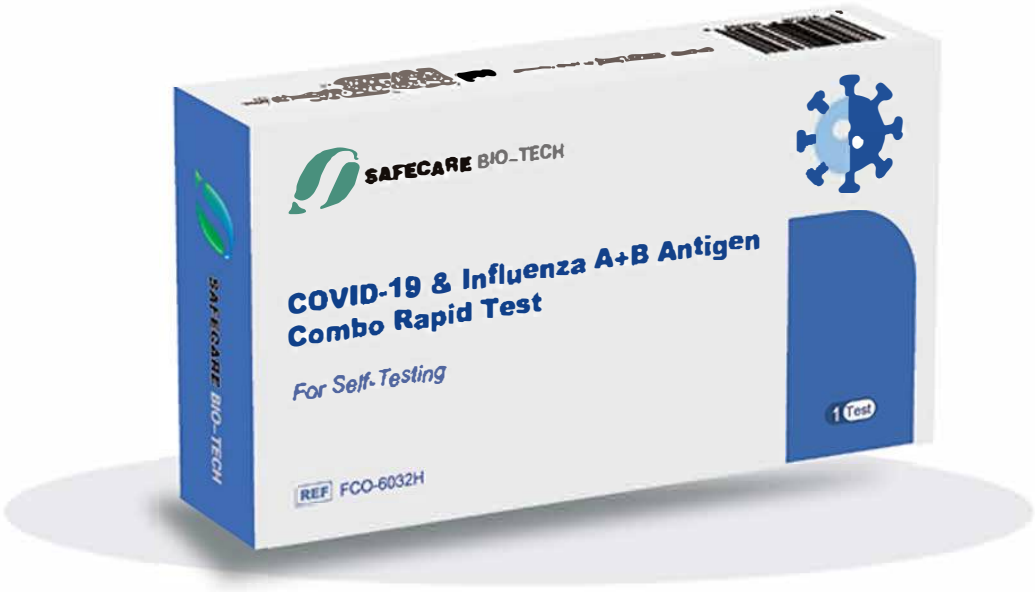
SAFECARE BIO-TECH

COVID-19 & Influenza A+B Antigen Combo Rapid Test

For Self-Testing



Intended Use:

The COVID-19 & Influenza A+B Antigen Combo Rapid Test is a single-use test kit intended for qualitative detection of nucleocapsid protein antigen of influenza A and B viral antigens and COVID-19 Antigen from nasal swab specimens at home.

Uvoznik za SLOVENIJO

3LAB+

3-LABPLUSd.o.o.
Nazorjeva ulica 3, 1000 Ljubljana, Slovenija

SAFECARE BIO-TECH

COVID-19 & Influenza A+B Antigen Combo Rapid Test

For Self-Testing

Product Features

- *High Accuracy*
- *Fast Results in 15 mins*
- *Easy Specimen Collection*
- *Easy for Private Home Use*
- *Simple operation, No equipment required*

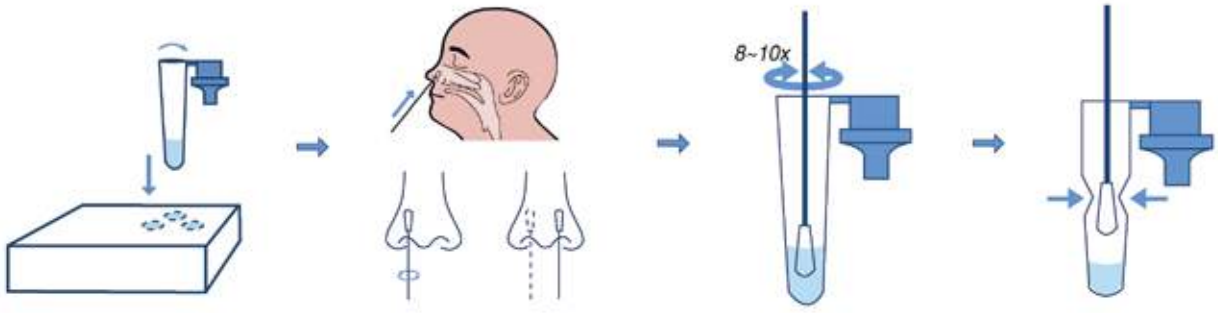
Contents

- *COVID-19 & Influenza A+B Antigen combo Test-1*
- *Extraction tube with buffer-1*
- *Sterilized nasal swab-1*
- *Package insert-1*
- *Waste bag-1*

SAFECARE BIO-TECH

使用过程
Convenient Procedure

Scan to see the test video



Peel off the foil film on the extraction tube and insert into the hole

Insert nasal swab to an appropriate depth, roll 5 times in each nostril

Rotate the swab 8-10 times

Press the swab and release as much liquid as possible

Place the cap

Add 3 drops to each sample well(S)

