COVID-19 Antigen Rapid Test Kit (Swab)
For Self-Testing
Package Insert

CE 1434 REF COV Ag-6012H English

For self testing and in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Rapid Test Kit (Swab) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19.
This test is intended for home use with self-collected nasal swab samples in individuals aged 18 and older. Sampling from anyone under the age of 18 should be performed under the guidance of an adult. People who are unable to carry out the test on their own should seek support.
This test utilizes the lateral flow immunoassay technology for the detection of nucleocapsid protein antigen in individuals with known or suspected COVID-19.
Positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses.
Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

PRINCIPLE

The COVID-19 Antigen Rapid Test Kit (Swab) is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens.
SARS-CoV-2 specific antibodies are immobilized onto the test region of the membrane and combined with other reagents/pads to construct a test strip.
During testing, the specimen reacts with anti-COVID-19 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the reagents in test line region. Therefore, if the specimen contains COVID-19 antigen, a colored line will appear in test line. If the specimen does not contain COVID-19 antigen, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
The test is desgined to detection of nucleocapsid protein antigens in nasal swab specimens, which is different from the mutation sites have occurred in the spike protein, so it is theoretically able to detect variants including those in UK, India, South Africa and Brazil.

KIT COMPONENTS

Component	1 Test /Kit	5 Tests /Kit
COVID-19 Antigen Test	1	5
Extraction tube with buffer	1	5
Sterilized nasal swab	1	5
Package insert	1	1

ADDITIONAL SPECIAL EQUIPMENT

Timer

POTENTIAL RISKS AND BENEFITS

- Potential risks include:

Possible discomfort during sample collection.
Possible incorrect test results (see Read Results section).

- Potential benefits include:

The results, along with other information, can help your healthcare provider make informed recommendations about your care.
The results of this test may help limit the spread of COVID-19 to your family and others in your community.

WARNINGS AND PRECAUTIONS

- Do not use after expiration date. Do not use if kit is damaged or open. Do not reuse the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Discard the using testing materials in accordance with local regulations.
- The extraction buffer contains a salt solution if the solution contacts the skin or eyes, flush with copious amounts of water.Don't swallow the buffer.When swallowing the buffer, rinse the mouth thoroughly with water and give plenty of water to dilute the substance.If any discomfort, seek medical attention immediately.
- Children and elder please use the test under the guardian.

STORAGE AND STABILITY

Store unused test devices unopened at 4°C-30°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

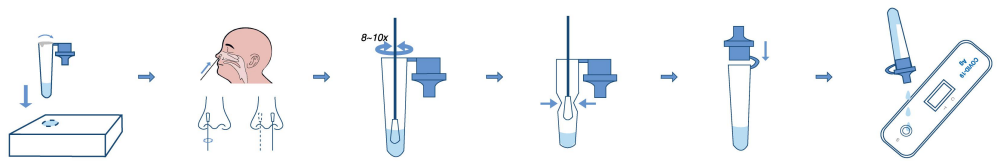
TEST PROCEDURE

Open the kit box. Check the components before use.

Please read all instructions carefully before you begin.
[Preparation before sampling]
1. Get a flat area ready, like a table. Make sure it is clear, clean and dry.
2. Take off hand jewellery.
3. Wash your hands for 20 seconds. Use soap and warm water, or hand sanitiser. Dry your hands using clean disposable paper towels.
   For better protection and avoid cross-contamination, disposable gloves, masks and eye protection (not provided in the package) are recommended.

