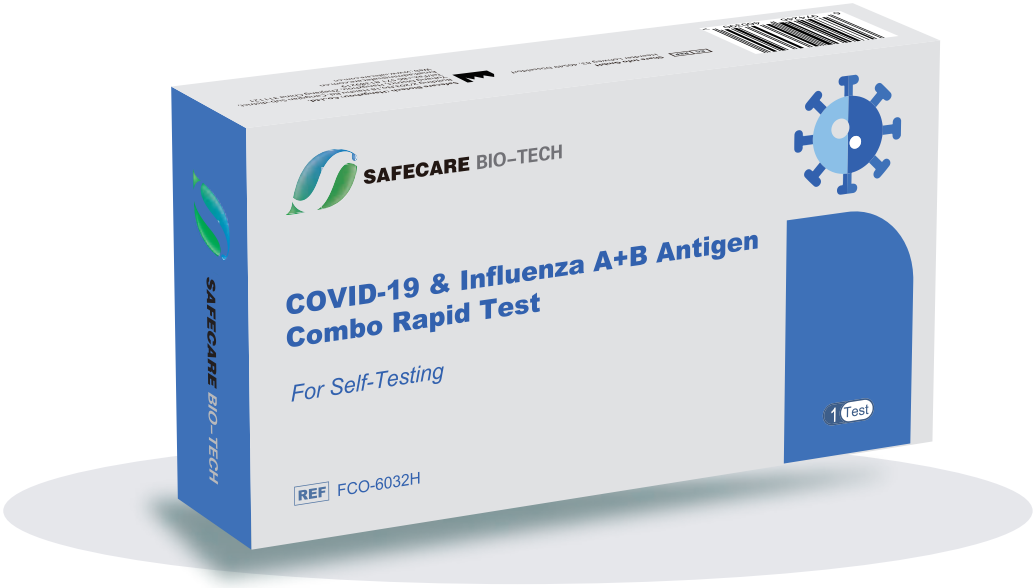
SAFECARE BIO-TECH

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

For Self-Testing

CE Cert. CERTIFICATE Self-Testing CE 2934



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.

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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*

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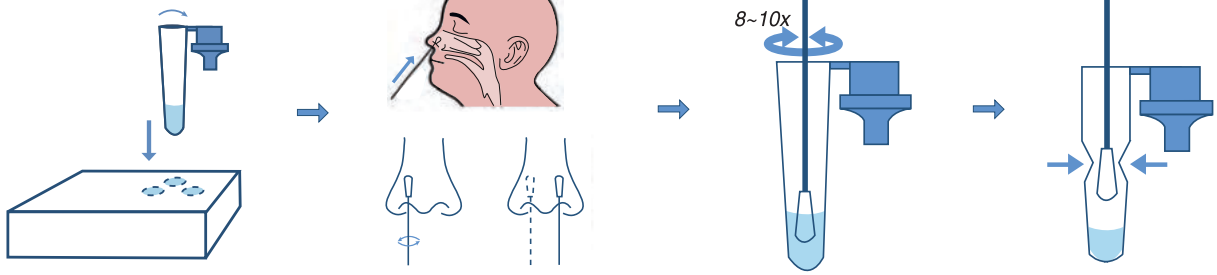
使用过程
Convenient Procedure

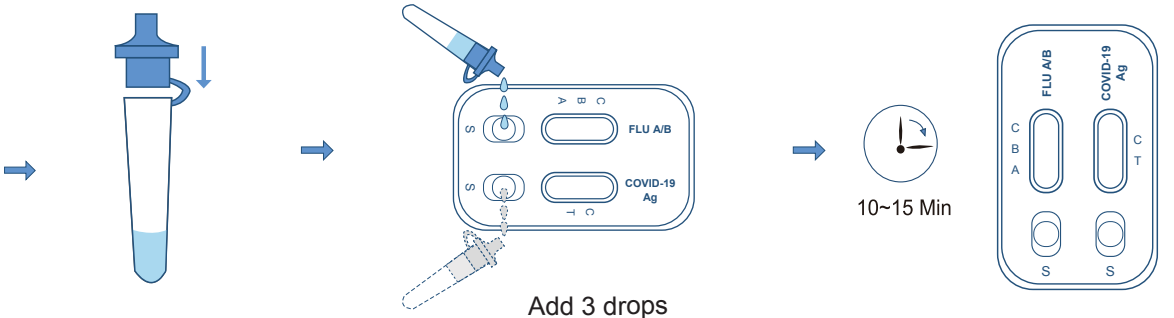


Peel off the foil film on the extraction tube and insert into the hole

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)

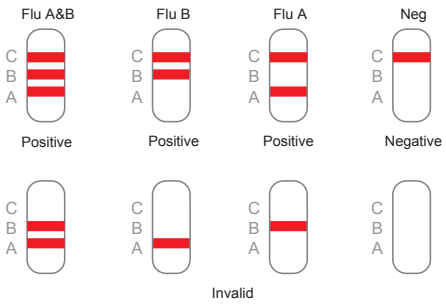
Read the result

Results Interpretation

For COVID-19

Positive Negative Invalid

For FLu A/B



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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:320Tests/CTN

G.W.:9.8 kgs

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnosis of Rapid Test of Fertility, Drug of Abuse, Cardiac Markers, Infectious Diseases

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-08-02
Certificate Registration No.:	SX 60149068 0001
An audit was performed. Report No.:	15096152 005
This Certificate is valid until:	2023-06-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2020-08-02

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Declaration of Conformity

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: 2021.3.17 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:

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Company Profile:

Safecare Biotech(Hangzhou)Co.,Ltd. is a premier and professional manufacturer and supplier of rapid diagnostic test kit with 165 workers, 8000 ㎡ non-dust workshop, a professional R&D team who has 15years experience in rapid test field, advanced automate machines and professional R&D team ensure the high quality, speedy delivery and large production capacity. SAFECARE earned the reputation as a premium brand known for exceptional quality, consistency and innovation.

Our product ranges drug of abuse and alcohol test in urine and saliva, Food Safety test, Women Health test, Infectious Diseases test, Cardiac Markers test and Tumor Markers test with CE & ISO approved. Our drugs tests are even US FDA 510K and CLIA Waived approved which can ensure you high and stable quality.

The available rapid test kits are designed for health-care professionals in laboratories, rehabilitation centers, treatment centers, hospitals, clinics, private practices, human resource departments, mining companies, construction companies and the judicial system. All the products are produced strictly under TUV ISO13485:2016 quality management system for medical devices.

With our highly trained staffs and good service, we are committed to provide professional service and a comprehensive, cutting-edge product offering, help you in selecting the accurate and fast rapid tests and to provide the free samples for your evaluation.

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