COVID-19 Antigen Rapid Test

In vitro diagnostics

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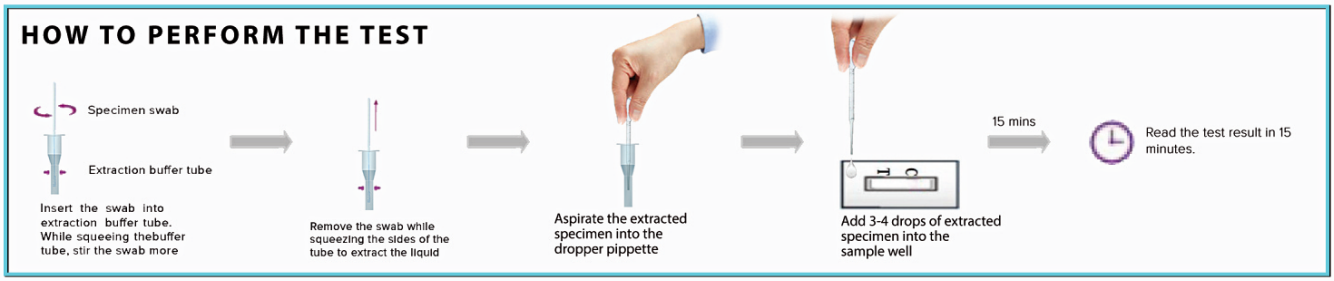
REF S064-01

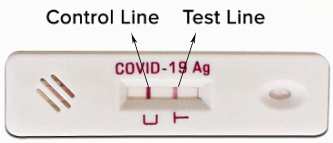


INTENDED USE

Sensit COVID-19 Antigen Rapid Test Kit is a qualitative immunochromatographic assay for the detection of nucleocapsid/spike protein of novel Coronavirus in human nasal swabs. Sensit COVID-19 Antigen Rapid Test Kit is only intended for initial screening and reactive samples should be confirmed by a supplemental assay.

TEST PRINCIPLE

Sensit COVID-19 Antigen Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad which contains Monoclonal Antibody against SARS-CoV2 Nucleocapsid/Spike Antigens; colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines; T: Monoclonal Antibody against SARS-CoV2 Nucleocapsid/Spike Antigen and C: Goat Anti- Mouse antibody.



COVID-19 Antigen Test cassette

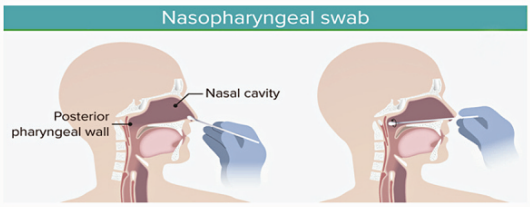
Test sample that is added to the well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad, where SARS-CoV-2 antigen present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone, where the complex accordingly will bind to the immobilized Monoclonal Antibody against SARS-CoV2 Antigens (on test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended and thus serves as a procedural control.

CONTENTS

1. Each test kit contains 25 test devices, each sealed in a foil pouch containing following items:
   a. COVID-19 Antigen test card
   b. Desiccant and Dropper Pipettes
2. Prefilled Extraction tube
3. Nozzle cap
4. Extraction Buffer
5. Sterile Nasal Swab
6. Instruction Leaflet

SAMPLE COLLECTION

1. Carefully insert the swab into the nostril of the patient,reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.



TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. **Sample Preparation**

- Peel-off the foil cover on the extraction buffer tube and place it on the work-bench. Insert the swab used to collect the specimen into the tube. Ensure the swab is stirred in the buffer at least five times while squeezing the sides of the tube for proper sample extraction
- Remove the swab by squeezing the sides of the tube to extract as much as specimen in the liquid from the swab. Dispose of swabs according to biohazard waste disposal method.

3. Add 3-4 drops of extracted specimen using dropper pipette into the sample well marked "S". Do not add more than 4 drops of sample

4. Wait for 15 minutes and read the result. Do not read after 20 minutes

For Off-Site Testing

Follow below procedure after Sample Preparation

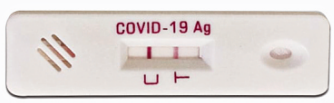
1. Fix the nozzle cap on the Extraction tube. Add exactly 2 drops of the Specimen into the Sample Well. **Don't add more than 2 drops of the specimen.** Addition of excess drops of extracted specimen may lead to erroneous result.
2. Wait for 15 minutes and read the result. Do not read after 20 minutes

Incase of insufficient volume of extraction buffer, use the buffer provided in the dropper bottle

TEST RESULTS

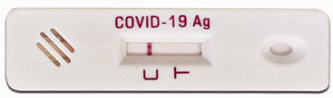
Positive (+)

Color bands at both the position, Control line "C" and Test line "T". Novel coronavirus antigen has been detected and the result is positive for antigen.



Negative (-)

Color band at position "C" alone. Novel coronavirus antigen has not been detected and the result is negative.



Invalid:

If the Control line C is not observed, it will be invalid regardless of whether there is Test line (as shown in the figure below), and the test shall be conducted again.

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STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. Test results should be read at 15 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used immediately (within 10 minutes)
4. Do not use expired devices.
5. Bring all reagents to room temperature (15-30°C) prior to use.
6. Do not mix components from different kits. Use only the buffer supplied along with the kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
11. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
12. Do not touch result window.
13. Use only for in-vitro diagnostic purpose.

LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of COVID-19 /SARS-CoV-2 virus in the nasal specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. Sensit COVID-19 Antigen Rapid Test is limited to the qualitative detection of SARS-CoV-2 viral antigens. The intensity of the test line does not necessarily correlate to SARS-CoV-2 virus titer in the specimen.
3. A negative or non-reactive result can occur if the quantity of SARS-CoV-2 virus present in the specimen is below the detection limit of the assay.
4. If symptoms persist and the result from Sensit COVID-19 Ag Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
5. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in COVID-19 Ag Rapid Test for single-step detection of novel CoronaVirus [COVID-19] Antigen are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980:2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to Symbols Used			
	Manufacturer		Expiration/ Use by Date
	Do not Reuse		Date of Manufacture
	Consult IFU (Instructions For Use)	LOT	Batch Code
30°C 2°C	Temperature Limitation 2-30°C	IVD	In Vitro Diagnostic Medical Device
Σ X	Contains Sufficient For 'X' Kits		Do Not Use if Package is Damaged
REF	Catalogue No.		Keep Dry
CE	CE Mark		Caution consult accompanying documents

Please read the user manual carefully before operating to ensure proper use.

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