Hangzhou AllTest Biotech Co.,Ltd.

ALLTEST
COVID-19 Antigen Rapid Tests (Swab)
We are now on the EU Recommendation 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	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

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, Agencija za lijekove i medicinske proizvode
10. **U.K.** — MHRA
11. **Brazil** — ANVISA
12. **Singapore** — HSA
13. **Philippines** — FDA Food and Drug Administration PHILIPPINES
14. **Malaysia** — Medical Device Authority, Ministry of Health Malaysia
15. **Myanmar**
16. **Japan** : Pmda 独立行政法人 医薬品医療機器総合機構 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.

Self Test Listing

CE1434 CERTIFICATE	**BFARM: AT1172/21 Germany** Bundesinstitut für Arzneimittel und Medizinprodukte
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 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%

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	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

CERTIFICATE

EC Certificate No. 1434-IVDD-429/2021

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

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 07.06.2021 to 27.05.2024

The date of issue of the Certificate: 07.06.2021

The date of the first issue of the Certificate: 28.05.2021

CE 1434

Issued under the Contract No. MD-136/2020
Application No: 333/2020a
Certificate bears the qualified signature.
Warsaw, 07.06.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.06.08 16:53:30 +02'00'

Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-429/2021

List of medical devices covered by the certificate:

Product	REF Number	Brand
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	ALLTEST
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Beright
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	JusChek
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Lambra
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	SCREEN CHECK TEST
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Rapid Response

CE 1434

Issued under the Contract No. **MD-136/2021**
Application No: 333/2020a
Certificate bears the qualified signature.
Warsaw, 07/06/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.06.08 16:52:41 +02'00'

Vice-President

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

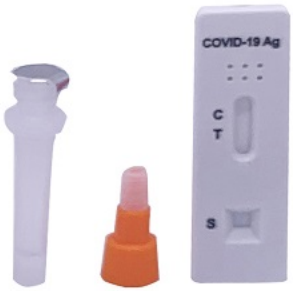
Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	Jinan Babio Biotechnology Co., Ltd.
GLINE-2019-nCoV Ag	Shenzhen YHLO Biotech Co. Ltd.
SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	Sansure Biotech Inc.
SARS-CoV-2 Antigen Schnelltestkassette	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
SARS-CoV-2-Antigen-Schnelltest	Hangzhou Careomedic Tech Co., Ltd.
AS-check COVID-19 Antigen Schnelltest	Asterion Otel Insaat Bilisim Medikal Maden Tic.Ltd.Sti.
Kanzone COVID-19 Antigen Rapid Test	Weihai Kangzhou Biotechnology Engineering Co., Ltd.
COVID-19 Antigen Test Kit	Surge Medical Inc.
GENEDIAN COVID-19 Antigen Test Cassette	Hangzhou DIAN Biotechnology Co., Ltd.
Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)	Changzhou Biowin Pharmaceutical Co.,Ltd.
SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)	Shenzhen Kang Sheng Bao Bio- Technology Co.,Ltd.
Rapidan Tester COVID-19 Ag Test	Türklab Tibbi Malzemeler San. ve Tic. A.S.
ISIA SARS-CoV-2 Antigen Rapid Test Kit	Chongqing ISIA BIO-Technology Co.,Ltd
Check Up SARS-CoV-2 Nasal Antigen Rapid Test	Cesna Biyoteknoloji Arastirma Gelistirme Laboratuvar Sist. Ins.Müh.Dan.San.Tic-Ltd.Sti (Istanbul, Turkey)
SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	Biohit Healthcare (Hefei) Co., Ltd. (Hefei, China)
Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)	Zhejiang Gene Science Co., Ltd. (Hangzhou Bay, China)
SARS-CoV-2 Antigen Rapid Test Cassette	Merlin Biomedical (Xiamen) Co., Ltd. (Xiamen, China)
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Shenzhen Dymind Biotechnology Co. Ltd. (Shenzhen, China)
Novel Coronavirus(2019-nCoV) Antigen Rapid Test	Bioscience (Tianjin) Diagnostic Technology Co., Ltd (Tianjin, China)
StrongStep® SARS-COV2 Antigen Rapid Test	Nanjing Liming Bio-Products Co., Ltd. (Nanjing, China)
COVID-19 Rapid Test Cassette Antigen Test Kit	Lifecosm Biotech Limited (Shenzhen, China)
COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)	Shenzhen Kingfocus Biomedical Engineering Co., Ltd.
SARS-Cov-2 Antigen Rapid Detection Kit	Shenzhen CAS-Envision Medical Technology Co., Ltd. (Shenzhen, China)
SARS-CoV-2 Ag Schnelltestkit	Hangzhou Jucheng Medical Products Co., Ltd
ZandCell COVID-19 Saliva Antigen-Test	ZandCell AB
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Wuhan HealthCare Biotechnology Co., Ltd.
AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	Hangzhou AllTest Biotech Co.,Ltd.
Saliva SARS-CoV-2 (2019-nCoV) Antigen Test Kit (Nanocarbon Assay)	Jiaxing Wisetest Bio-Tech Co., Ltd.
Bisdeal SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Test Cassette	Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.


