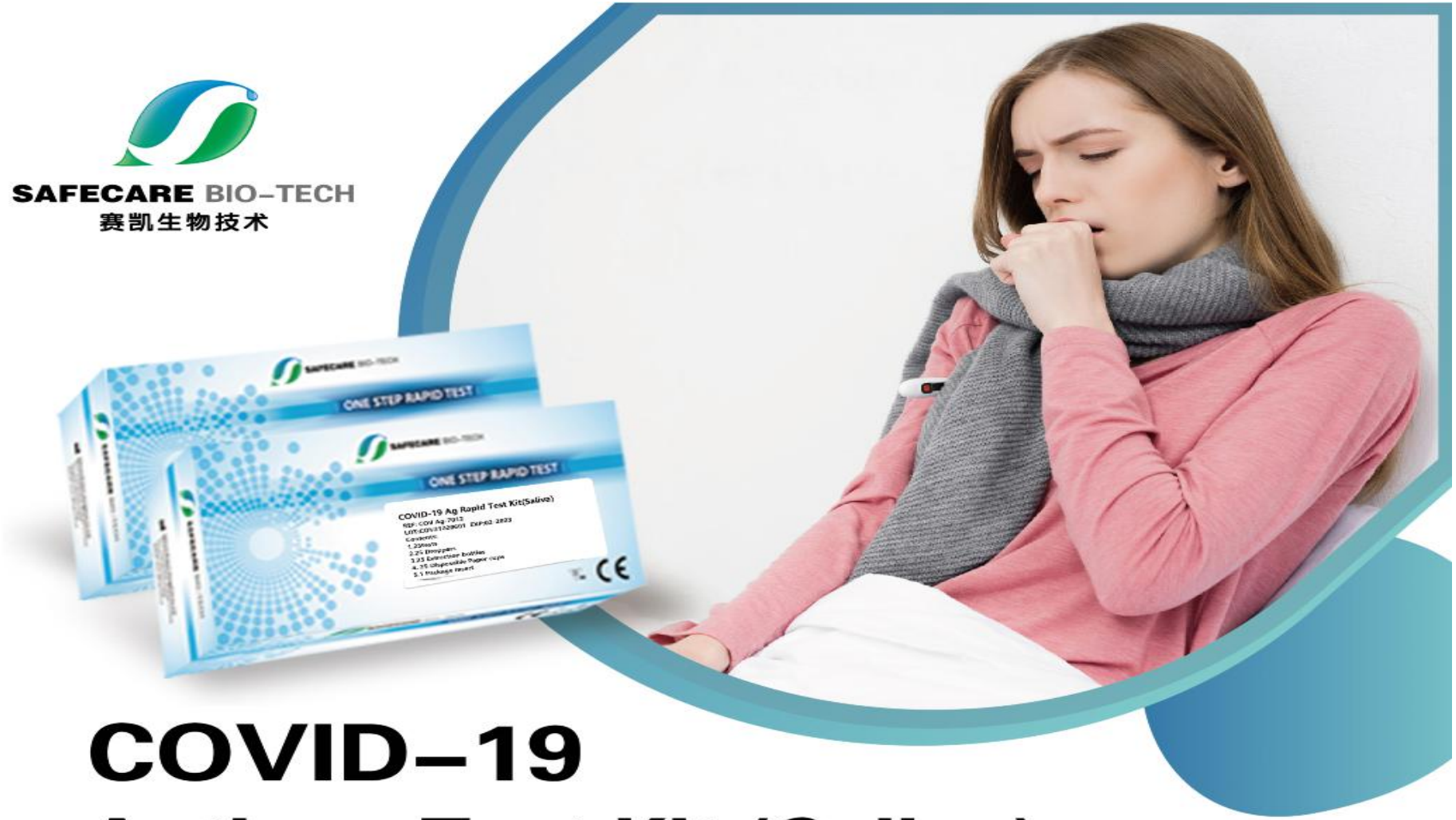
Safecare Biotech (Hangzhou) co.,ltd

SAFECARE BIO-TECH
赛凯生物技术



COVID-19
Antigen Test Kit (Saliva)

INTRODUCTION

The COVID-19 Antigen Rapid Test Kit (Saliva) is a lateral flow immunoassay intended for qualitative detection of nucleocapsid protein antigen in oropharyngeal saliva specimens from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

·Saliva Specimen

·Easy to use

·Fast Result in 10 min

·Room temperature storage

PRODUCT PHOTOS

COMPONENT/(BOX)

25 tests packed in one Kit :

