

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:

- | | |
|---|--|
| <p>1 BFARM: AT766/21
AT1151/21
Germany</p>  | <p>11 Brazil</p>  |
| <p>2 Switzerland</p>  <p>Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra</p> | <p>12 Singapore</p>  |
| <p>3 Belgium</p>  | <p>13 Philippines</p>  |
| <p>4 France</p>  | <p>14 Malaysia</p>  |
| <p>5 Slovenia</p>  <p>REPUBLIKA SLOVENIJA
GOV.SI</p> | <p>15 Myanmar</p>  |
| <p>6 Portugal</p>  | <p>16 Japan</p>  |
| <p>7 Italy</p>  | <p>17 India</p>  |
| <p>8 Austria</p>  <p>Austrian Federal Office for Safety in Health Care
BASG</p> | <p>18 Turkey</p>  |
| <p>9 Croatia</p>  | <p>19 Chile</p>  |
| <p>10 U.K.</p>  | |

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

BFARM: AT1172/21
Germany

Czech Republic



Austria



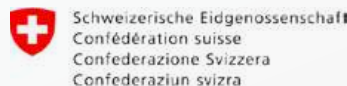
France



Sweden



Switzerland



U.K.



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%

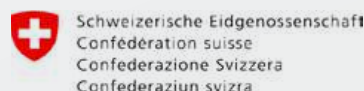
- 3 Malaysia: IMR(Institute for Medical Research) Evaluation with good results: Sensitivity 96.0%, Specificity 100%



- 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-real-life-approach-for-evaluation-of-rapid-ag-testing-in-sarscov2-infection.pdf>



CERTIFICATE

EC Certificate No. 1434-IVDD-036/2022

**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#, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, P.R. China**

**in vitro diagnostic medical devices
for self-testing**

COVID-19 Antigen Rapid Test (Oral Fluid)

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 **16.03.2022** to **27.05.2025**

The date of issue of the Certificate: **16.03.2022**

The date of the first issue of the Certificate: **28.05.2021**



Issued under the Contract No. MD-136/2020
Application No: 333/2020
Certificate bears the authorized person signature.
Warsaw, 16/03/2022
Module A1


President
Aleksandra Kostrzewa



ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-036/2022

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	Product Name	REF. No.
1	ALLTEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
2	Beright	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
3	JusChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
4	Lambra	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
5	SCREEN CHECK TEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
6	Rapid Response	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
7	AllChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
8	RYPO	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
9	Mila	Mila Covid-19 Szybki Test Antygenowy Ze Śliny	ICOV-802H
10	Novasalus	Test Rapido per l'Antigene COVID-19 (Fluido Orale)	ICOV-802H
11	Detect	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
12	DNA DIAGNOSTIC	COVID-19 Antigen Rapid Test (Oral Fluid)	CV19OFH
13	EQL PHARMA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-EQL1
14	INNOVA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
15	the one medical	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H



Issued under the Contract No. MD-136/2020
Application No: 333/2020
Certificate bears the authorized person signature.
Warsaw, 16/03/2022


President
Aleksandra Kostrzewa



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: COVID-19 Antigen Rapid Test (Oral Fluid)

Model: Cassette

Classification: Self-testing of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC, Annex III, Article 6

GMDN Code: 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 13532:2002, EN ISO 15223-1:2016.

Notified Body: Polish Center for Testing and Certification

Notified Body No.: CE1434

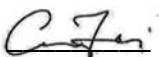
Address: 469, Pulawska Street, 02-844 Warsaw, Poland

EC Certificate Number: 1434-IVDD-429/2021

Expire date of the Certificate: 2024-05-27

Start of CE Marking: 2021-06-07

Place, Date of Issue: in Hangzhou on 2021-05-28

Signature: 

Name: Gao Fei (Position: General Manager)

2021-06-07

Date:

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological
Development Area,
Hangzhou -310018, P.R. China

