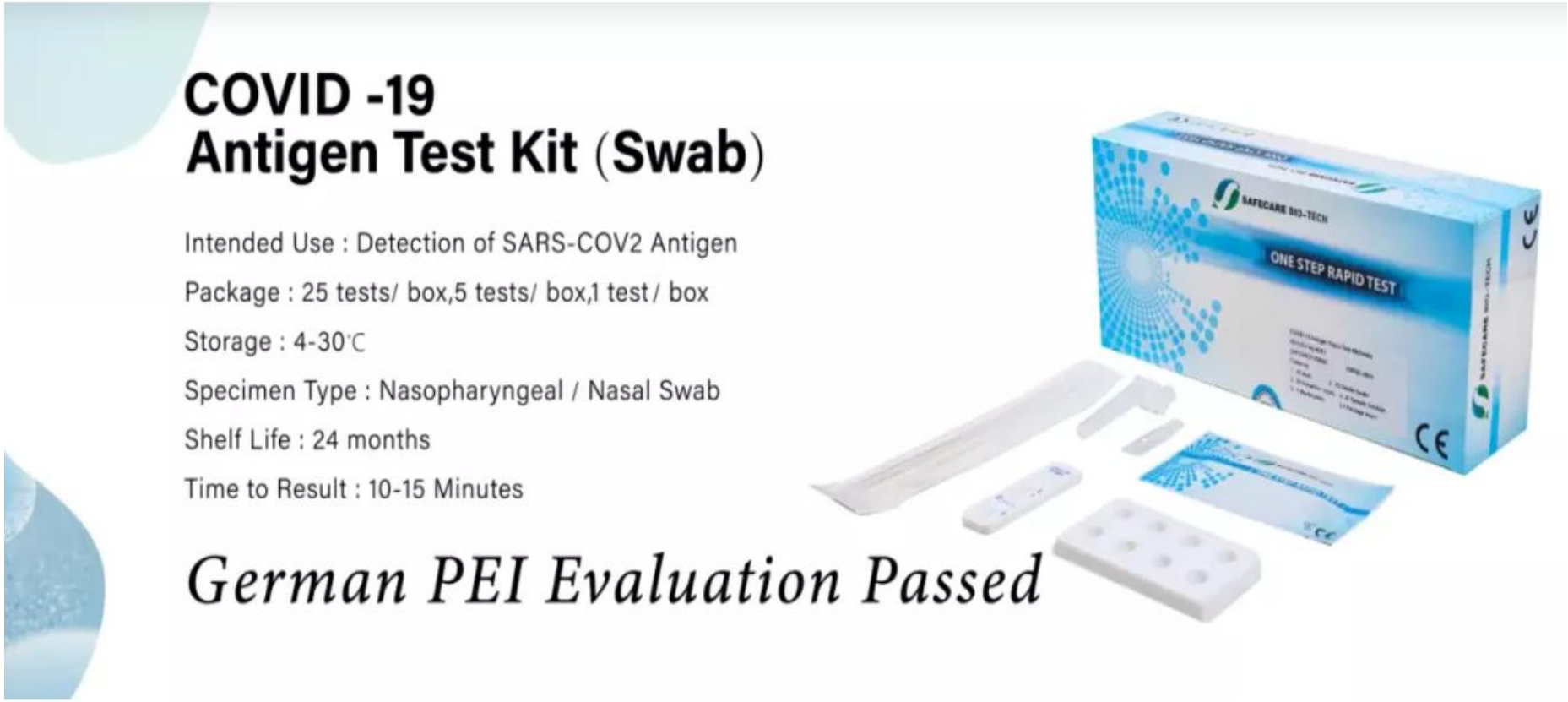
Safecare Biotech (Hangzhou) co.,ltd

Safecare Covid-19 Antigen Rapid Test Device (Swab)