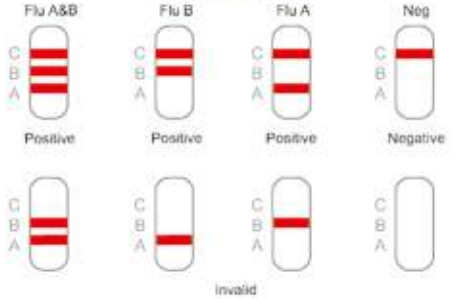
Read the result

Results Interpretation

For COVID-19

Positive Negative Invalid

For FLu A/B



SAFECARE BIO-TECH

包装信息
Packing Information

Brand:SAFECARE

Product name:COVID-19 & Influenza A+B Antigen Combo Rapid Test For Self-Testing

Package:1T/box

CTN Size:63×37×30cm

QTY:300Tests/CTN

G.W.:9kgs

N.W.:7kgs

Inner box size:122×67×22mm

CeCert.

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Safecare Biotech (Hangzhou) Co., Ltd.
Building 2/203, No. 18 Haishu Rd., Cangqian Sub-district, Yuhang District, Hangzhou, 311121, Zhejiang, P.R. China

in vitro diagnostic medical device for self-testing

COVID-19 & Influenza A+B Antigen Combo Rapid Test
catalogue number: FCO-6032H

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 29.04.2022 – 26.05.2025

Issue date: 29.04.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/063/W/E.1

Warsaw, 09.08.2024

CeCert Sp. z o.o.
ul. Warecka 11A
00-034 Warszawa

Safecare Biotech (Hangzhou) Co., Ltd., address: Building 2/203, No.18 Haishu Rd, Cangqian Sub-district Yuhang District, Hangzhou, 311121, P.R. China

Ref: CeCert/672/2024

Dear Sirs,

With reference to the application 137A/2022 regarding the assessment of the non-significant change related to an IVD medical device for self-testing: COVID-19 & Influenza A+B Antigen Combo Rapid Test; REF: FCO-6032H, consisting of shelf-life extension to 36 months, I would like to inform that the evaluation of above mentioned change and related documentation has been completed and approved by CeCert.

The certificate of conformity no. CeCert/063/W/E.1 remains in force.

Sincerely,

Director of in Vitro Diagnostic Medical Devices Certification Department

CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC

(For self-testing)

Manufacturer: Safecare Biotech （Hangzhou）Co., Ltd.

Address: Building 2/203, No.18 Haishu Rd.Cangqian Sub-district， Yuhang District, Hangzhou, Zhejiang China 311121
Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn

EC Representative: Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	COVID-19 & Influenza A+B Antigen Combo Rapid Test
	Type/model, identification of product allowing traceability (Where applicable)	Cassette(FCO-6032H)
of Category	For Self testing	

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO23640:2015	EN ISO 18113-1:2011
	EN 13612:2002	EN ISO 18113-4:2011
	EN 13641:2002	EN ISO 15223-1:2021
	EN ISO 14971:2019	EN 62366-1:2015
	ISO13485:2016	EN13532:2002
Conformity assessment procedure	**EC Declaration of Conformity(Annex III,- Section 6)**	
Notified Body (name & number)	CeCert Sp. z o.o. Notified Body number : 2934	

Signed on: 2022.3.17 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu

Name of authorized signatory: Kebin, Qiu
Position held in the company: General Manager
Seal/Stamp:

COVID-19 & Influenza A+B Antigen Combo Rapid Test For Self-Testing

Package Insert

CE 2934 | IVD | REF FCO-6032H | English

INTENDED USE

The COVID-19 & Influenza A+B Antigen Combo Rapid Test is a single-use test kit intended for qualitative detection of nucleocapsid protein antigen of influenza A and B viral antigens and COVID-19 Antigen from nasal swab specimens.
This test is intended for home use with self-collected nasal swab samples in individuals aged 12 and older. Sampling from anyone under the age of 12 and over the age of 70 should be performed under the guidance and assistance of their guardian. People who are unable to carry out the test on their own should seek support.
The test is intended for symptomatic individuals within 7 onset days or asymptomatic individuals contact with persons who have been diagnosed positive or with individuals suspected to be infected.
Positive results are indicative of the presence of Influenza and 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 Influenza and SARS-CoV-2 infection. Individuals who test negative and continue to experience Influenza or COVID-like symptoms should seek follow up care from their healthcare provider.

PRINCIPLE

The COVID-19 & Influenza A+B Antigen Combo Rapid Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2, Influenza A and B nucleocapsid protein from nasal swab specimens.
SARS-CoV-2, Influenza A and B specific antibodies are immobilized onto the test region of the membrane and combined with other reagents/pads to construct a test strip.
The test is designed to detection of nucleocapsid protein antigens in nasal swab specimens, which is different from the mutation sites have occurred in the spike protein, so it is theoretically able to detect variants including those in UK, India, South Africa and Brazil.