25 Test Devices

25 collection paper cups

25 Extraction bottle with buffer

25 droppers

1 Package Insert

PACKAGE SIZE /CARTON

Length:630mm

Width:370mm

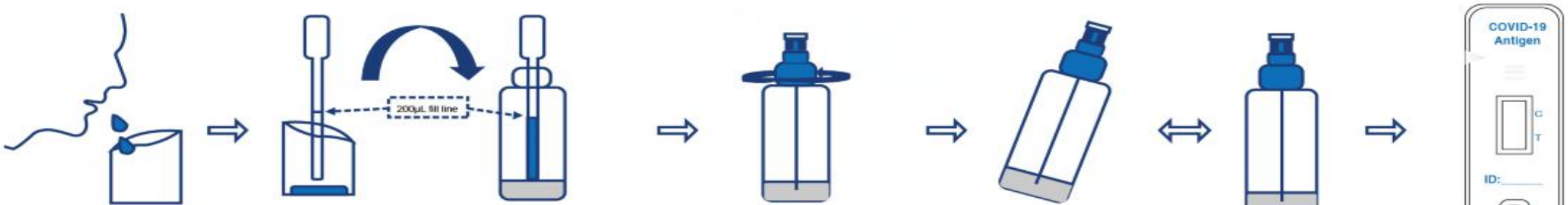
Height:300mm

Weight:12.5Kgs

Include: 27 boxes/carton

675pcs/carton

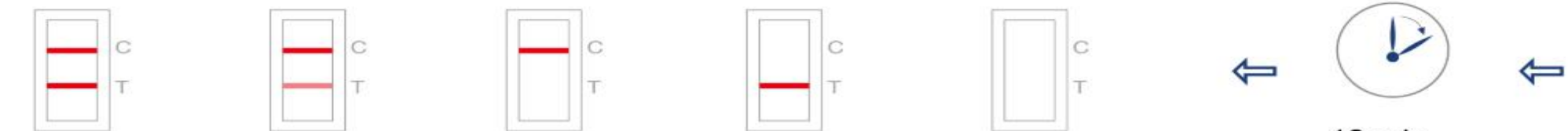
Test Procedure and Interpretation



Transfer 200μL saliva samples from disposable paper cup to Extraction bottle

Screw the Extraction bottle

Shake the Extraction bottle and Mix Completely



Positive

Positive

Negative

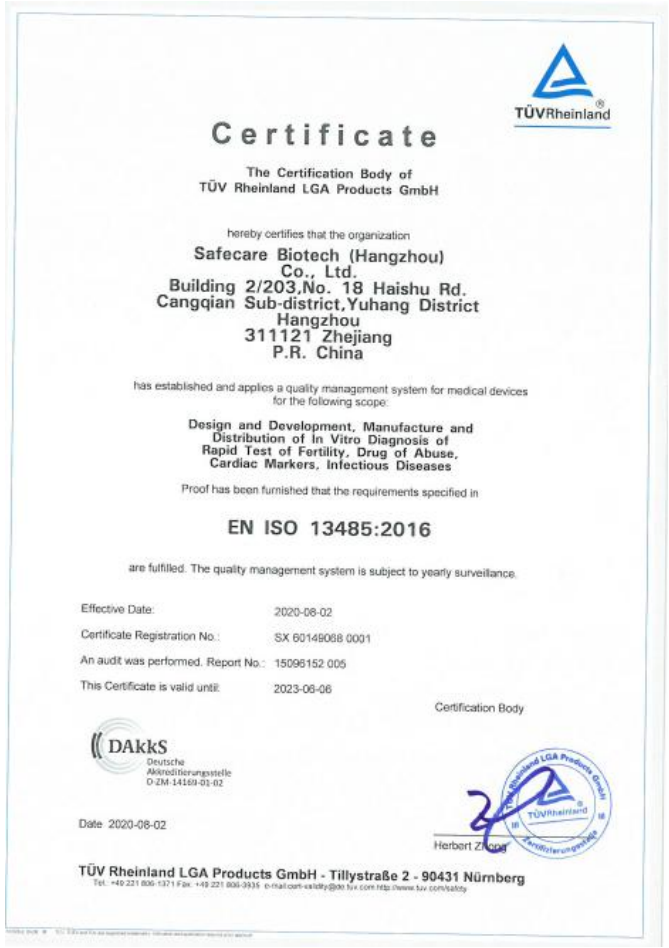
Invalid

Invalid

10 min

(Do not read after 20 minutes)

CERTIFICATE



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 60148088 0001
An audit was performed. Report No.:	15096152 005
This Certificate is valid until:	2023-08-06

Certification Body

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

Date 2020-08-02

Herbert Zi...

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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(Saliva)

Type/model, identification of product allowing traceability (Where applicable): COV Ag-7012

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- 2016, EN ISO15223-1:2016

Conformity assessment procedure: Module A (EC Declaration of Conformity) (Annex III, except point 6)