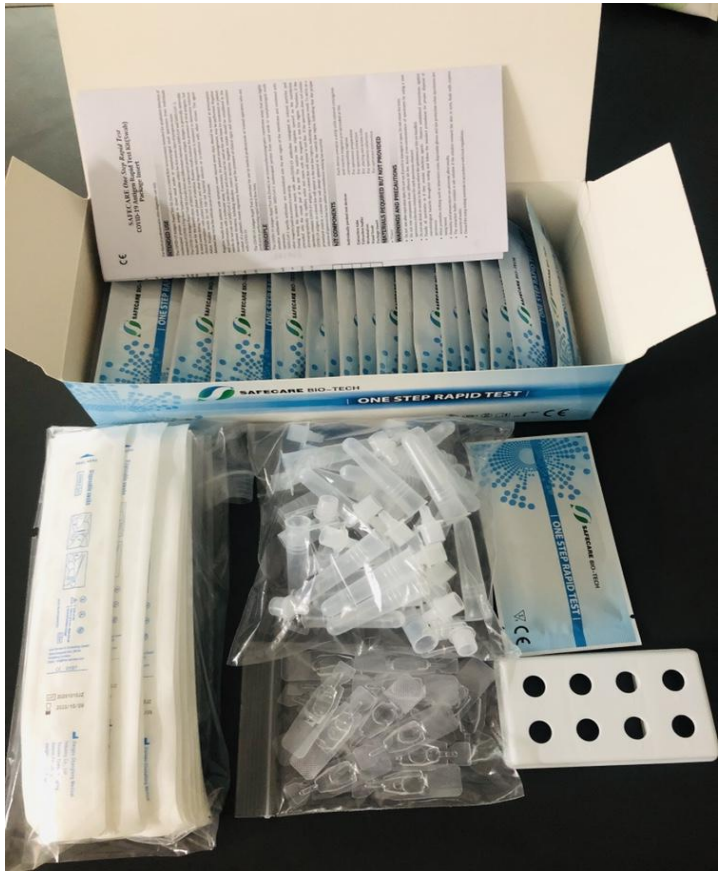
I N T RO D U C T I O N



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 tests packed in one box :

25 Test Device

25 Nasal Swabs

25 Extraction tube

1 workstation

1 Bottle of butter

1 Package Insert

PACKAGE SIZE /CARTON

Length:630mm

Width:370mm

Height:300mm

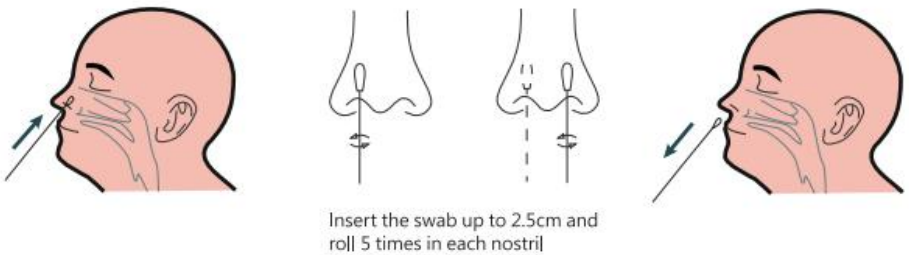
Weight:10Kgs

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

检测过程

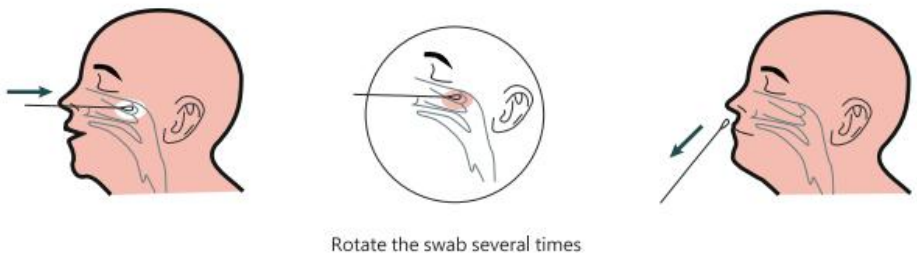
TEST PROCEDURE

Nasal Sample:

