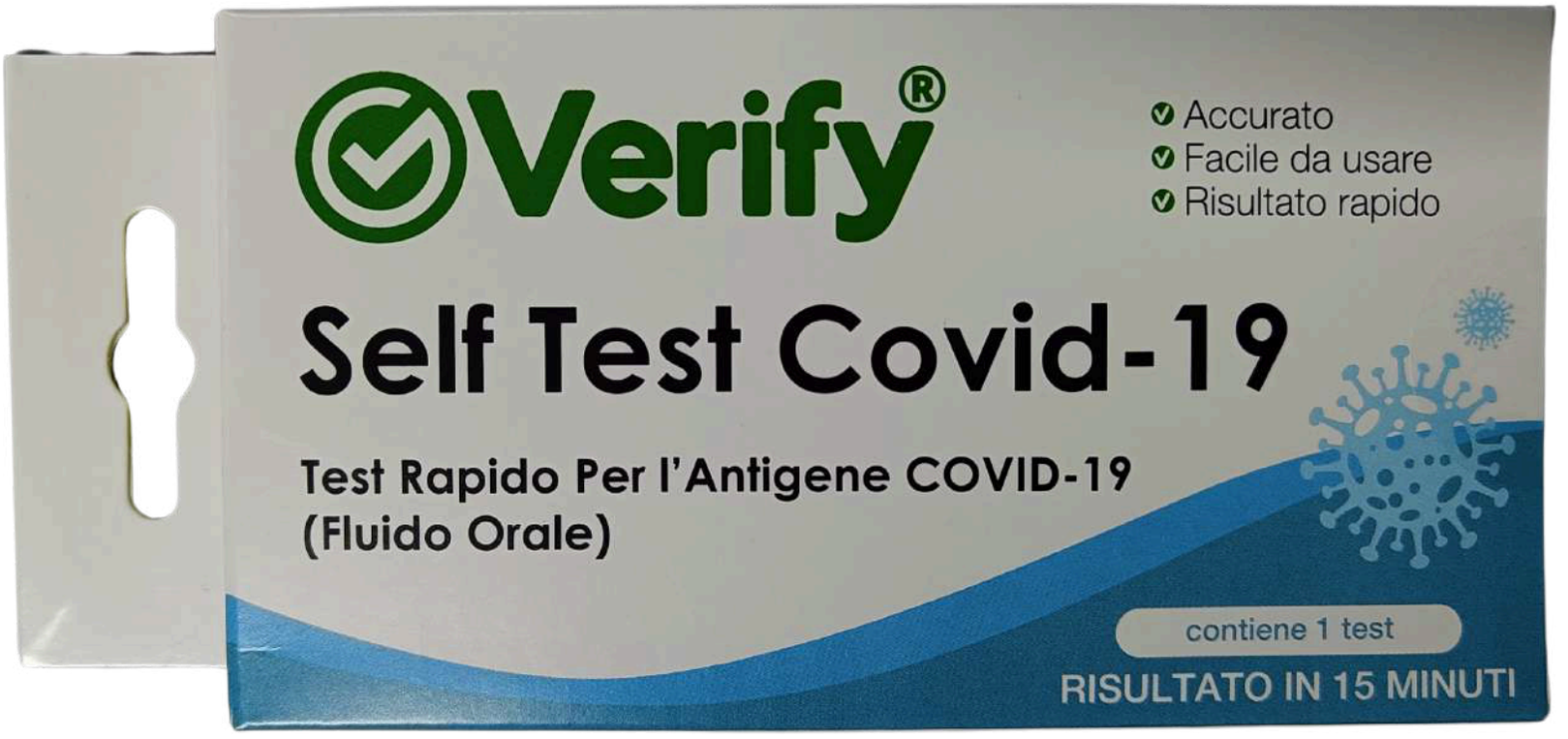
Verify®
Accurato
Facile da usare
Risultato rapido
Self Test Covid-19
Test Rapido Per l'Antigene COVID-19
(Fluido Orale)
contiene 1 test
RISULTATO IN 15 MINUTI

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#, Yinhai 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

CE 1434

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

Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

CE 1434

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 EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany.

Product Name: COVID-19 Antigen Rapid Test (Oral Fluid)
Catalogue No.: ICOV-802H
Analyte: SARS-CoV-2 nucleocapsid protein antigens in human 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 (CE1434)
Address: 469, Pulawska Street, 02-844 Warsaw, Poland
EC Certificate Number: 1434-IVDD-036/2022
Expire date of the Certificate: 2025-05-27
Start of CE marking: 2021-05-28
Place, Date of First Issue of DOC: in Hangzhou on 2021-05-28
The Date of Issue of DOC on 2022-04-21

HANGZHOU ALLTEST BIOTECH CO.,LTD. 3301180084165

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

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

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地 址：杭州市经济技术开发区
银海街550号
邮 编：310018

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EMAIL：info@alltests.com.cn
http:// www.alltests.com.cn

电 话：+86 571 56267891
邮 箱：info@alltests.com.cn
网 址：www.alltests.com.cn

Certificate of Analysis

Product Name: COVID-19 Antigen Rapid Test(Oral Fluid)

Catalog No.: ICOV-802H

Batch No.: COV25020003

Quantity:1000PCS

Expiry Date:2027-01

Date of Sampling: 2025-03-04

Date of Analysis: 2025-03-04

Other information:/

QC Item		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	Positive Sample	Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others	/

Final QC Conclusion：	This batch of product met the QC Criteria.

QC supervisor: Freeman.zheng

Date: 2025.03.04

杭州奥泰生物技术股份有限公司 质检章