Safecare Biotech (Hangzhou) co.,ltd

COVID-19 Antigen Rapid Test Device(Swab)

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for qualitative detection of nucleocapsid protein antigen in direct nasal swabs or nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

SAFECARE COVID-19 Ag

Rapid test kit

Intended Use: Detection of SARS-CoV2 Antigen
Package: 25Tests/Box
Storage: 4-30°C
Specimen Type: Nasopharyngeal
Shelf Life: 24 months
Time to Result: 10-15 Minutes

SPECIMENS PREPARATION AND TEST PROCEDURE

<Assay Procedure>

Preparation of Extraction solution

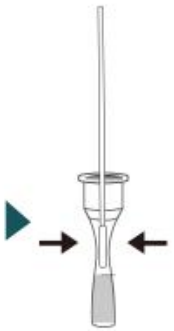
Add 6 drops of extraction buffer into the extraction tube

Nasopharyngeal swab collection

Nasal Swab collection

Collect the specimens from the patient using provided swab

Mix the swab with extraction solution



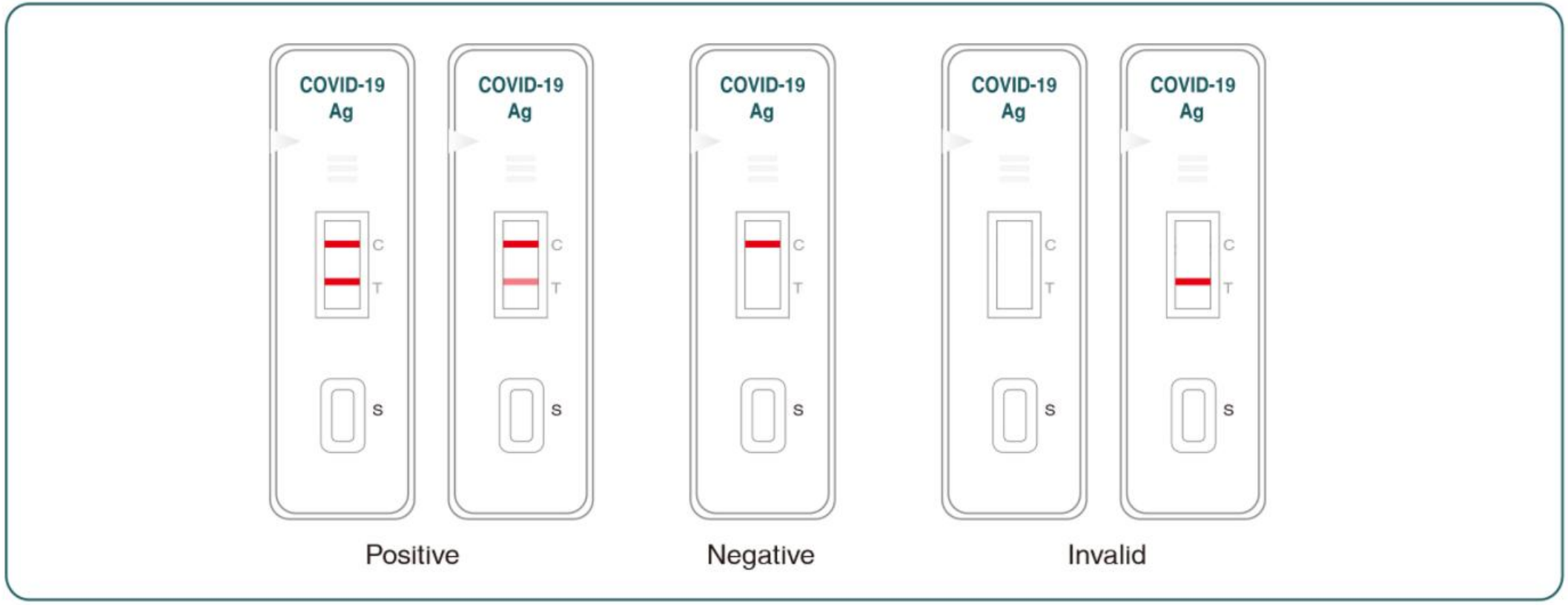
Press the swab and release as much liquid as possible

Place the cap

Add 3 drops of the solution into the sample well

10~15 min

INTERPRETATION OF RESULTS



CERTIFICATE

CE CE

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of **NOT Annex II and NOT self-test**)