Notified Body (name & number): **NOT applicable**

Certificate & number

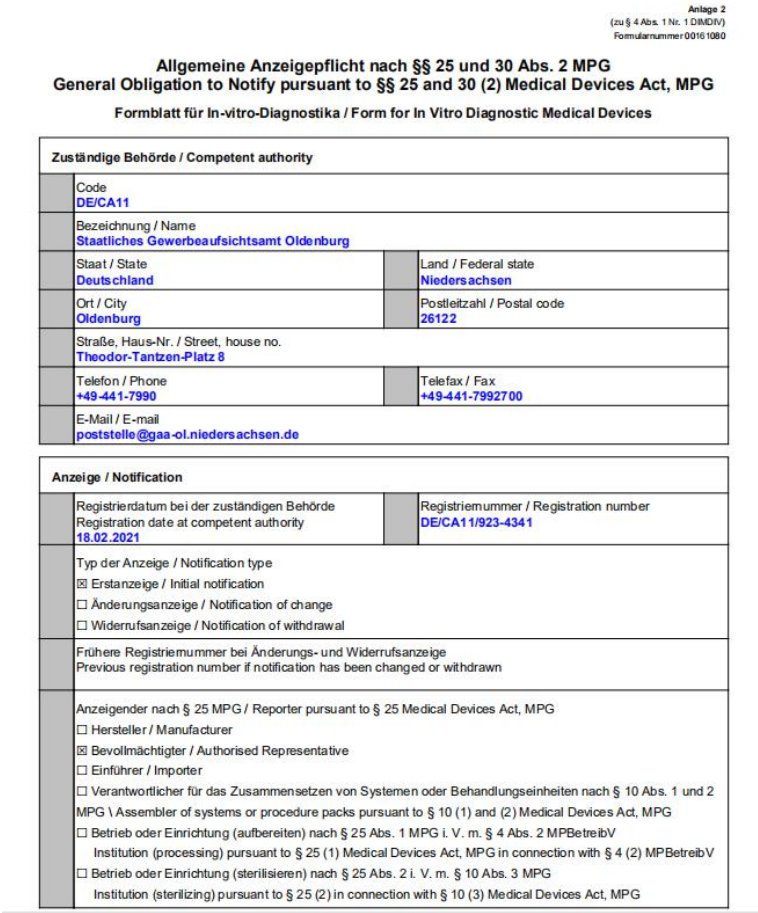
Signed on 3th Feb.,2021 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Kebin, Qiu

Position held in the company: General Manager

Seal/Stamp:



Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00161080

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority

Code
DE/CA11

Bezeichnung / Name
Staatliches Gewerbeaufsichtsamt Oldenburg

Staat / State	Land / Federal state
Deutschland	Niedersachsen

Ort / City	Postleitzahl / Postal code
Oldenburg	26122

Straße, Haus-Nr. / Street, house no.
Theodor-Tantzen-Platz 8

Telefon / Phone	Telefax / Fax
+49-441-7990	+49-441-799270 0

E-Mail / E-mail
poststelle@gaa-ol.niedersachsen.de

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority	Registriernummer / Registration number
18.02.2021	DE/CA11/923-4341

Typ der Anzeige / Notification type
☒ Erstanzeige / Initial notification
☐ Änderungsanzeige / Notification of change
☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG
☐ Hersteller / Manufacturer
☒ Bevollmächtigter / Authorised Representative
☐ Einführer / Importer
☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG
☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV
☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

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 10 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 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: COV20101001

3 Protocol:

1） Sample Size:

Positive Sample: >100

Negative Sample:>100

2） Sample's collection:

loropharyngeal saliva and 1 oropharyngeal swab were collected at the same time from each patient. The oropharyngeal saliva was tested directly with Safecare COVID-19 Ag Card test kit according to product instructions. The oropharyngeal swab was eluted in viral transport media (VTM) .All samples were randomly blinded and assigned to testing with PCR assay as the comparator method for this study.

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.

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.

5) Comparator method

All samples was confirmed by RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing) manufactured by Sansure BioTech Inc.

PCR tests performed on ABI7500.

4 Operator and site:

Site 1: CDC-Immunology Laboratory

Researcher: Dr. ZHANG LEI

Site 2: Hospital- Immunology Laboratory

Researcher: Dr.Xuwei

5 Statistical methods:

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

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

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

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

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 95%.

The total NPA should be no less than 95%.

7 Statistical results of the clinical evaluation

1) Test result

		Referencing Method (RT-PCR)		Total
		Positive	Negative	
Test-strip	Positive	131	1	132
	Negative	2	182	184
Total		133	183	316

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity-PPA （%）	131/133	98.50% （94.67%~99.82%）
Relative Specificity-NPA （%）	182/183	99.45% （96.99%~99.99%）
Overall Agreement （%）	313/316	99.05% （97.25%~99.80%）

2) 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	0.9805, Good consistency.
Standard Error Se(K)	0.0112
95% Confidence Interval	0.9585～1.0025
Standard Error Se0(K)	0.056
Test Value Z	Z=17.4302 Probability value P=0.0000
Test Result	P<0.05,refuse H0， Kappa values come from populations other than 0.

3) Specimens correlation

The performance of Safecare COVID-19 Antigen Rapid Test Kit(Saliva) 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<30	Ct≧30
Positive	128	3
Negative	0	2
Total	128	5
Positive Agreement(95% CI)	100.00% (97.16%～100.00%)	60.00% (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 <30.

8 Conclusion

1) A side-by-side comparison was conducted using the research reagent and referencing reagent. Compare with RT-PCR:

The Relative Sensitivity is 98.50%, the Relative Specificity is 99.45%, the Overall Agreement is 99.05%.

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: Wu Gang Date: 2021.01.25

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 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.