SARS-CoV-2 Antigen
Rapid Test (Nasal Swab)
1 Test
ALL TEST
SARS-CoV-2
Antigen Rapid Test (Nasal Swab)
For Self-testing | REF: INCP-502H
CE 1434 IVD


COVID-19 Ag
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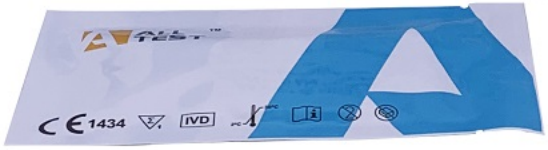
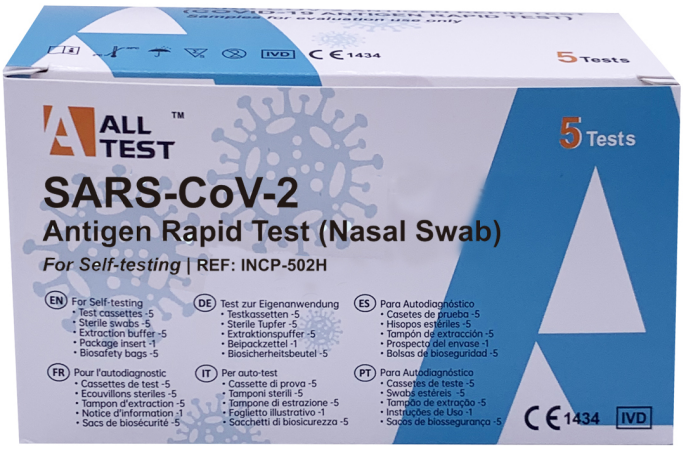

ALL TEST
CE 1434 IVD


ALL TEST
SARS-CoV-2
Antigen
Rapid Test
(Nasal Swab)
CE 1434 IVD
REF: INCP-502H
Hangzhou AllTest Biotech Co.,Ltd.


BIOHAZARD
SPECIMEN BAG


ALL TEST
SARS-CoV-2
Antigen Rapid Test (Nasal Swab)
For Self-testing | REF: INCP-502H
5 Tests
EN For Self-testing
• Test cassettes -5
• Sterile swabs -5
• Extraction buffer -5
• Package insert -1
• Biosafety bags -5
DE Test zur Eigenanwendung
• Testkassetten -5
• Sterile Tupfer -5
• Extraktionspuffer -5
• Beipackzettel -1
• Biosicherheitsbeutel -5
ES Para Autodiagnóstico
• Casetes de prueba -5
• Hisopos estériles -5
• Tampón de extracción -5
• Prospecto del envase -1
• Bolsas de bioseguridad -5
FR Pour l'autodiagnostic
• Cassettes de test -5
• Ecouvillons steriles -5
• Tampon d'extraction -5
• Notice d'information -1
• Sacs de biosécurité -5
IT Per auto-test
• Cassette di prova -5
• Tamponi sterili -5
• Tampone di estrazione -5
• Foglietto illustrativo -1
• Sacchetti di biosicurezza -5
PT Para Autodiagnóstico
• Cassetes de teste -5
• Swabs estéreis -5
• Tampão de extração -5
• Instruções de Uso -1
• Sacos de biossegurança -5
CE 1434 IVD


COVID-19 Ag
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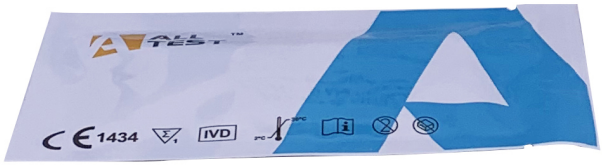

ALL TEST
CE 1434 IVD


ALL TEST
SARS-CoV-2
Antigen
Rapid Test
(Nasal Swab)
EN: For Self-testing P 1
DE: Test zur Eigenanwendung P 10
ES: Para Autodiagnóstico P 20
FR: Pour l'autodiagnostic P 30
IT: Per auto-test P 40
PT: Para Autodiagnóstico P 50
CE 1434 IVD
REF: INCP-502H
Hangzhou AllTest Biotech Co.,Ltd.