[Specimen Preparation]
1. Press the hole on the box, peel off the foil film on the extraction tube and insert into the hole.
2. Open nasal swab package at the sticky end and take the nasal swab out.
3. Gently insert the soft tip of the nasal swab into left nostril about 2.5cm (1 inch) for adult.
   Note: For child, the maximum depth of insertion into the nostril may be less than 2.5 cm and should be carefully and appropriately adjusted by the person, who collects sample.
4. Firmly brush against the inside of the nostril in a circular motion 5 times or more.
5. Move the nasal swab to the right nostril and repeat the previous action. Make sure an adequate sample is collected.
6. Insert the nasal swab into the tube which contains extraction buffer.
7. Rotate nasal swab at least 8-10 times while pressing nasal swab tip against the bottom and the side of the tube.
8. Remove the nasal swab while squeezing and rolling the nasal swab against the sides of the tube to release as much liquid as possible .
9. Cover the tube with dropper tip tightly and insert the tube back into the box.

[Test Procedure]
1.Open the sealed pouch and take out the test cassette. For best results, the test should be performed in one hour.
2.Hold the tube vertically upside down over the sample well.
3. Add 3 drops specimen into the sample well by gently squeezing the sides of the tube, then start the timer.



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 sample well(S)

4.Wait for colored lines to appear.The test result can be read in 10-15 minutes, DO NOT read after 20 minutes.

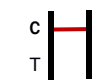
[After the testing]
1. After you have done the test, put all parts of the kit in the waste bag. Discard the waste bag in accordance with local regulations.
2. If you are doing more than 1 test, clean the table with 75% alcohol or sanitiser. Wash your hands between each test.

INTERPRETATION OF TEST RESULT

POSITIVE RESULT

A colored line appears in the control line region (C) and a colored line appears in test line region (T).
***NOTE:** The intensity of the color in the test line region will vary depending on the concentration of COVID-19 antigen in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE RESULT



A colored line appears in the control line region (C) and no line appears in test line region (T).

INVALID RESULT

No line appears in control line region(C). Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

BUILT-IN CONTROL

This test contains a built-in control feature, the C line on the test. The C line develops after adding sample solution. Otherwise, review the whole procedure and repeat test with a new device.

WHAT SHOULD I DO AFTER TEST

If the test result is positive	There is currently a suspicion of a COVID-19 infection ➢ Contact your doctor / general practitioner or the local health department immediately ➢ Comply with local guidelines for self-isolation ➢ To have a PCR confirmatory test performed
If the test result is negative	Continue to comply with all applicable rules regarding contact with others and protective measures ➢ An infection may also be present if the test is negative ➢ If it is suspected, repeat the test after 1 - 2 days, as the coronavirus cannot be accurately detected in all phases of an infection
If the test result is invalid	Possibly caused by incorrect test execution ➢ Repeat the test ➢ If the test results remain invalid, contact a doctor or a COVID-19 test center

Note: Do not take any decision of medical relevance without first consulting your medical practitioner

PERFORMANCE CHARACTERISTICS

1. Limit of Detection: The Limit of Detection (LoD) was determined by evaluating different dilutions of heat inactivated SARS-CoV-2 virus. LoD is defined as the virus concentration - 1.3 x 10^2 $TCID_{50}$/mL at which a minimum of 19 replicates out of 20 generate a Reactive result.
2. High-dose Hook Effect: No hook-effect was observed at 3.33X10^6 $TCID_{50}$/mL of inactivated SARS-CoV-2 virus culture.
3. Clinical study: A comparison was conducted with RT-PCR, according the test data listed below table, the Relative Sensitivity is 96.4% (212/220), the Relative Specificity is 100%(200/200) and the overall agreement is 98.1% ((212+200)/420).

		PCR result		Total
		Positive	Negative	
Safecare Test	Positive	212	0	212
	Negative	8	200	208
Total		220	200	420

4. Cross-reactivity: Cross-reactivity studies are performed to demonstrate that the test does not react with the following microorganisms in the table below at concentration of 1x10^5 $TCID_{50}$ /mL for viruses and 1x10^5 CFU/mL for bacteria.