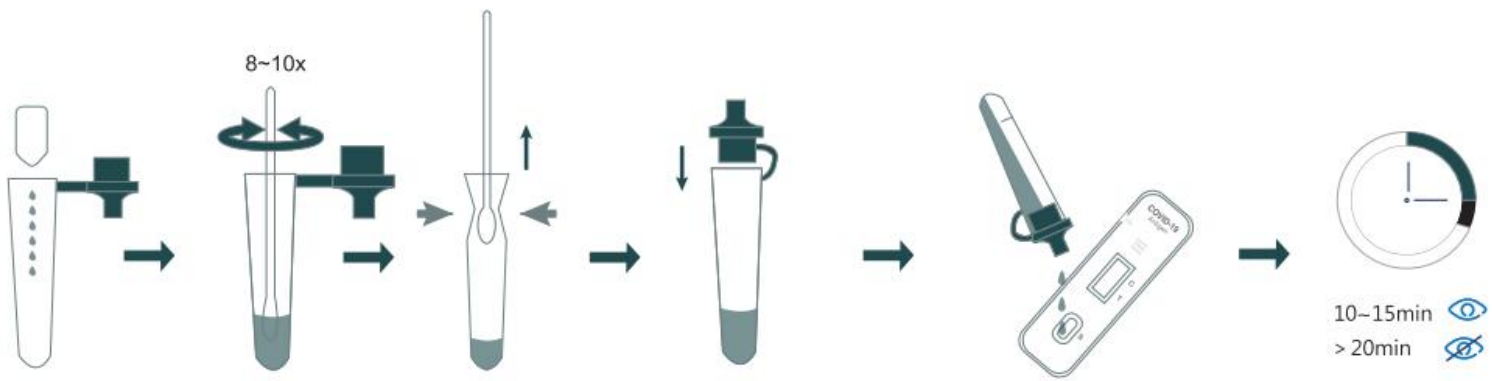


Insert the swab up to 2.5cm and roll 5 times in each nostril

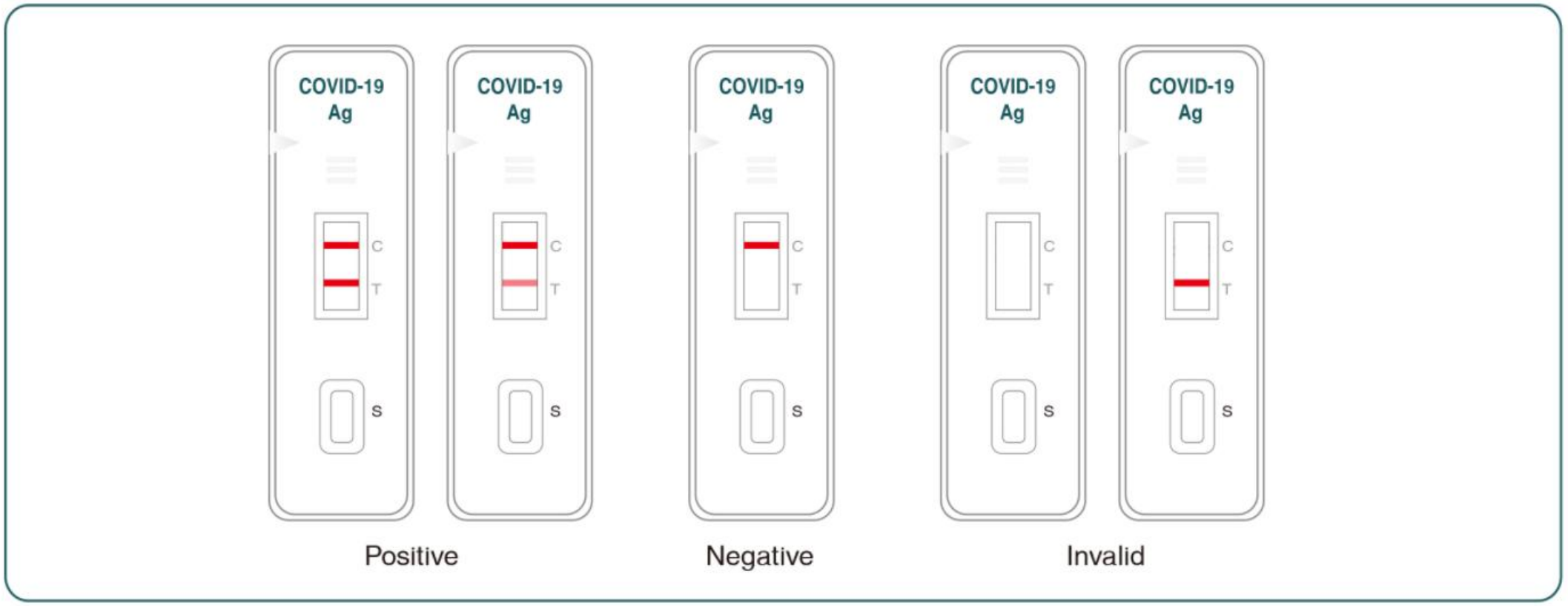
Nasopharygeal Sample:



