

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.

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*



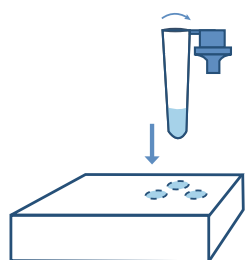
Contents

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

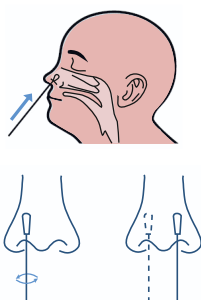


使用过程

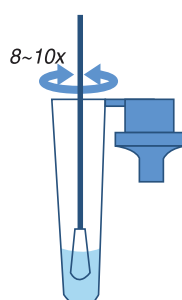
Convenient Procedure



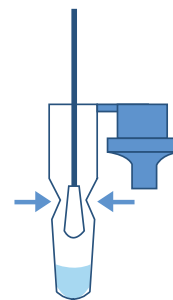
Peel off the foil film on the extraction tube and insert into the hole



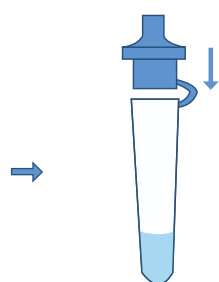
Insert nasal swab to an appropriate depth, roll 5 times in each nostril



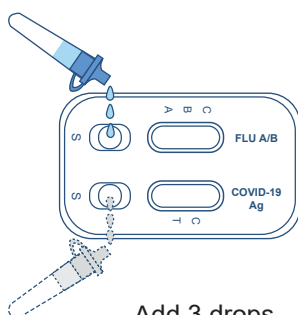
Rotate the swab 8-10 times



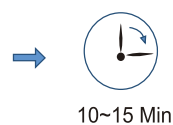
Press the swab and release as much liquid as possible



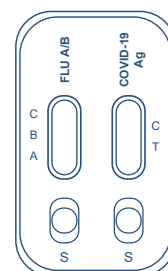
Place the cap



Add 3 drops to each sample well(S)



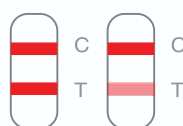
10~15 Min



Read the result

Results Interpretation

For COVID-19



Positive



Negative



Invalid

For FLU A/B



Positive



Positive



Positive



Negative

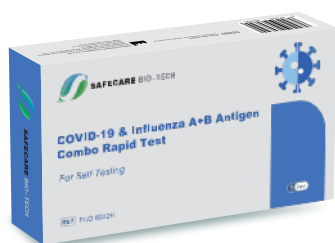


Invalid



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

Ce Cert.

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.



2934

Validity date: 29.04.2022 – 26.05.2025

Issue date: 29.04.2022

Check it



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

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

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

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

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



Date 2020-08-02



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 13612:2002
EN 13641:2002
EN ISO 14971:2019
ISO13485:2016

EN ISO 18113-1:2011
EN ISO 18113-4:2011
EN ISO 15223-1:2021
EN 62366-1:2015
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: 2022.3.11

Place: Hangzhou, Zhejiang, China

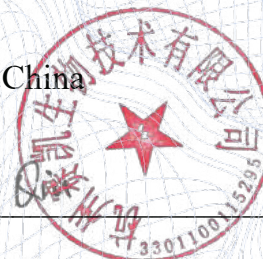
Signature (on behalf of the manufacturer)

Kebin Qiu

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp:



Company Profile :

Safecare Biotech(Hangzhou)Co.,Ltd. is a premier and professional manufacturer and supplier of rapid diagnostic test kit with 165 workers, 8000 m² 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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Email:admin@safecare.com.cn
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