Human metapneumovirus (hMPV)	Human parainfluenza virus 1	Adenovirus	*Bordetella pertussis*	*Streptococcus pneumoniae*
Human coronavirus OC43	Human parainfluenza virus 2	Rhinovirus	*Chlamydia pneumoniae*	*Streptococcus pyogenes*
Human coronavirus 229E	Human parainfluenza virus 3	Enterovirus	*Haemophilus influenzae*	*Mycobacterium tuberculosis*
Human coronavirus NL63	Human parainfluenza virus 4	Influenza A	*Legionella pnuemophila*	*Staphylococcus aureus*
Respiratory Syncytial Virus	MERS	Influenza B	*Mycoplasma pneumoniae*	*Candida albicans*

5. Interference: The following endogenous interference substances were evaluated at the concentrations listed and no effect was found.

Whole blood (2%), three OTC nasal sprays (10%), three OTC nasal drop (25%), three nasal mouthwashes (25%), 4-Acetamidophenol (10mg/mL), Acetylsalicylic acid (20mg/mL), Chlorpheniramine (5 mg/mL), Dextromethorphan (10mg/mL), Diphenhydramine (5mg/mL), Ephedrine (20mg/mL), Guaiacol glyceryl ether (20mg/mL), Oxymetazoline (10mg/mL), Phenylephrine (100mg/ml), Phenylpropanolamine (20mg/mL) ,Oseltamivir Phosphate (10mg/mL), Mupirocin (10mg/mL),Vitamin A (10%), D-Panthenol (10%)

LIMITATIONS AND POSSIBLE ERRORS

1.The COVID-19 Antigen Rapid Test Kit (Swab) is intended for use as a self-test and may only be used for qualitative detection of SARS-CoV-2 antigens. The colour intensity of a positive line shall not be evaluated as quantitative or semi-quantitative.
2. The COVID-19 Antigen Rapid Test Kit (Swab) should be only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
3.The performance was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. A negative result does not exclude the possibility of COVID-19 infection
5. The results obtained with this assay, especially in the case of weak test lines which are difficult to interpret, should retest or go to a medical institution for testing.
6. The test is intended for infection detection and not for determine infection status.The test is used for the auxiliary diagnosis of patients with the COVID-19 and can not be used as the sole diagnostic indicator of whether the test subject is infected with the COVID-19.

ACCESSORIES

Accessory	Manufacturer	EC Representative	CE Mark
Swab A	Jiangsu Changfeng Medical Industry Co.,Ltd. Touqiao Town,Guangling District Yangzhou Jiangsu 225109, P.R.China	Llins Service & Consulting GmbH Obere Seegasse 34/2.69124 Heidelberg Germany	CE 0197 acc.93/42/EEC
Swab B	Goodwood Medical Care Ltd. 1-2 Floor,3-919 Yongzheng Street,Jinzhou District,Dalian 116100 Liaoning, P.R.China	CMC Medical Devices & Drugs S.L. C/Horacio Lengo No.18,CP29006,Málaga,Spain	CE 0197 acc.93/42/EEC
Swab C	CITOTEST LABWARE MANUFACTURING CO.,Ltd. No.339 Beihai West Road,Haimen, 226100 Jiangsu, P.R. China	Wellkang Ltd Enterprise Hub,NW Business Complex,1 Beraghmore Road,Derry,BT48 8SE Northern Ireland	CE 0197 acc.93/42/EEC

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4°C 30°C	Stored between 4-30℃		Consult instruction for use
	Keep away from sunlight	LOT	Lot number
	Use-by date	Σ	Contains sufficient for <n> tests
	Manufacturer		Date of Manufacture
STERILE EO	Sterilized using ethylene oxide	STERILE R	Sterilized using irradiation
EC REP	Authorized Representative in the European Community	CE 1434	CE Mark

Safecare Biotech(Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd, Cangqian Sub-district
Yuhang District, Hangzhou, 311121, China
Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn

EC REP
NIC GmbH
Erlenweg 13, 49076 Osnabrück, Germany
Tel.:+49 541 9116706
Email:info@nic-industry.com

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