KIT COMPONENTS

Component	1Test /Kit	5 Tests /Kit	10 Tests /Kit	20 Tests /Kit	25 Tests /Kit
COVID-19 & Influenza A+B Antigen combo Test	1	5	10	20	25
Extraction tube with buffer	1	5	10	20	25
Sterilized nasal swab	1	5	10	20	25
Waste bag	1	5	10	20	25
Workstation	/	/	1	1	1
Package insert	1	1	1	1	1

ADDITIONAL SPECIAL EQUIPMENT

Timer

WARNINGS AND PRECAUTIONS

- Do not use after expiration date. Do not use if kit is damaged or open. Do not reuse the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Discard the using testing materials in accordance with local regulations.
- The extraction buffer contains a salt solution if the solution contacts the skin or eyes, flush with copious amounts of water.Don't swallow the buffer.When swallowing the buffer, rinse the mouth thoroughly with water and give plenty of water to dilute the substance.If any discomfort, seek medical attention immediately.
- Children and elder please use the test under the guardian.

STORAGE AND STABILITY

Store unused test devices unopened at 4°C-30°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

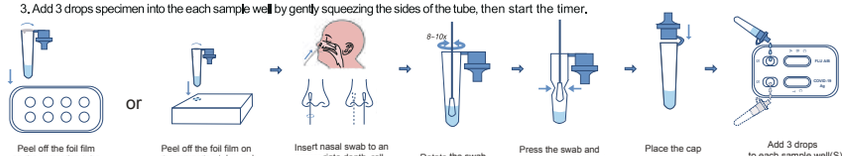
TEST PROCEDURE

Open the kit box. Check the components before use.

Please read all instructions carefully before you begin.
[Preparation before sampling]
1. Get a flat area ready, like a table. Make sure it is clear, clean and dry.
2. Take off hand jewellery.
3. Wash your hands for 20 seconds. Use soap and water, or hand sanitiser. Dry your hands using clean disposable paper towels.
For better protection and avoid cross-contamination, disposable gloves, masks and eye protection (not provided in the package) are recommended.

[Specimen Preparation]
1. Peel off the foil film on the extraction tube and insert into the hole of workstation. (For 1 test/kit and 5 tests/kit, Insert the extraction tube into the hole of the box.)
2. Open nasal swab package at the sticky end and take the nasal swab out.
3. Gently insert the soft tip of the nasal swab into left nostril about 2.5cm (1 inch) for adult.
Note: For child, the maximum depth of insertion into the nostril may be less than 2.5 cm and should be carefully and appropriately adjusted by the person, who collects sample.
4. Firmly brush against the inside of the nostril in a circular motion 5 times or more.
5. Move the nasal swab to the right nostril and repeat the previous action. Make sure an adequate sample is collected.
6. Insert the nasal swab into the tube which contains extraction buffer.
7. Rotate nasal swab at least 8-10 times while pressing nasal swab tip against the bottom and the side of the tube.
8. Remove the nasal swab while squeezing and rolling the nasal swab against the sides of the tube to release as much liquid as possible.
9. Cover the tube with cap tightly and insert the tube back into the workstation or box.

[Test Procedure]
1. Open the sealed pouch and take out the test cassette. For best results, the test should be performed in one hour.
2. Hold the tube vertically upside down over the sample well.
3. Add 3 drops specimen into the each sample well by gently squeezing the sides of the tube, then start the timer.

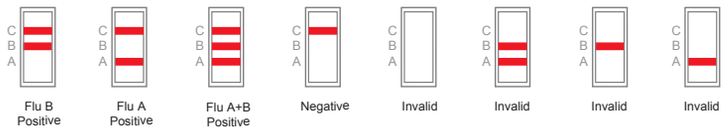


Peel off the foil film on the extraction tube and insert into the hole of workstation | Peel off the foil film on the extraction tube and insert into the hole of box | Insert nasal swab to an appropriate depth, roll 5 times in each nostril | Rotate the swab 8-10 times | Press the swab and release as much liquid as possible | Place the cap | Add 3 drops to each sample well(S)

4. Wait for colored lines to appear. The test result can be read in 10-15 minutes, DO NOT read after 20 minutes.

[After the testing]
1. After you have done the test, put all parts of the kit in the waste bag. Discard the waste bag in accordance with local regulations.
2. If you are doing more than 1 test, clean the table with 75% alcohol or sanitiser. Wash your hands between each test.

