

Safecare Biotech (Hangzhou) co.,ltd



The image features a woman with long brown hair, wearing a white shirt, lying down and blowing her nose into a white tissue. In the upper left corner, there is a product shot of the Safecare COVID-19 Ag Antigen Rapid Test Device (Swab). The product includes a blue and white box labeled 'SAFECARE BIO-TECH' and 'COVID-19 Ag Rapid Test Kit(Swab)', several individual test strips, and a small plastic tray containing various components. The background is a soft, blurred gradient from white to teal.

SAFECARE
COVID-19 Ag

COVID-19 Antigen Rapid Test Device(Swab)

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

Covid-19 Antigen Rapid Test Device (Swab)

INTRODUCTION



INTENDED USE

For in vitro qualitative detect of Covid-19 antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

PRODUCT PHOTOS





COMPONENT/(BOX)

25 test packed in one box :

25 Test Device

25 Nasal Swab

25 Extraction tube

1 workstation

1 Bottle of buffer

1 Package Insert

PACKAGE SIZE /CARTON

Length:630mm

Width:370mm

Height:300mm

Weight:10Kgs

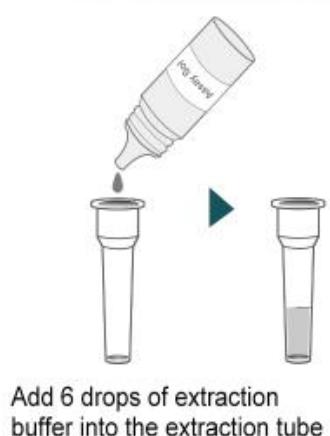
Include:27 box, 675PCS (product& carton)



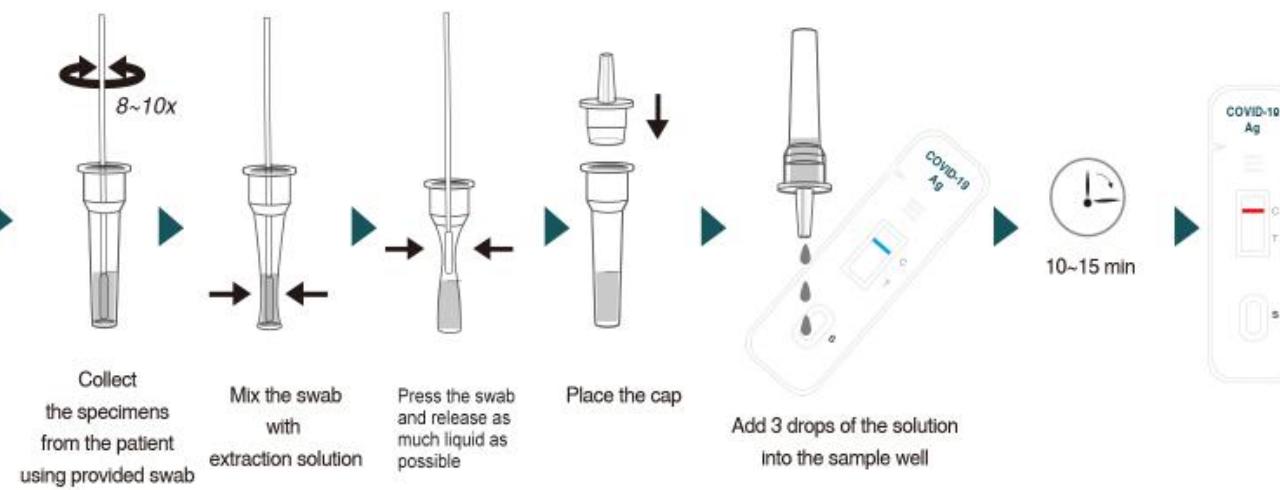
SPECIMENS PREPARATION AND TEST PROCEDURE