BIOHAZARD
SPECIMEN BAG

Cat. No.	Product Description	Specimen	Quantity/box	Quantity/Carton Package		Weight/Carton
INCP-502H	SARS-CoV-2 Antigen Rapid Test (for self testing)	Nasal Swab	1T per kit 20T一个中盒	480pcs (=24个中盒)	55*39.5*46 (0.1cbm)	15
INCP-502H	SARS-CoV-2 Antigen Rapid Test (for self testing)	Nasal Swab	5	300	40.5*38.9*32.7(0.052cbm)	8.5

ALL TEST™

SARS-CoV-2 Antigen Rapid Test

(Nasal Swab)

Package Insert

For Self-testing

REF: INCP-502H | English

CE 1434

Hangzhou AllTest Biotech Co.,Ltd.

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen. For self-testing in vitro diagnostic use.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2 that causes COVID-19 with self-collected nasal swab specimen from symptomatic individuals who are suspected of being infected with COVID-19.

Results are for the detection of SARS-CoV-2 Nucleocapsid protein Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases[1].

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.

- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- Test for children and young people should be used with an adult.
- Do not use the test on children under 2 years old.
- Small children should be swabbed with the help of a second adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test cassette
- Sterile swab

(CE0413, Medico Technology Co.,Ltd-Room 201of Building 14th and Building 17th Hengyi Lane,Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, Guangdong, China – EU Representative Wellkang Ltd. (www.CE-marking.eu) - Enterprise Hub.NW Business Complex, 1 BeraghmoreRD. Derry, BT 488SE, N.Ireland. UK)

- Package insert
- Extraction buffer
- Biosafety bag

Materials required but not provided

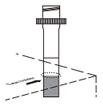
- Timer

PROCEDURE

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

1

Remove the cover of the tube with Extraction buffer and place the tube in the tube holder in the box.



2

Nasal swab specimen Collection

1. Remove the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.

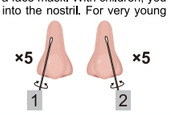
Note:

This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.

If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

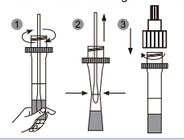
3. Gently remove the swab.
4. Using the same swab, repeat step 2 in your other nostril.
5. Withdraw the sterile swab



3

Specimen Preparation

1. Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for **10-15 seconds**.
2. Remove the swab while squeezing the swab head against the inside of the Extraction tube. Place the swab in the biosafety bag.
3. Close the cap of the extraction tube.



4

Testing

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

Place the test cassette on a plat and level surface.

2. Open the small cap and Invert the specimen extraction tube and add **3 drops of extracted specimen** to the **sample well(S)** of the test cassette and start the timer. Do not move the test cassette during test developing.
3. **Read the result at 15 minutes.** Do not read the result after 20 minutes.

Note: After test is completed, place all the components into plastic Biosafety Bag and dispose according to local regulation.

READING THE RESULTS

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T).
*NOTE: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

A positive results means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility according to the rules of your local authority. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed, mitigation/traveling, attending events and etc. should follow your local COVID guidelines/requirements.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact with a COVID-19 test center.

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.

ALL TEST™

2. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected, It is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
6. Failure to follow these procedures may alter test performance.
7. False negative results may occur if a specimen is improperly collected or handled.
8. False negative results may occur if inadequate levels of viruses are present in the specimen.

PERFORMANCE CHARACTERISTICS

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 Antigen Rapid Test with RT-PCR test result. The clinical trial included 847 nasal swab specimens. The results demonstrated 99.4% specificity and 95.4% sensitivity with an overall accuracy of 97.8%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	347	331	95.4% (Sensitivity)
Negative sample	500	497	99.4% (Specificity)
Total	847	828	97.8% (Total Accuracy)

95.4% Sensitivity: In total 347 PCR confirmed positive samples: 331 PCR confirmed positive samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are 16 false negative cases.
99.4% Specificity: In total 500 PCR confirmed negative samples: 497 PCR confirmed negative samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are only 3 false positive cases.
97.8% Accuracy: In total 847 PCR confirmed samples: 828 PCR confirmed samples were correctly detected by SARS-CoV-2 Antigen Rapid Test.
The observed accuracy may vary depending on the prevalence of the virus in the population.

Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.

Description	Test Level
Human coronavirus 229E	5x 10^5 $TCID_{50}$/ml
Human coronavirus NL63	1x 10^6 $TCID_{50}$/ml
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/ml
MERS coronavirus Florida	1.17x10^4 $TCID_{50}$/ml
Human coronavirus HKU1	1x 10^6 $TCID_{50}$/ml
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml
Influenza B	3.16 x 10^6 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^6 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 x 10^5 $TCID_{50}$/ml
Human Rhinovirus 16	8.89 x 10^5 $TCID_{50}$/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml
Arcanobacterium	1.0x10^8 org/ml
Candida albicans	1.0x10^8 org/ml
Corynebacterium	1.0x10^8 org/ml
Escherichia coli	1.0x10^8 org/ml
Moraxella catarrhalis	1.0x10^8 org/ml
Neisseria lactamica	1.0x10^8 org/ml
Neisseria subflava	1.0x10^8 org/ml
Pseudomonas aeruginosa	1.0x10^8 org/ml
Staphylococcus aureus subspaureus	1.0x10^8 org/ml
Staphylococcus epidermidis	1.0x10^8 org/ml
Streptococcus pneumoniae	1.0x10^8 org/ml
Streptococcus pygenes	1.0x10^8 org/ml
Streptococcus salivarius	1.0x10^8 org/ml
Streptococcus sp group F	1.0x10^8 org/ml

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Substance	Concentration	Substance	Concentration
Whole Blood	20μl/ml	Oxymetazoline	0.6mg/ml
Mucin	50μg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200μl/ml	Rebetol	4.5μg/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1μg/ml
Mupirocin	12mg/ml	Tobramycin	2.43mg/ml

EXTRA INFORMATIONS

1. How does the SARS-CoV-2 Antigen Rapid Test work?
The test is for the qualitative detection of SARS-CoV-2 antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 antigens present in the specimen.
2. When should the test be used?
SARS-CoV-2 antigen can be detected in acute respiratory tract infection, it is recommended to run the test when symptoms including sudden onset of at least one of the following: cough, fever, shortness of breath, fatigue, decreased appetite, myalgia.
3. Can the result be incorrect?
The results are accurate as far as the instructions are carefully respected.
Nevertheless, the result can be incorrect if inadequate sampling volume or the SARS-CoV-2 Antigen Rapid Test gets wet before test performing, or if the number of extraction buffer drops are less than 3 or more than 4. Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.
4. How to interpret the test if the color and the intensity of the lines are different?
The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the color intensity of the test line is.
5. What do I have to do if the result is negative?
A negative result means that you are negative or that the viral load is too low to be recognized by the test. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative.
If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility using the rules of your local authority. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection.
Distance and hygiene rules must still be observed.
Even with a negative test result, distance and hygiene rules must be observed, mitigation/traveling, attending events and etc. should follow your local COVID guidelines/requirements.

6. What do I have to do if the result is positive?
A positive result means the presence of SARS-CoV-2 antigens. A positive results means it is very likely you have COVID-19. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner / doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

BIBLIOGRAPHY

Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.

INDEX OF SYMBOLS

IVD	For *in vitro* diagnostic use only
2°C 30°C	Store between 2-30°C
	Do not use if package is damaged
	Manufacturer
EC REP	Authorized Representative
REF	Catalog #
Σ	Tests per kit
	Use by
LOT	Lot Number
	Consult Instructions For Use
	Do not reuse

EC REP **MedNet GmbH**
Borkstrasse 10 48163 Muenster Germany

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 1434

Number: 146424301
Effective Date: 2021-07-20

Black Pantone 638 C Pantone 151 C

☐ US ■ OUS ☐ DOMESTIC ☐ OTHER

Description	INCP-502H Alltest CE1434 English Package Insert	Part Number	146424301	Size	350x125mm
Designer	Fang	Design Date/Version	Jul 20 2021/A	Mold Num.	
Artwork Checked By		Material/ Checked By	128g铜版纸，折好到货		
Approved By Customer/Date		Approved By R&D/Date			
Approved By QA/RA/Date		Approved By P.M.T. /Date			
Approved By QA/Date		Effective Date			