Rotate the swab several times



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: NIC GmbH
Erlenweg 13,49076 Osnabrück,Germany

We, the manufacturer, declare under our sole responsibility that

the medical device(s) Product Name: COVID-19 Antigen Rapid Test Kit(Swab)

Type/model, identification of product allowing traceability (Where applicable): Cassette(COV Ag-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**

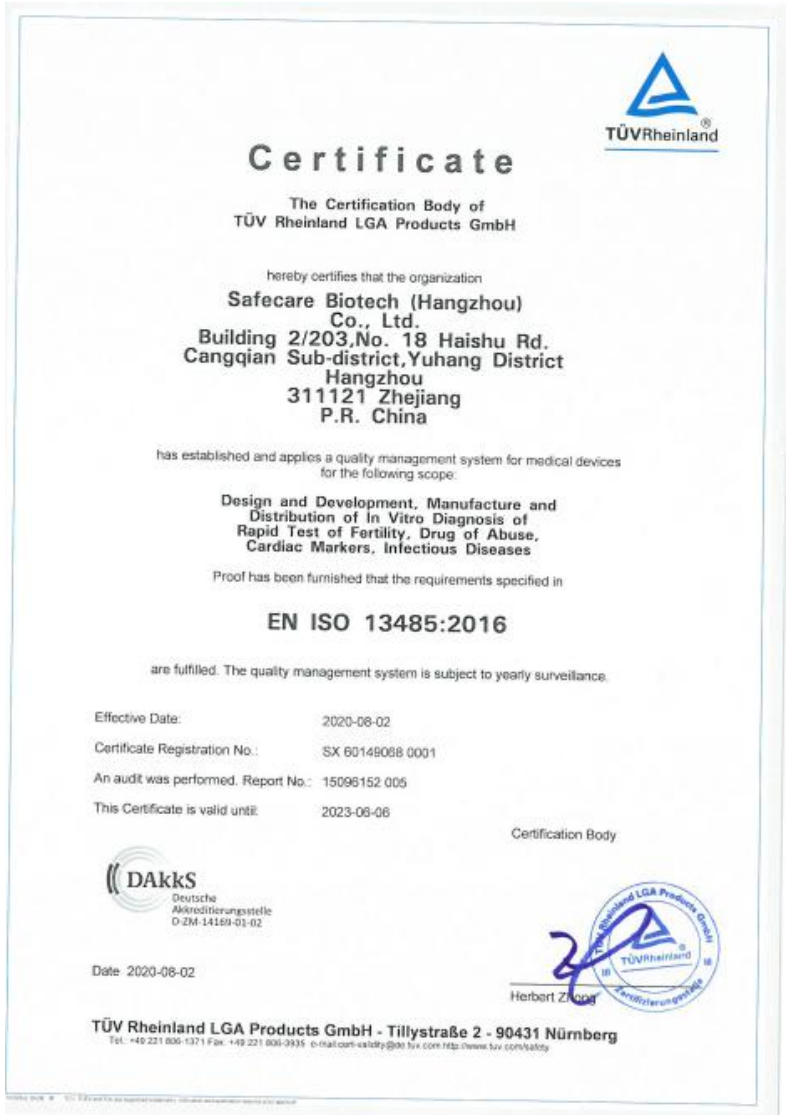
Signed on 28th Sep.,2020 Place: Hangzhou, Zhejiang, China

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 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

Date 2020-08-02

Herbert Zinner

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum | Administration

safecare | Los | Aktionen | Zurücksetzen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche(r) Vertreiber	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall
AT199/20	COVID-19 Antigen Rapid Test Kit (Swab)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,27	94,45 - 98,89	99,42	97,93 - 99,93
AT483/20	Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,04	92,59 - 99,19	99,44	96,94 - 99,99
AT027/21	Multi-Respiratory Virus Antigen Test Kit(Swab) (Influenza A+B/ COVID-19)	Ja	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	CN	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	97,04	92,59 - 99,19	99,44	96,94 - 99,99
[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	POC (ohne Gerät)	[redacted]	[redacted]	[redacted]	[redacted]
AT319/21	COVID-19 Antigen Rapid Test Kit (Saliva)	Nein	Safecare Biotech (Hangzhou) Co., Ltd.	Hangzhou	China	NIC GmbH	Osnabrück	DE	Details	POC (ohne Gerät)	98,50	94,67-99,82	99,45	96,99-99,99

