



SEMO TRADING CO.,LTD.

Rapid Diagnostic Test Kits

Asan Easy Test COVID-19 Ag

RDT for SARS-CoV-2 virus antigen

Immunochromatography

● INTENDED USE

The Asan Easy Test® COVID-19 Ag is a qualitative test for visual detection of SARS-CoV-2 antigens from nasopharyngeal swab specimens. It is intended for health care professional use as an aid on the diagnosis of SARS-CoV-2 antigens.

● EXPLANATION OF THE TEST

The Asan Easy Test® COVID-19 Ag kit is a chromatographic immunoassay for the rapid qualitative determination of SARS-CoV-2 antigens from nasopharyngeal swab specimens. SARS-CoV-2 virus antigens in specimens are allowed to react with the colloidal gold-mouse monoclonal anti-SARS-CoV-2 antibody conjugate, and mouse monoclonal anti-SARS-CoV-2 antibody on the test line which has been pre-dried on the test line. The mixture of conjugate-SARS-CoV-2 virus antigens moves upward on the membrane by the capillary action. For positive result, a visible line appears in the test line of the membrane.

● MATERIALS PROVIDED

The Asan Easy Test® COVID-19 Ag kit contains following items to perform the assay.

1. Asan Easy Test COVID-19 Ag (1 Device/Pouch x 25)
2. Disposable extraction tube with extraction buffer (with 350µl of extraction buffer - 25 tubes)
3. Dropper filter tip (25 caps)
4. Sterile swabs for sample collection. (25 swabs)
5. Instruction for use. (1 sheet)

● PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not eat drink, smoke, store or prepare foods within the work area.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Clean up spills thoroughly using an appropriate disinfectant.
5. Specimens and all materials coming into contact with them should be handled and disposed of as though potentially infectious.
6. The Asan Easy Test® COVID-19 Ag should be stored at room temperature (1~30°C).
7. The test device is sensitive to humidity as well as to heat.
8. Use the test device immediately after opening the pouch.
9. Do not use the test device beyond the expiration.
10. The test may be performed using fresh human swab specimens.
11. If specimens are not immediately tested they should be refrigerated at 2-8°C. For prolonged storage, freezing is recommended. They should be brought to room temperature prior to use.

● SPECIMEN COLLECTION AND STORAGE

1) Specimen Collection

To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril of the patient, reaching to the nasopharynx. Using gentle rotation, push the swab until resistance is met the level of the turbinate. Rotate the swab at least a few times against the nasopharyngeal wall.

2) Specimen Transport and Storage

Specimen should be tested as soon as possible after collection. Specimens may be stored at room temperature for up to 1 hour or at refrigerated up to 4 hours in a clean, dry, closed container prior to testing.

● WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminated and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

● TEST PROCEDURE

1. All materials should be equilibrated to room temperature (15~25°C) before performing the test.
2. When ready to test, remove the test device from the aluminum pouch and place it on a clean, dry. Label the test device with specimen's ID.
3. Peel off the upper aluminum seal of the extraction tube. Hold the extraction tube vertically on the rack.
4. Insert the patient swab specimen into the extraction tube. Swirl the swab at least 10 times while pressing the head against the bottom and side of test tube to release viral antigens from swab.
5. Swirl the swab head against the inside of the test tube as you remove it. Dispose of the used swab in accordance with your biohazard waste.
6. Press dropper filter tip tightly onto the extraction tube.
7. Apply 4 (90~100µl) drops of extracted specimen to the sample dropping well of the test device.
8. Read the result in 15~20 minutes after started reaction. The test result should not be read later than 30 minutes after started the reaction.

● INTERPRETATION OF THE TEST

1. POSITIVE RESULT:

The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



2. NEGATIVE RESULT:

The presence of only one red color band ("C" band) within the result window indicates a negative result.



3. INVALID RESULT:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



● STORAGE & EXPIRATION

1. Asan Easy Test® COVID-19 Ag Kit should be stored between 1 to 30°C (33.8~86°F).
2. Expiration date of this kit is 24 months after its manufacture date.



● LIMITATION OF RESULTS

Asan Easy Test® COVID-19 Ag is designed for primary screening test. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

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SEMOTRADING.CO.,LTD.

WWW.SEMOTRADING.KR
info.semotrading@gmail.com

A. Specimen collection B. Test Procedure