INTERPRETATION OF TEST RESULT For Flu A+B



Flu B Positive | Flu A Positive | Flu A+B Positive | Negative | Invalid | Invalid | Invalid | Invalid

- **Positive Influenza A:***
Two distinct colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).
- **Positive Influenza B:***
Two distinct colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).
- **Positive Influenza A and Influenza B:***
Three distinct colored lines appear in the left window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).
- **Negative:**
One colored line appears in the control region (C) of the left window. No apparent colored line appears in the test line region (B/A).
- **Invalid:**
Control line fails to appear in the left window. 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 Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

INTERPRETATION OF TEST RESULT For COVID-19

Positive | Positive | Negative | Invalid | Invalid

- **Positive COVID-19:***
Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Test region (T).
- **Negative:**
One colored line appears in the control region (C) of the right window. No apparent colored line appears in the test line region (T).
- **Invalid:**
Control line fails to appear in the right window. 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 Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

***NOTE:** The intensity of the color in the test line region will vary depending on the concentration of the analyses in the specimen. Therefore, any shade of color in the test line region should be considered positive.

BUILT-IN CONTROL

This test contains a built-in control feature, the C line on the test. The C line develops after adding sample solution. Otherwise, review the whole procedure and repeat test with a new device.

WHAT SHOULD I DO AFTER TEST

If the test result is positive	There is currently a suspicion of a COVID-19 or Flu A or Flu B infection ➢ Contact your doctor / general practitioner or the local health department immediately ➢ Comply with local guidelines for self-isolation ➢ To have a PCR confirmatory test performed
If the test result is negative	Continue to comply with all applicable rules regarding contact with others and protective measures ➢ An infection may also be present if the test is negative ➢ If it is suspected, repeat the test after 1 - 2 days, as the virus cannot be accurately detected in all phases of an infection
If the test result is invalid	Possibly caused by incorrect test execution ➢ Repeat the test ➢ If the test results remain invalid, contact a doctor or a COVID-19 test center

Note: Do not take any decision of medical relevance without first consulting your medical practitioner

PERFORMANCE CHARACTERISTICS

1. Clinical study: A comparison was performed using nasal samples collected for the research reagent and nasopharyngeal samples collected for comparative PCR reference testing.The test data listed in below table:

		Influenza A/B			COVID-19		
		Reference test result		Total	PCR		Total
		Positive	Negative		Positive	Negative	
Safecare Test	Positive	42	0	42	95	0	95
	Negative	0	568	568	15	455	470
Total		42	568	610	110	455	565
Relative Sensitivity		100.00% (95%CI:91.59% ~ 100.00%)			86.36% (95%CI:78.51% ~ 92.16%)		
Relative Specificity		100.00% (95%CI:99.35% ~ 100.00%)			100%(95%CI: 99.19% ~ 100.00%)		
Overall Agreement		100.00% (95%CI:99.40% ~ 100.00%)			97.35%(95% CI: 95.66% ~ 98.51%)		

2. Cross-reactivity: Cross-reactivity studies are performed to demonstrate that the test does not react with the following microorganisms in the table below at concentration of $1x10^5$ $TCID_{50}$/mL for viruses and $1x10^6$ CFU/mL for bacteria.

Human metapneumovirus (hMPV)	Human parainfluenza virus 1	Rhinovirus	*Bordetella pertussis*	*Streptococcus pneumoniae*
Human coronavirus OC43	Human parainfluenza virus 2	Enterovirus	*Chlamydia pneumoniae*	*Streptococcus pyogenes*
Human coronavirus 229E	Human parainfluenza virus 3	Adenovirus	*Haemophilus influenzae*	*Mycobacterium tuberculosis*
Human coronavirus NL63	Human parainfluenza virus 4	MERS	*Legionella pnuemophila*	*Staphylococcus aureus*
Human coronavirus HKU1	Respiratory Syncytial Virus		*Mycoplasma pneumoniae*	*Candida albicans*

3. Interference: The following endogenous interference substances were evaluated at the concentrations listed and no effect was found.

Whole blood (2%), three OTC nasal sprays (10%), three OTC nasal drop (25%), three nasal mouthwashes (25%), 4-Acetamidophenol (10mg/mL), Acetylsalicylic acid (20mg/mL), Chlorpheniramine (5 mg/mL), Dextromethorphan (10mg/mL), Diphenhydramine (5mg/mL), Ephedrine (20mg/mL), Guaiacol glyceryl ether (20mg/mL), Oxymetazoline (10mg/mL), Phenylephrine (100mg/ml), Phenylpropanolamine (20mg/mL) ,Oseltamivir Phosphate (10mg/mL), Mupirocin (10mg/mL),Vitamin A (10%), D-Panthenol (10%)