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

ADVANTAGES

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

ADVANTAGE

Clinical Evaluation Report

1. **Purpose:**
In order to verify the clinical performance of the improved test

2. **Material:**
Fresh negative COVID-19 samples were collected from the hospital and validated by PCR.
Fresh positive COVID-19 samples were collected from CDC and validated by PCR.
Product used: COV20082701

3. **Protocol:**
3.1 Sample Size:
Positive Sample: >100
Negative Sample:>150

3.2 Sample's collection:
Nasal swab specimen or nasopaharygeal swab specimen can be used by Safecare COVID-19 Antigen Rapid Test Kit(Swab) to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on both nasal swab specimens and nasopaharygeal swab specimen, no statistic difference was observed among those specimens. All swabs were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

3.3 Sample Entry criteria:
The samples from hospital outpatient screening cases and COVID-19 Patients who presented within 7 days of symptom onset;
Samples of people that gender and age are not limited.

3.4 Sample Exclusion criteria:
Samples without PCR test results;
Samples that the quantity is not enough to complete the test;
Samples with failed test results (C-line has not appeared);
Freeze samples repeatedly.

3.5 Comparator method
All samples was confirmed by PCR.
PCR tests used from Sansure Biotech Inc. and performed on ABI7500.

4. **Operator and site:**
Site 1:
Study Site Info: ZHEJIANG PROVINCIAL CENTER FOR DISEASE CONTROL AND PREVENTION
Researcher: Dr. ZHANG LEI
Lab Name (or Hospital or Doctor's office)： Immunology Laboratory
Address: 3399 Binsheng Road, Binjiang District, Hangzhou City, Zhejiang Province
Site 2:
Study Site Info: THE FIRST AFFILIATED HOSPITAL ZHEJIANG UNIVERSITY SCHOOL OF MEDICINE
Researcher: Dr.Xuwei
Lab Name (or Hospital or Doctor's office):Immunology Laboratory
Address: No. No. 366, Wutong Road, Xihu District, Hangzhou, Zhejiang

5. **Statistical methods:**
5.1 Statistical of test result

		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%
Overall Agreement=(A+D)/(A+B+C+D)*100%

5.2 Statistical of Specimens correlation
Record and statistics the correlation of antigen-positive/PCR-positive and antigen-negative/PCR-positive samples with the Ct values of the PCR to determine the mean Ct value of antigen-positive samples

6. **Evaluation indicators:**
The total PPA should be no less than 80%.
The total NPA should be no less than 90%.

7. **Statistical results of the clinical evaluation**
7.1 Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	131	1	132
	Negative	4	179	183
Total		135	180	315

7.2 Statistical results

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA (%)	131/135	97.04% (92.59%~99.19%)
Relative Specificity-NPA (%)	179/180	99.44% (96.94%~99.99%)
Overall Agreement (%)	310/315	98.41% (96.33%~99.48%)

7.3 Kappa consistency test
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	0.9675, Good consistency.
Standard Error Se(K)	0.0144
95% Confidence Interval	0.9392~0.9958
Standard Error Se0(K)	0.056
Test Value Z	Z=17.1747 Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

7.4 Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid TestKit(Swab) with positive results stratified by the comparator method (Ct) counts were collected and assessed to determine the correlation of assay performance to the Ct.

Safecare COVID-19 Antigen Rapid Test	Comparator Method (POS by Ct≦40)	
	Ct<28	Ct≧28
Positive	130	1
Negative	0	4
Total	130	5
Positive Agreement(95% CI)	100.00% (97.20%~100.00%)	20.00% (0.51%~71.64%)

Based on above table, the positive agreement of the Safecare COVID-19 Antigen Rapid TestKit(Swab) is higher with samples of a Ct count <28.

8. **Conclusion**

A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:
The Relative Sensitivity is 97.04%, the Relative Specificity is 99.44%, the Overall Agreement is 98.41%.
In summary, The study showed that there is a high coincidence rate between the test-strip and RT-PCR, and have the equivalence on the clinical usage.

Reporter: Wei Lihua Date: 2020.12.16

Safecare Biotech (Hangzhou) Co.,Ltd

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