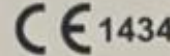




MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany



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



LOT AT SIN22100004

2024-08

SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)



6 936983 111065



For Self-testing | REF: ISIN-525H



SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)

PL Szybki test do wykrywania antygenów wirusów SARS-CoV-2 oraz Grypy A+B (wymaz z nosa). Do samodzielnego badania. Zawartość:
• Kasetka testowa - 1
• Bufor ekstrakcyjny - 1
• Ułóżki izolacyjne do opakowania - 1
• Sterylny wacik - 1

FR Test antigénico rápido combinado per SARS-CoV-2 e influenza A/B (tampono nasale). Per uso autodiagnostico. Contenuto:
• Cassette di test - 1
• Soluzione tampone di estrazione - 1
• Foglio illustrativo - 1
• Tampone sterile - 1

DK kombinerede SARS-CoV-2- og Influenza A+B antigen-hurtigttest (næsepodning). Til selvtestning. Indhold:
• Testkassette - 1
• Ekstraktionsbuffer - 1
• Indlægsstedel - 1
• Steril podespind - 1

DE SARS-CoV-2 und Influenza A+B Antigen-Kombi-Schnelltest (Nasenabstrich). Test zur Eigenanwendung. Inhalt:
• Testkassette - 1
• Extraktionspuffer - 1
• Packungsbeflage - 1
• Steriler Tupfer - 1

EN SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab). For Self-testing. Contents:
• Test cassette - 1
• Extraction buffer - 1
• Package insert - 1
• Sterile swab - 1

FI Yhdistelmä SARS-CoV-2- ja Influenza A+B -pika-antigeenitesti (nenänyytteistä). Kosteesti. Sisältö:
• Testikasetti - 1
• Uuttospuikku - 1
• Pakkausohje - 1
• Steriili näytelauku - 1

ES Prueba rápida combinada de antígenos del SARS-CoV-2 y de la gripe A y B (hisopo nasal). Para pruebas de autodiagnóstico. Índice:
• Casete de prueba - 1
• Tampón de extracción - 1
• Prospecto - 1
• Hisopo estéril - 1

RO Test rapid antigen combo SARS-CoV-2 și gripă A+B (tampon nazal). Pentru auto-testare. Conținut:
• Casetă de testare - 1
• Soluție tampon de extractivă - 1
• Prospect - 1
• Tampon steril - 1

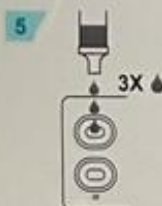
NL SARS-CoV-2- en Influenza A+B-antigeencombinatietest (wattenstaafje in de neus). Voor zelftest. Inhoud:
• Testkassette - 1
• Extractiebuffer - 1
• Bijlouter - 1
• Steriel wattenstaafje - 1

FR Test rapide de combinaison des antigènes SARS-CoV-2 et gripe A et B (écouvillon nasal). Pour l'autotest. Table des matières:
• Cassette de test - 1
• Tampon d'extraction - 1
• Notice - 1
• Écouvillon stérile - 1

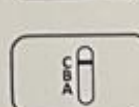
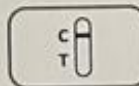
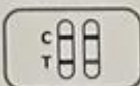
HU SARS-CoV-2 és influenza A+B Antigen Combo gyorseszét (orr-tampon). Önteszteléshez. Tartalom:
• Tesztokazetta - 1
• Extrakciós puffer - 1
• Használati útmutató - 1
• Steril tampon - 1

LT SARS-CoV-2 ir gripo A+B antigenų sudėtinis greitasis testas (nosies tepinėlis). Skirtas savikontrolėi. Turinys:
• Testo kasetė - 1
• Pakuotės informacinis lapelis - 1
• Sterilus tamponas - 1
• Ekstrahavimo buferinis tirpalas - 1

1
Test



SARS-CoV-2:



+

-

Tube holder

GreMDS ΦΟΤΕΙΝΗ ΛΟΥΜΠΑΡΙΑ

Επιστροφή Επιλογές

Κοινότητα In Vitro (Διανομέας) - Αρ. αίτησης #118163 - Προϊόντα

1 Μπορείτε να εξαγάγετε έμμεσα το όνομα, την περιγραφή και τον κωδικό κατασκευαστή κίνησης 'κ/κ' στο αντίστοιχο κελί.

α.α.	Όνομα (EL/EN)	Περιγραφή (EL/EN)	Κωδ. κατασκ.	Κατηγορία	Κωδικός προϊόντος
1 >	ALL TEST SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)	ALL TEST SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)		Device for Self-testing	
	ALL TEST SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)	ALL TEST SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)			

GreMDS ΦΟΤΕΙΝΗ ΛΟΥΜΠΑΡΙΑ

Επιστροφή Επιλογές

Κοινότητα In Vitro (Διανομέας) - Αρ. αίτησης #118163 - Γενικά στοιχεία

Γενικά στοιχεία αίτησης

Κατηγορία αίτησης	Κοινότητα In Vitro (Διανομέας)
Διαδικασία αίτησης	Νέα αίτηση
Κατάσταση αίτησης	Υποβολή
Ημ. Δημιουργίας	15/12/2022
Αρ. Πρωτοκόλλου	140866 / 15/12/2022