LIMITATIONS AND POSSIBLE ERRORS

1. The COVID-19 & Influenza A+B Antigen Combo Rapid Test is intended for use as a self-test and may only be used for qualitative detection of SARS-CoV-2, Influenza A and B antigens. The colour intensity of a positive line shall not be evaluated as quantitative or semi-quantitative.
2. The COVID-19 & Influenza A+B Antigen Combo Rapid Test should be only for the detection of SARS-CoV-2, Influenza A and B antigens,not for any other viruses or pathogens.The test does not differentiate between SARS-CoV and SARS-CoV- 2.
3. The performance was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. A negative result does not exclude the possibility of COVID-19 and /or Influenza A and /or Influenza B infection.
5. The results obtained with this assay, especially in the case of weak test lines which are difficult to interpret, should retest or go to a medical institution for testing.
6. The test is intended for infection detection and not for determine infection status.The test is used for the auxiliary diagnosis and can not be used as the sole diagnostic indicator of whether the test subject is infected with the COVID-19 and /or Influenza A and /or Influenza B.
7. False negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
8. False negative results may occur if a specimen is improperly collected, transported, or handled.
9. False positive test results are more likely during periods of low COVID activity when prevalence is moderate to low.
10. Testing of individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19, more false positive results may be returned.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4°C 30°C	Stored between 4-30℃		Consult instruction for use
	Keep away from sunlight	LOT	Lot number
	Use-by date	Σ	Contains sufficient for <n> tests
	Manufacturer		Date of Manufacture
STERILE EO	Sterilized using ethylene oxide	STERILE R	Sterilized using irradiation
REF	Catalog No.	CE 2934	CE Mark
EC REP	Authorized Representative in the European Community	BIO	Contains biological material of animal origin

Safecare Biotech(Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd, Cangqian Sub-district
Yuhang District, Hangzhou, 311121, China
Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn

EC REP Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf

Version No.: 01 Revision Date: 2024.01.11

COVID-19 & gripa A+B Antigenski Kombo Hitri Test Za Samotestiranje

Navodila za uporabo - Slovenščina

CE 2934 | IVD | REF | FCO-6032H

NAMEN UPORABE

COVID-19 in gripa A+B Antigenski Kombo Hitri Test je enkratna testna naprava, namenjena kvalitativnemu odkrivanju nukleokapsidnih beljakovin antigena gripe A in B ter antigena COVID-19 iz vzorcev brisa nosu.

Ta test je namenjen za domačo uporabo z vzorci brisa nosu, ki jih zbirajo posamezniki, stari 12 let in več. Zbiranje vzorcev pri osebah, mlajših od 12 let, in starejših od 70 let mora potekati pod vodstvom in pomočjo skrbnika. Osebe, ki same ne morejo opraviti testa, naj poiščejo pomoč.

Test je namenjen za simptomatske posamezneke v roku 7 dni po pojavu simptomov ali asimptomatske posameznike, ki so bili v stiku z osebami, pri katerih je bila postavljena pozitivna diagnoza ali obstaja sum okužbe.

Pozitivni rezultati kažejo na prisotnost gripe in SARS-CoV-2. Posamezniki, ki dobijo pozitiven rezultat, naj se izolirajo in poiščejo dodatno zdravstveno pomoč. Pozitiven rezultat ne izključuje bakterijske okužbe ali sočasne okužbe z drugimi virusi.

PRINCIP DELOVANJA

COVID-19 in gripa A+B Antigenski Kombo Hitri Test je imunokromatografski membranski test, ki uporablja zelo občutljiva protitelesa za odkrivanje SARS-CoV-2, gripe A in B nukleokapsidnih beljakovin iz vzorcev brisa nosu. Protitelesa, specifična za SARS-CoV-2, gripo A in B, so imobilizirana na testnem območju membrane in se kombinirajo z drugimi reagenti/ploščicami za tvorbo testnega traku. Test je zasnovan za odkrivanje nukleokapsidnih beljakovin iz vzorcev brisa nosu, kar je drugačno od mutacij, ki so se pojavile v spike proteinu, zato je teoretično sposoben zaznati različice, vključno z različicami iz Združenega kraljestva, Južne Afrike in Brazilije.

KOMPONENTE KOMPLETA

Komponente	1 test/ kpl.	5 test/ kpL	10 test/ kpl.	20 test/ kpL	25 test/ kpl.
COVID-19 in gripa A+B Antigenska testna ploščica	1	5	10	20	25
Epruveta z ekstrakcijsko tekočino	1	5	10	20	25
Sterilizirana palčka	1	5	10	20	25
Vrečka za odpadke	1	5	10	20	25
Delovna postaja	/	/	1	1	1
Priložena navodila	1	1	1	1	1

DODATNA OPREMA

Merilna naprava (zahtevan pripomoček, ni priložen kompletu)

