTest Biotech Co.,Ltd.