<Assay Procedure>

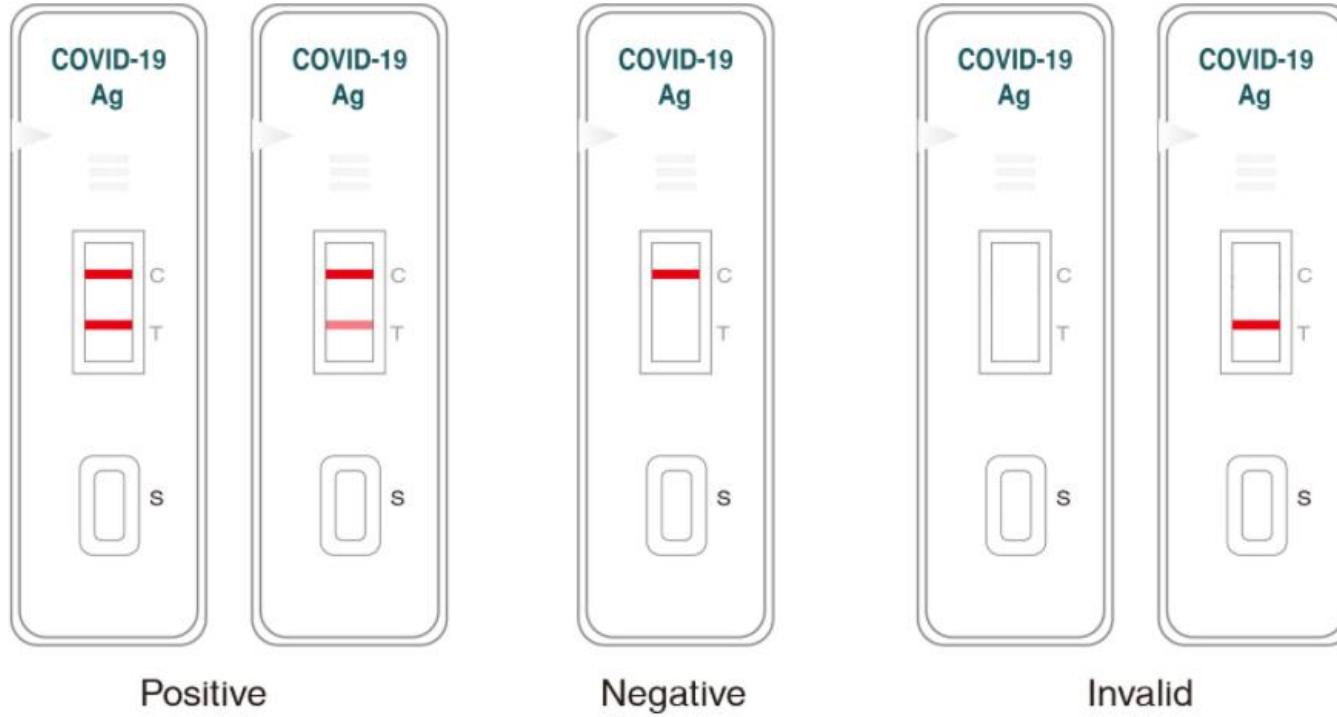
Preparation of Extraction solution



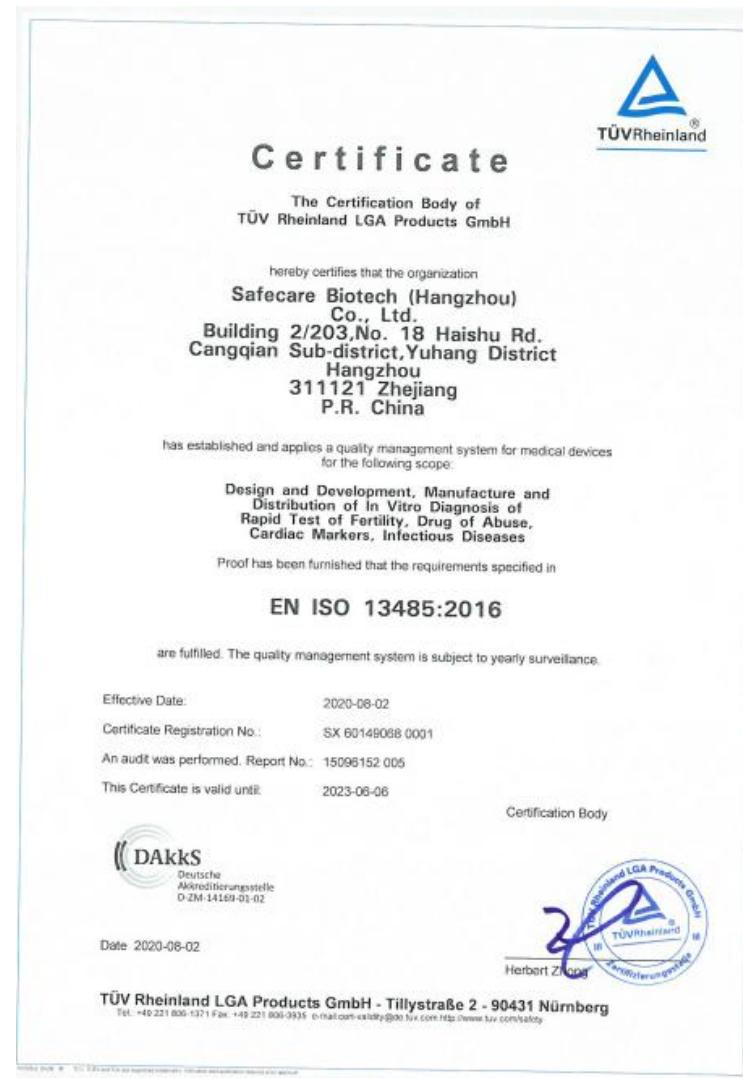
Add 6 drops of extraction buffer into the extraction tube



INTERPRETATION OF RESULTS



CERTIFICATE



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

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 3 日



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.

ADVANTAGE



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%)



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, $\alpha = 0.05$.

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%.

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.