OPOZORILA IN PREVIDNOSTNI UKREPI

- Ne uporabljajte po preteku roka uporabnosti. Ne uporabljajte, če je komplet poškodovan ali odprt. Ne uporabljajte testov ponovno.
- Ne jejte, ne pijte in ne kadite na območju, kjer so obravnavani vzorci ali kompleti.
- Ravnajte z vsemi vzorci, kot da vsebujejo nalezljive snovi. Opuščene testne materiale zavrzite v skladu z lokalnimi predpisi.
- Tekočina za ekstrakcijo vsebuje slano raztopino. Če tekočina pride v stik s kožo ali očmi, jih takoj sperite z obilo vode. Ne pogoltnite tekočine. Če tekočino zaužijete, temeljito sperite usta z vodo in popijte veliko vode, da razredčite snov. V primeru neugodja takoj poiščite zdravniško pomoč.
- Otroci in starejši naj test opravijo pod nadzorom skrbnika.

IZVEDBA IN SHRANJEVANJE

Shranjujte neuporabljene testne naprave neodprte pri 4°C-30°C. Če so shranjene pri 4°C-8°C, zagotovite, da je testna naprava pred uporabo prinešena na sobno temperaturo. Testna naprava je stabilna do izteka roka uporabnosti, ki je naveden na zaprti vrečki. Ne zamrzujte kompleta in ga ne izpostavljajte temperaturam nad 30°C.

POSTOPEK TESTIRANJA

Odprite škatlo s kompletom. Pred uporabo preverite komponente.

Pred začetkom odvzema vzorca skrbno preberite vsa navodila.

[Priprava pred odvzemom vzorca]

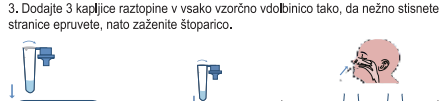
1. Pripravite ravno površino, kot je miza. Prepričajte se, da je čista, suha in jasna.
2. Odstranite nakit.
3. Umijte roke vsaj 20 sekund z milom in vodo ali uporabite razkužilo za roke. Roke osušite s čistimi papirnatimi brisačami. Za boljšo zaščito in preprečevanje navzkrižne kontaminacije se priporoča uporaba rokavic, mask in očal (niso priloženi v kompletu).
4. Trdno podrgnite notranjost nosnice v krožnih gibih 5-krat ali več.
5. Premaknite nosni bris v desno nosnico in ponovite postopek. Prepričajte se, da je zbran ustrezen vzorec.
6. Vstavite nosni bris v epruveto, ki vsebuje tekočino za ekstrakcijo.
7. Zavrtite bris vsaj 8-10-krat, medtem ko ga pritiskate ob dno in stranice epruvete.
8. Odstranite nosni bris in med stiskanjem in vrtenjem brisa proti stenam epruvete iztisnite čim več tekočine.
9. Tesno zaprite epruveto s pokrovčkom in jo vstavite nazaj v delovno postajo.

[Postopek testiranja]

1.Odprite zaprto vrečko in vzemite testno kaseto. Za najboljše rezultate izvedite test v eni uri.

2. Epruveto držite pokonci in jo nežno pritisnite nad vzorčno vdolbinico.

3. Dodajte 3 kapljice raztopine v vsako vzorčno vdolbinico tako, da nežno stisnete stranice epruvete, nato zaženite štoparico.



Odlepite folijo z epruvete za ekstrakcijo in jo vstavite v luknjo delovne postaje

Odlepite folijo z epruvete za ekstrakcijo in jo vstavite v luknjo na škatli

Vstavite bris na ustrezno globino in ga zavrtite 5-krat v vsaki nosnici.

Zavrtite bris 8–10-krat.

Pritisnite bris in iztisnite čim več tekočine.

Namestite pokrovček.

Dodajte 3 kapljice v vsako vzorčno vdolbinico (S).

4. Počakajte, da se pojavijo obarvane črte. Rezultati testa so vidni po 10-15 minutah, NE BERI testnih rezultatov po 20 minutah.

[Po testiranju]

1. Po opravljenem testu vse dele kompleta odvrzite v vrečko za odpadke v skladu z lokalnimi predpisi.
2. Če opravljate več kot en test, očistite delovno površino z 75 % alkoholom ali razkužilom. Umijte si roke med vsakim testom.