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Pro-med COVID-19 Antigen Rapid Detection Kit	Pro-med (Beijing) Technology Co., Ltd.
Covid-19 Antigen Rapid Test (Oral fluid)	Hangzhou Alltest Biotech Co., Ltd.
Novel Coronavirus (COVID-19) Antigen Rapid Test Kit	Qingdao AIBO Diagnostic CO., LTD.
Rapid SARS-CoV-2 Antigen Test (Colloidal Gold)	InTec Products, Inc.
2019-nCoV Antigen Test Kit	Chongqing M&D Biotechnology Co. Ltd.
Synthgene Neues Coronavirus (SARS-CoV-2) Antigen-Schnellerkennungs-Kit (Collate Gold-Methode)	Nanjing Synthgene Medical Technology Co., Ltd.
Joysbio SARS-CoV-2 Antigen rapid test kit - PRO (Colloidal Gold)	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SureScreen COVID-19 Antigen Rapid	SureScreen Diagnostics Ltd.
2019-nCoV Ag Test (Latex Chromatography Assay)	Innovita (Tangshan) Biological Technology Co., LTD.
SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	Wuxi Biohermes Bio & Medical Technology Co., Ltd.
SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Zijian SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method)	Shen Zhen Zi Jian Biotechnology Co., Ltd.
New Coronavirus (COVID-19) Antigen Rapid Test	Anhui Formaster Biosci Co., Ltd
Sienna COVID-19 Antigen-Schnelltestkassette (Nasenabstrich)	Hangzhou Biotest Biotech Co., Ltd
SARS-CoV-2 Antigen Rapid Detection Kit (LFA)	Acro Diagnostics Co., Ltd
SARS-CoV-2 Antigen Test Cassette	Jiangsu Mole Bioscience Co., Ltd
SARS-CoV-2-Antigen-Schnelltestgerät	Hangzhou Funworld Biotech. Co., Ltd
COVID-19 Antigen Test Kit	Beijing Homa Biological Engineering Co., Ltd.
InstantSure Covid-19 Ag CARD	Suzhou Soochow University SAIER IMMUNO BIOTECH Co., Ltd.
KaiBILI COVID-19 Antigen Pro	Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.
SARS-Cov-2-Antigen-Schnelltest-Karte	BioDetect (Xiamen) Biotechnology Co., Ltd
Neuartiges Coronavirus (2019-nCoV) Antigendetektionsreagenz (immunochromatographischer Assay)	Zhongxiu Science and Technology Co., Ltd
Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)	Genobio Pharmaceutical Co., Ltd.
SARS-CoV-2 Ag Rapid Test	BioMaxima S.A.
SARS-Cov-2 Nucleocapsid(N) Antigen Rapid Test Cassette	Hangzhou Zheda Dixun Biological Gene Engineering CO. Ltd.
SARS-CoV-2 Antigen Rapid Test	Nantong Egens Biotechnology
Convergys® COVID-19 Rapid Antigen Test	Convergent Technologies
INVBIO One Step Diagnostic Rapid Test Cassette	Innovation Biotech (Beijing) Co. LTD
SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Shenzhen Huaree Technology Co., Ltd
Dräger Antigen Test SARS-CoV-2	Dräger Safety AG & Co. KGaA
LionRun™ SARS-CoV-2 Antigen Rapid Test Kit (Lateral Flow Immunoassay)	Shanghai Liangrun Biomedicine Technology Co., Ltd.
SARS-CoV-2 Antigen Saliva Rapid Test Kit	Shenzhen Huaree Technology Co., Ltd
SARS-CoV-2 Antigen Assay Kit by Latex Immunochromatography method	Sichuan Xincheng Biological Co., LTD
COVID-19 Schnelltestgerät	Jiangsu Well Biotech Co., Ltd.

Manufacturer	Cat. No.	Product Description	Specimen	Quantity/box	Quantity/ Carton Package		Weight/ Carton
ALLTEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (for self testing)	Nasal Swab	1T per kit 20T /Box	480 pcs (=24 Boxes)	55*39,5*46 cm (0,1 cbm)	18.9 kg
ALLTEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (for self testing)	Nasal Swab	5	500	50*34*33 cm (0,1 cbm)	11 kg
ALLTEST	INCP-802H	COVID-19 Antigen Rapid Test (Oral Fluid) For Self-testing	Oral Fluid	1	480	56.5*43.5*43.5 (0.1cbm)	20 kg