SARS-COV-2 Antigen Rapid Test Kit

INTENDED USE

The SARS-COV-2 Rapid Antigen Test is a lateral flow immunoassay designed to qualitatively detect the nucleocapsid protein antigen from SARS-CoV-2 in upper respiratory samples with nasal swabs during the acute phase of infection.

INTRODUCTION

The SARS-COV-2 Rapid Antigen Test kit is a lateral flow immunoassay for the qualitative detection of SARS-COV-2 antigen (nucleocapsid protein) in upper respiratory samples with nasal swabs during the acute phase of infection. Results are interpreted for the identification of SARS-COV-2 nucleocapsid antigen. Generally, an antigen is detected in the nasal swab, nasopharyngeal swab and oropharyngeal swab during the acute phase of infection.

PRINCIPLE

The SARS-COV-2 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. SARS-COV-2 nucleocapsid protein monoclonal antibody conjugated with colour microparticles is used as a detector and sprayed on the conjugation pad. During the test, SARS-COV-2 antigen in the specimen interacts with SARS-COV-2 antibody conjugated with colour microparticles, making an antigen-antibody labelled complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the pre-coated SARS-COV-2 nucleocapsid protein monoclonal antibody. A colored test line (T) would be visible in the result window if SARS-COV-2 antigens are present in the specimen. Absence of the T line suggests a negative result. The control line (C) is used for procedural control and should always appear if the test procedure is performed properly.

MATERIALS AND METHODS

1. Individual sealed pouches, each containing:
   a. 1 × Test kit
   b. 1 × Silica Desiccant
   c. 1 × Dropper
2. Buffer Tube
3. Sterile Swabs

STORAGE AND STABILITY

- Keep the test kit between (4 - 30°C) in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required.

SPECIMEN COLLECTION

A sterile swab is inserted into the patient's nostril to the surface of the posterior nasopharynx. The swab is rotated three to four times and withdrawn from the nasal cavity.

For the nasal swab, insert the swab about 2.5 cm (1 inch) into the nostril until resistance is met at the turbinates. Then rotate the swab 5 times against the nasal wall and repeat in the other nostril using the same swab.

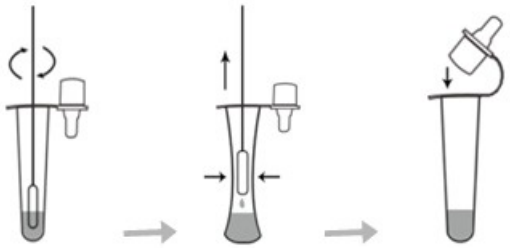
For the oropharyngeal swab specimen collection, insert the swab into the posterior pharynx and tonsillar areas. Rub the swab 5 times against both tonsillar pillars and posterior pharyngeal wall, and avoid touching the tongue, teeth, and gums.

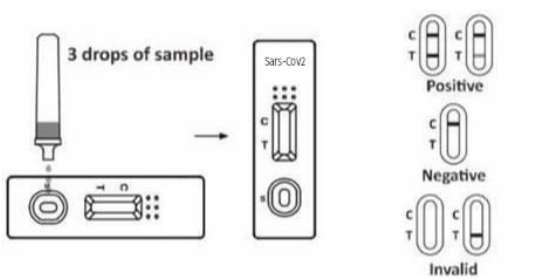
SPECIMEN TRANSPORT AND STORAGE

Discard the swab after using it for sample collection. Freshly collected specimens should be processed no later than one hour after sample collection. Specimens may be stored at 2-8°C for no more than 24 hours, and for a long time store at -70°C but avoid freeze-thaw cycle.

TEST PROCEDURE

1. Allow the test kit, buffer and specimen to equilibrate to room temperature (15-30°C).
2. The swab is placed into a buffer tube. The swab is stirred at least five times while pressing the head against the bottom and side of the tube. Leave the swab in the extraction buffer tube for one minute.
3. Removing the swab, the sides of the tube are squeezed to extract the liquid from the swab, and then the nozzle cap is pressed tightly onto the tube.
4. Three drops of the extracted sample are added to the specimen well of the test device. You can now wait for the test results.
5. The test result is ready to be read within 15 minutes. It should not be read after 20 minutes.
6. The test results can help healthcare professionals to make appropriate decisions quickly.
7. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.





RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

LIMIT OF DETECTION

The Limit of Detection (LoD) is 5.7×10^2 $TCID_{50}$/mL.

LIMITATIONS

1. To ensure an appropriate diagnosis, the test results, like any other diagnostic technique, should be analyzed in conjunction with the patient's clinical findings, medical history, and results from additional diagnostic procedures.
2. The product is used for qualitative detection; hence, the intensity of the test line does not necessarily correlate to the concentration of the antigen in the specimens.
3. A negative result can occur if the concentration of SARS-COV2 antigens present in the sample is below the detection threshold of the assay.

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