INTERPRETACIJA REZULTATOV TESTA ZA GRIPO A+B

Pozitivno na gripo B

Pozitivno na gripo A

Pozitivno na gripo A+B

Negativno

Neveljavno

Neveljavno

Neveljavno

Neveljavno

- **Pozitivno na gripo A**:
Dve različni obarvani črti se prikažeta v levem oknu. Ena obarvana črta mora biti v kontrolnem območju (C), druga obarvana črta pa v območju gripe A (A).
- **Pozitivno na gripo B**:
Dve različni obarvani črti se prikažeta v levem oknu. Ena obarvana črta mora biti v kontrolnem območju (C), druga obarvana črta pa v območju gripe B (B).
- **Pozitivno na gripo A+B**:
Tri različne obarvane črte se prikažejo v levem oknu. Ena obarvana črta mora biti v kontrolnem območju (C), dve obarvani črti pa v območjih gripe A (A) in gripe B (B).
- **Negativno**:
Ena obarvana črta se prikaže v kontrolnem območju (C) levega okna. Nobena obarvana črta se ne prikaže v območju testa (B/A).
- **Neveljavno**:
Če se kontrolna črta ne prikaže v levem oknu, je najverjetnejši razlog pomanjkljiva količina vzorca ali napačna izvedba postopka. Preverite postopek in ponovite test z novo testno kaseto. Če težava vztraja, takoj prenehajte z uporabo testa in kontaktirajte lokalnega distributerja.

INTERPRETACIJA REZULTATOV TESTA ZA COVID-19

Pozitivno Negativno Neveljavno Neveljavno

• Pozitivno na COVID-19:
Dve različni obarvani črti se prikažeta v desnem oknu. Ena obarvana črta mora biti v kontrolnem območju (C), druga obarvana črta pa v testnem območju (T).
• Negativno na COVID-19:
Ena obarvana črta se prikaže v kontrolnem območju (C) desnega okna. Nobena obarvana črta se ne prikaže v testnem območju (T).
• Neveljavno:
Če se kontrolna črta ne prikaže v desnem oknu, je najverjetnejši razlog pomanjkljiva količina vzorca ali napačna izvedba postopka. Preverite postopek in ponovite test z novo testno kaseto. Če težava vztraja, takoj prenehajte z uporabo testa in kontaktirajte lokalnega distributerja.
***OPOMBA:** Intenzivnost barve v območju testne črte (T) se bo razlikovala glede na koncentracijo analiz v vzorcu. Zato se šteje vsak odtenek barve v testnem območju za pozitiven rezultat.

VGRAJENA KONTROLA

Ta test vsebuje vgrajeno kontrolno funkcijo, črto C na testu. Črta C se prikaže po dodajanju vzorčne raztopine. Če se črta C ne prikaže, preverite celoten postopek in ponovite test z novo napravo.

KAKO UKREPATI PO TESTIRANJU

• Če je rezultat testa pozitiven:
Obstaja sum na okužbo s COVID-19, gripo A ali gripo B:
- Takoj se obrnite na zdravnika/splošnega zdravnika ali lokalni zdravstveni oddelek
- Upoštevajte lokalne smernice za samoizolacijo
- Opravite potrditveni PCR test
• Če je rezultat testa negativen:
Še naprej upoštevajte vse veljavne smernice glede stika z drugimi osebami in zaščitnih ukrepov:
- Okužba je lahko prisotna tudi, če je test negativen
- Če je sum na okužbo, ponovite test po 1–2 dneh, saj virusa v vseh fazah okužbe ni mogoče natančno zaznati
• Če je rezultat testa neveljaven:
Verjetno zaradi nepravilne izvedbe testa
- Ponovite test
- Če rezultati ostanejo neveljavni, se posvetujte z zdravnikom ali obiščite COVID-19 testni center
*OPOMBA: Ne sprejemajte nobenih zdravstvenih odločitev brez posvetovanja z vašim zdravnikom.

ZNAČILNOSTI UČINKOVITOSTI

1. Klinična študija:
Primerjava je bila izvedena z vzorci nosnih brisov, zbranih za raziskovalne reagente in vzorce nazofaringealnih brisov, ki so bili testirani s primerjalnim PCR testom. Podatki testa so navedeni v spodnji tabeli:Primerjava je bila izvedena z vzorci nosnih brisov, zbranih za raziskovalne reagente in vzorce nazofaringealnih brisov, ki so bili testirani s primerjalnim PCR testom. Podatki testa so navedeni v spodnji tabeli:

		Gripa A/B			COVID-19		
		Referenčni rezultat		Skupaj	PCR		Skupaj
		Pozitivno	Negativno		Pozitivno	Negativno	
Test za samo-testiranje	Pozitivno	42	0	42	95	0	95
	Negativno	0	568	568	15	455	470
Skupaj		42	568	610	110	455	565
Relativna občutljivost:		100,00% (95%CI:91,59%~100,00%)			86,36% (95%CI:78,51%~92,16%)		
Relativna specifičnost:		100,00% (95%CI:99,35%~100,00%)			100,00% (95%CI:99,19%~100,00%)		
Skupno ujemanje:		100,00% (95%CI:99,40%~100,00%)			97,35% (95%CI:95,66%~98,51%)		

