SAFECARE CE
COVID-19 Antigen Rapid Test Device (Swab)
Package Insert

For Medical professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Rapid Test Device (Swab) 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.
The COVID-19 Antigen Rapid Test Device (Swab) does not differentiate between SARS-CoV and SARS-CoV- 2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The COVID-19 Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

PRINCIPLE

The COVID-19 Antigen Rapid Test Device (Swab) is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab or nasopharyngeal 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.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Extraction tube	For specimens preparation
Extraction buffer	For specimens extraction
Workstation	For placing extraction tube
Nasal Swab	For specimens collection
Package insert	For operation instruction

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

WARNINGS AND PRECAUTIONS

- Do not use after expiration date. Do not use if pouch is damaged or open.Do not reuse the tests.
- Do not mix components from different kit lots. Avoid cross-contamination of specimens by using a new specimens collection container for each specimens obtained.
- 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. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The extraction buffer contains a salt solution if the solution contacts the skin or eyes, flush with copious amounts of water.
- Discard the using testing materials in accordance with local regulations.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

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.

SPECIMEN COLLECTION AND HANDLING

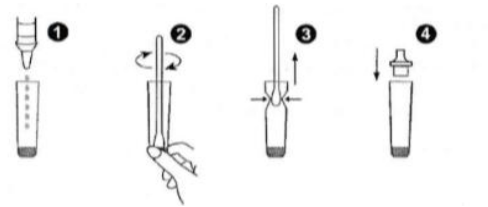
[Specimen Collection]

- Inadequate specimen collection or improper specimen handling may yield a false result.
- Prior to collecting the nasal swab, the patient should be instructed to blow their nose.
- Nasal Swabbing:
  To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

- Nasopharyngeal Swabbing:
  To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.
- Specimens Transport and Storage:
  Specimens should be tested as soon as possible.If transport of the samples is required, the following transport media are recommmended and have been tested and shown not to interfere with the performance of the test: Hank's balance Mkd salt solution, M5 media, or saline.Alternatively, samples may be stored refregerated(2-8℃) or at room temperature(15-30℃) in a clean,dry, closed container for up to 8 hours before testing.

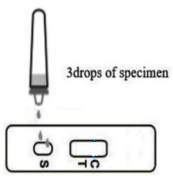
[Specimen Preparation]

1. Add 4 drops of extraction buffer into the extraction tube, and put it on the workstation.
2. Insert the swab into the extraction tube which contains buffer. Rotate the swab at least 10times while pressing the swab against the bottom and side of the extraction tube.
3. Pinch the extraction tube with fingers and roll the swab head against the inside of the Extraction tube when you remove it to release as much liquid as possible. The extracted solution will be used as test specimen.
4. Insert a dropper tip into the specimen extraction tube tightly.



ASSAY PROCEDURE

Allow the test device and specimens to equilibrate to room temperature(15-30℃ or 59-86℉)prior to testing. For best results, the test should be performed in one hour.
1. Remove the test device from the sealed pouch.
2. Reverse the specimen extraction tube, Holding the specimen extraction tube upright, transfer 3 drops to the specimen well(S) of the test device, then start the timer.
3. Wait for colored lines to appear. Interpret the test results at 10minutes. Do not read results after 20 minutes.



INTERPRETATION OF ASSAY 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.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C band. The C line develops from blue to red after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative to assure the proper performing of the assay.

PERFORMANCE CHARACTERISTICS

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

		PCR result		Total
		Positive	Negative	
Safecare Test	Positive	30	0	30
	Negative	2	52	54
Total		32	52	84
Relative Sensitivity		93.75% (79.19%~99.23%)		
Relative Specificity		100% (93.15%~100%)		
Overall Agreement		97.62% (91.66%~99.71%)		

2. Cross-reactivity: Cross-reactivity studies are performed to demonstrate that the test does not react with the the following microorganisms in the table below. Bacterial isolates were evaluated at a concentration between 10^6 and 10^9 org/ml. Viral isolates were evaluated at a concentration of 10^5~10^8 $TCID_{50}$/ML.

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

3. 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)

LIMITATIONS OF TEST

1.For professional in vitro diagnostic use and should be only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

2.This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.

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 test result may occur if the level of antigen in a sample is below the detection limit of the test.If the test result is negative but clinical symptoms persist,additional testing using other

clinical methods is recommended. As with all diagnostic tests, a confirmed diagnosis should only be made by physician after all clinical and laboratory findings have been evaluated.

5.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

6.Positive and negative predictive values are highly dependent on prevalence.False positive test results are more likely during periods of low COVID activity when prevalence is moderate to low.

7.False negative results may occur if a specimen is improperly collected, transported, or handled.

8.Children tend to shed virus for longer periods of time than adults,which may result in differences in sensitivity between children and adults.

9.If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

REFERENCES

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2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013:825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
5. Wong G, Liu W, Liu Y, Zhou B, Bi Y, Gao GF. MERS, SARS, and Ebola: the role of super-spreaders in infectious disease. Cell Host Microbe 2015;18:398-401.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
EC REP	Authorized Representative in the European Community		

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