CERTIFICATE

EC Certificate No. 1434-IVDD-217/2022

**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 and Technological
Development Area, Hangzhou- 310018, P.R. China**

in vitro diagnostic medical devices
for self-testing

**SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test
(Nasal Swab)**

Copyright Reserved

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 24.05.2022 to 27.05.2025

The date of issue of the Certificate: 24.05.2022

The date of the first issue of the Certificate: 24.05.2022



Issued under the Contract No. MD-232/2021
Application No: 465/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

**Director
Medical Devices Certification
Department**

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD

Address: # 550, Yin Hai 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: SARS-COV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)

Cat. No.: ISIN-525H

Analyte: Qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen

Model: Cassette

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

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

EDMA Code: 15 70 90 90 00

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 transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under 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-217/2022

Expire date of the Certificate: 2025-05-27

Start of CE Marking: 2022-05-24

Signature: 

Name: Gao Fei (Position: General Manager)



Letter of Declaration

To whom it may concern,

We, HANGZHOU ALLTEST BIOTECH CO., LTD., located at #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

Declare that:

Alltest SARS-CoV-2(COVID-19) and Influenza A+B Antigen Combo Rapid Test is designated to detect the nucleocapsid protein (NP) of SARS-CoV-2 virus. Epitope of capture antibody and detection antibody used in Alltest SARS-CoV-2(COVID-19) and Influenza A+B Antigen Combo Rapid Test is not in the mutation area. Thus, above mentioned SARS-CoV-2 variants with spike protein mutation and nucleocapsid protein mutation of Alpha(B.1.1.7), Beta(B.1.351), Gamma(P.1), Delta(B.1.617.2), Lambda(C.37), Zeta(P.2), Kappa(B.1.617.1), Eta(B.1.525), Lota(B.1.526), Epsilon(B.1.427), Theta(P.3), Omicron(B.1.1.529), Omicron(BA.1), Omicron(BA.2), Omicron(BA.3), Omicron XE, Omicron BA.4 and Omicron BA.5 do not affect the detection performance of Alltest SARS-CoV-2(COVID-19) and Influenza A+B Antigen Combo Rapid Test.

Signature:

A handwritten signature in black ink, appearing to read 'Kael Chen', written over a horizontal line.

R&D Manager: Kael Chen

Date: April 22th, 2022

Hangzhou Alltest Biotech CO., Ltd

Add: #550 Yinhai Street, Hangzhou Economic and Technologic Development Area
310018, P.R China



WHO label	Pango lineage	GISAID clade/lineage	Neststrain clade	Spike protein mutations	Nucleocapsid protein mutations
Alpha	B.1.1.7	GRY, GR/501Y.V1	20I/501Y.V1, 20B/501Y.V1	del69/70, del144/144, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H	D3L, R203K, G204R, S235F
Beta	B.1.351	GH/501Y.V2	20H/501Y.V2	D80A, D215G, K417N, E484K, N501Y, D614G, A701V	T205I
Delta	B.1.617.2	G/452R.V3	21A/S:478K	T19R, G142D, E156G, del157/158, L452R, T478K, D614G, P681R, D950N	D63G, R203M, D377Y
Epsilon	B.1.427 & B.1.429	GH/452R.V1	20C/S.452R	S13I, W152C, L452R, D614G	T205I
Eta	B.1.525	G/484K.V3	20A/S484K	Q52R, A67V, del69/70, del144/144, E484K, D614G, Q677H, F888L	S2Y, del3/3, A12G, T205I



Gamma	P.1	GR/501Y.V3	20J/501Y.V3	L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I, V1176F	P80R, R203K, G204R
Kappa	B.1.617.1	G/452R.V3	21A/S:154K	L452R, E484Q, D614G, P681R, Q1071H	R203M, D377Y
Lambda	C.37	GR/452Q.V1	20D	G75V, T76I, R246N, del247/253, L452Q, F490S, D614G, T859N	P13L, R203K, G204R, G214C
Lota	B.1.526	GH	20C/S:484K	L5F, T95I, D253G, D614G	/
Omicron	B.1.1.529	GR/484A	21K	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, G339D, S371L, S373P, K417N, N440K, G446S, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	P13L, del31/33, R203K, G204R



Theta	P.3	GR	20B/S:265C	E484K, N501Y, D614G, P681H, E1092K, H1101Y, V1176F	R203K, G204R
Zeta	P.2	GR	20B/S.484K	E484K, D614G, V1176F	A119S, R203K, G204R, M234I
Omicron	BA.1	n/a	n/a	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, G339D, S371L, S373P, S375F, K477N, T478K, E484A, Q493R, Q496S, Q498R, N510Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, N856K, Q954H, N969K, L981F	P13L, del31/33, R203K, G204R
Omicron	BA.2	n/a	n/a	T95I, L24S, del25/27, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S,	P13L, del31/33, R203K, G204R, S413R



				K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N510Y, Y505H, T547K, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K,	
Omicron	BA.3	n/a	n/a	A67V, del69/70, T95I, G142D, del143/145, N211I, del212/212, T478K, D614G, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K	P13L, del31/33, R203K, G204R, S413R
Omicron	BA.4	n/a	n/a	T95I, L24S, del25/27, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N510Y, Y505H,	P13L, del31/33, P151S, R203K, G204R, S413R



				D614G, H655Y, N679K, P681H, D796Y, Q954H, N969K,	
Omicron	BA.5	n/a	n/a	T95I, L24S, del25/27, del69/70, G142D, V213G, G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N510Y, Y505H, D614G, H655Y, N679K, N764K, P681H, D796Y, Q954H, N969K,	P13L, del31/33, R203K, G204R, S413R