Manufacturer:	Safecare Biotech (Hangzhou) Co., Ltd.
Address:	Building 2/203, No.18 Haishu Rd.Cangqian Sub-district, Yuhang District, Hangzhou, Zhejiang China 311121
EC Representative:	Wellkang Ltd, 16 Castle St,Dover, Kent, CT16 1PW,England,UK Enterprise Hub,NW Business Complex,1 Beraghmore Road,Derry,BT48 8SE Northern Ireland(NI)

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	COVID-19 Antigen Rapid Test Device(Swab)
	Type/model, identification of product allowing traceability (Where applicable)	Cassette(NCO-6012)
of Category:	**Common/Others IVD** (Devices of **NOT Annex II** and **NOT self-test**)	

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 ISO 18113-2: 2009 EN1041- 2008 EN ISO15223-1:2016
Conformity assessment procedure	Module A (EC Declaration of Conformity) (Annex III, except point 6)	
Notified Body (name & number) Certificate & number	**NOT applicable**	

Signed on 28th Sep.,2020 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer) Kebin Qiu 2020.9.28

Name of authorized signatory: Kebin Qiu

Position held in the company: General Manager

Seal/Stamp:

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 60149088 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

Date 2020-08-02

Herbert Zinpel

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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医疗器械生产许可证

许可证编号：浙食药监械生产许 20140151 号

企业名称：杭州赛凯生物技术有限公司

生产地址：杭州市余杭区仓前街道海曙路 18 号 2 号楼 203 室

法定代表人：唐燕芬

生产范围：第二类:6840-体外诊断试剂***

企业负责人：裘科斌

住　　所：杭州市余杭区仓前街道海曙路 18 号 2 号楼 203 室

发证部门：浙江省药品监督管理局

有效期限：至 2024 年 8 月 12 日　　发证日期：2019 年 8 月 13 日

国家食品药品监督管理总局制

ADVANTAGE

1.Easy to collect samples， simple operation，without professional equipment.

2.The test results are available in 15 minutes, and the test results are clearly visible.

3.Convenient transportation and low price, higher accuracy.

4.Suitable for large-scale rapid screening.

Clinical Evaluation Report

1. **Purpose:**
   In order to verify the clinical performance of the registered test, this clinical evaluation is conducted in R&D lab.
2. **Product information:**
   COVID-19 Antigen Rapid Test Device (Swab) was produced by Safecare Biotech(Hangzhou) Co.,Ltd., Lot number is COV20081201, valid until August,2022.
3. **Sample requirement:**
   Fresh samples were collected from CDC and validated by PCR.
4. **Supporting equipment:**
   PCR tests are performed on ABI7500.
   The test-strips are manually operated and visually interpreted.
5. **Clinical evaluation:**
   Researcher: Dr. ZHANG LEI

6. **Statistical methods:**

		Referencing reagent Test		Total
		Positive	Negative	
Research Reagent	Positive	A	B	A+B
	Negative	C	D	C+D
Total		A+C	B+D	A+B+C+D

Percent Positive Agreement=A/(A+C)*100%

Negative Percent Agreement=D/(B+D)*100%

7. **Evaluation indicators:**

   The total PPA should be no less than 80%.
   The total NPA should be no less than 90%.
8. **The test data: Refer to the Data Sheet.**
9. **Statistical results of the clinical evaluation**

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	30	0	30
	Negative	2	52	54
Total		32	52	84

Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity（%）	30/32	93.75% (79.19%~99.23%)
Relative Specificity（%）	52/52	100.00% (93.15%~100.00%)

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Positive expectation Rate（%）	30/30	100.00% (88.43%~100.00%)
Negative expected Rate（%）	52/54	96.30% (87.25%~99.55%)
Overall Agreement（%）	82/84	97.62% (91.66%~99.71%)

3) Kappa consistency test

According to the literature [5.1], Calculate the Kappa value and standard error; test hypothesis is established for Kappa: H0: k = 0, Kappa value comes from 0 population, H1: k > 0, Kappa value comes from non-0 population, α = 0.05.

Project	Value
Kappa Value	0.9489, Good consistency.
Standard Error Se(K)	0.0357
95% Confidence Interval	0.8790~1.0188
Standard Error Se0(K)	0.109
Test Value Z	Z=8.7082, Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

4) Conclusion

A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:
The Relative Sensitivity is 93.75%, the Relative Specificity is 100%, the Overall Agreement is 97.62%.