2. Navzkrižna reaktivnost:
Testi navzkrižne reaktivnosti so bili izvedeni, da bi dokazali, da test ne reagira z naslednjimi mikroorganizmi pri koncentraciji 1×10X5 $TCID_{50}$/mL za viruse in 1×10^6 CFU/mL za bakterije:
•Human metapneumovirus (HMPV), Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63I, Human coronavirus HKU1 Respiratorni sincicijski virus (RSV), Human parainfluenca virus 1, Human parainfluenca virus 2, Human parainfluenca virus 3, Human parainfluenca virus 4 Rinovirus, Adenovirus, Enterovirus, MERS, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycobacterium tuberculosis ,Candida albicans, Staphylococcus aureus

3. Motenje:
Naslednje endogene motnje niso vplivale na rezultat pri testiranih koncentracijah:
• Celotna kri (2%), Nosni spreji OTC (10%), Kapljice za nos OTC (25%), Tri vrste ustnih vodic (25%), Acetaminofen (10 mg/ mL), Acetilsalicilna kislina (20 mg/ mL), Klorfeniramin (5 mg/mL), Dekstrometorfan (10 mg/mL), Difenhidramin (5 mg/ mL), Efedrin (20 mg /mL), Gvajakol gliceril eter (20 mg/mL),Oksimetazolin (10 mg/mL) , Fenilefrin (100 mg/ mL), Fenilpropanolamin (20 mg/mL), Oseltamivir fosfat (1 mg/mL), Mupirocin (10 mg/mL) , Vitamin A (10%), D-pantenol (10%)

OMEJITVE IN MOŽNE NAPAKE

1.Test COVID-19 & Influenza A+B Antigenski Kombo Hitri Test je namenjen za samotestiranje in se lahko uporablja samo za kvalitativno odkrivanje antigenov SARS-CoV-2, gripe A in B. Barvna intenzivnost pozitivne črte ne sme biti ovrednotena kot kvantitativni ali polkvantitativni rezultat.
2. Test COVID-19 & Influenza A+B Antigenski Kombo Hitri Test je namenjen samo za odkrivanje antigenov SARS-CoV-2, gripe A in B, ne pa za druge viruse ali patogene. Test ne loči med SARS-CoV in SARS-CoV-2.
3. Učinkovitost je bila ovrednotena z uporabo postopkov, opisanih v teh navodilih za uporabo. Vsaka sprememba teh postopkov lahko vpliva na delovanje testa.
4. Negativen rezultat testa ne izključuje možnosti okužbe s COVID-19 in/ali gripo A in/ali gripo B.
5. Rezultati, pridobljeni s tem testom, še posebej v primeru šibkih testnih črt, ki jih je težko interpretirati, zahtevajo ponovni test ali obisk zdravstvene ustanove za nadaljnje testiranje.
6. Test je namenjen odkrivanju okužbe, ne pa določanju stanja okužbe. Test se uporablja kot pomožno diagnostično orodje in ga ni mogoče uporabiti kot edini diagnostični pokazatelj, ali je oseba okužena s COVID-19 in/ali gripo A in/ali gripo B.
7. Lažno negativen rezultat testa se lahko pojavi, če je raven antigena v vzorcu pod mejo zaznavanja testa.
8. Lažno negativni rezultati se lahko pojavijo, če je vzorec nepravilno zbran, transportiran ali obdelan.
9. Lažno pozitivni rezultati so bolj verjetni v obdobjih nizke aktivnosti COVID-19, ko je razširjenost virusa zmerna do nizka.
10. Testiranje oseb brez simptomov COVID-19 in/ali oseb, ki živijo v območjih z nizkim številom okužb s COVID-19 in brez znanega stika s COVID-19, lahko privede do več lažno pozitivnih rezultatov.

RAZLAGA SIMBOLOV

	Ni za ponovno uporabo	IVD	In vitro diagnostični medicinski pripomoček
4°C 30°C	Temperaturno območje shranjevanja		Pred uporabo natančno preberite navodila
	Hraniti stran od sončne svetlobe	LOT	Številka serije
	Datum izteka roka uporabnosti	Σ	Število testov v kompletu
	Proizvajalec		Datum proizvodnje
STERILE EO	Sterilizirano z etilen oksidom	STERILE R	Sterilizirano z obsevanjem
REF	Kataloška številka	CE 2934	Oznaka CE
EC REP	Pooblaščeni zastopnik v Evropski uniji	BIO	Vsebuje biološki material živalskega izvora

Safecare Biotech(Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd, Cangqian Sub-district
Yuhang District, Hangzhou, 311121, China

EC REP Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf

Uvoznik: 3-LAB PLUS d.o.o.
Nazorjeva 3, 1000 Ljubljana
info@3-lab.si

Verzija št.: 01 Datum revizije: 11.1.2024