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Description of Product

1 BACKGROUND

The novel coronaviruses belong to the p genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

1.1 Test Principle

The COVID-19 Antigen Test Cassette (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human Nasopharyngeal Swab specimen. SARS-CoV-2 antibody is coated in test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test.The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in est line region. If the specimen contains SARS-CoV-2 Antigens,a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region,indicating that the proper volume of specimen has been added and membrane wicking has occurred.

1.2 Illustrations

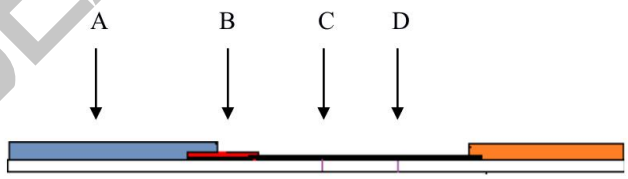


Figure 1: Test Principle

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the colored conjugate (B). COVID-19 antigen present in the specimen binds to the conjugate, forming a colored antibody-antigen complex. The anti-COVID-19 immobilized in the test zone of the membrane captures the test region (C). The formation of a visible colored line in the test region indicates a positive result (C). The absence of a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (D) confirms control line.

1.3 Performance and Specification

COVID-19 Antigen Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of s SARS-CoV-2 antigens present in human nasopharynx.

1.4 Precautions

- This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Wash hands thoroughly after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results

1.5 Storage and Stability

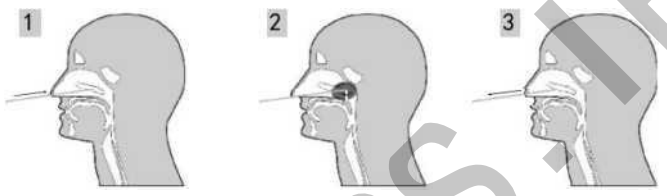
Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

TESTSEALABS®
Rapid Test Kit

1.6 Specimen Collection and Preparation

> Specimen Collection

1. Only the swab provided in the kit is to be used for nasopharyngeal swab collection. To collect a nasopharyngeal Swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. 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 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril..



2. Withdraw the sterile swab from the nasal cavity.

Specimens should be tested as soon as possible after collection.If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 8 hours at room temperature and 24 hours at 2-8 ° C.

> Specimen Preparation

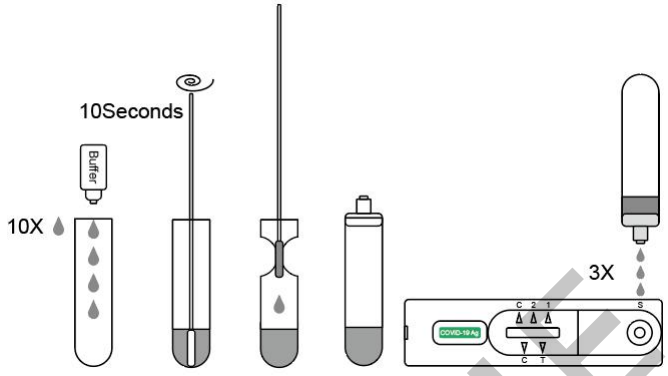
Preparation with Extraction buffer with non- Integrated Extraction Tube:

1. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically.Squeeze the bottle to let the solution drip freely into the extraction tube without touching the edge of the extraction tube. Add 10 drops of solution to the Extraction Tube.

2.Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

3. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

TESTSEALABS®
Rapid Test Kit



1.7 Standard Testing Procedure

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Invert the specimen collection tube and add 3 drops of the extracted specimen (approx. 100 µ I) to the specimen well(S) and then start the timer.
- Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

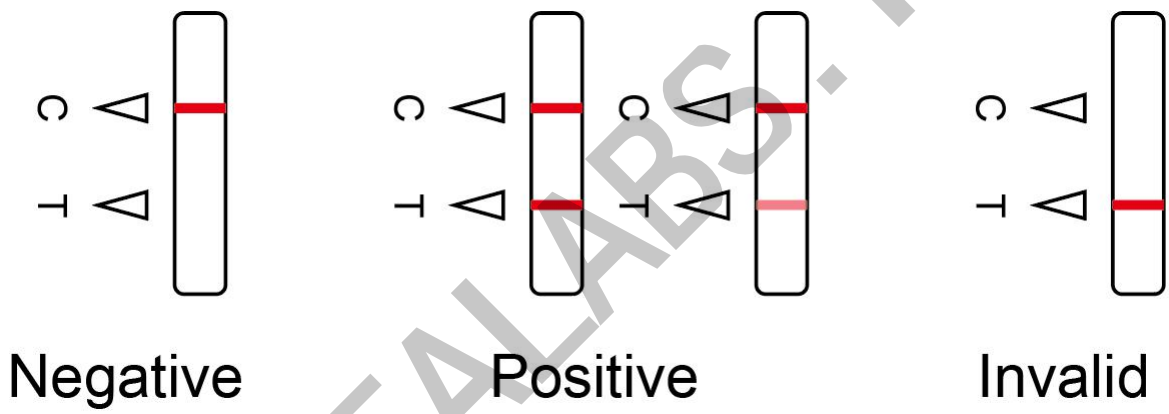


Figure 2: Interpretation of Results for Test Cassette

1.8 Interpretation of Results

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of SARS-COV-2 antigens in the sample.

***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of SARS-COV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

1.9 Quality Control

1.9.1 Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

1.9.2 External Quality Control

Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.[1]

1.10 Limitations

- The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- The COVID-19 Antigen Test Cassette (Swab) is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
- The COVID-19 Antigen Test Cassette (Swab) will only indicate the presence of SARS- CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
- The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
- If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
- The test will show negative results under the following conditions: The titer of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

1.11 Description of Test Methods

1.11.1 General remarks

The Quality Control department performs testing according to written procedures. Testing equipment is checked prior to use and calibrated at scheduled frequencies.

1.11.2 Receiving inspection and control of raw materials

A sample batch of each raw material (chemicals, packaging and labeling) is inspected/tested (where applicable) for suitability and functionality. Primary packaging is inspected for correct dimensions,

cleanliness and suitability. Only QC ᵘAPPROVED" raw material is employed for production.

1.12 Composition of Product

1) Goat anti Mouse IgG	2) Mouse IgG
3) Anti-SARS-CoV2 Antibody for capture	4) Anti-SARS-CoV2 Antibody for detection
5) Absorbent pad	6) Membrane
7) Adhesive plastic backing	8) Plastic cassette
9) Sample pad	10) Label pad
11) Pouch	12) Desiccant
13) Extraction Buffer	14) Package insert
15) Sterile swab	16) Extraction tubes and tips (Optional)
17) Workstation	

1.13 Manufacturing Procedure

- Coat the latex conjugated Anti-SARS-CoV2 antibody and mouse-latex on the label pad.
- Use the sprayer to dispense Anti-SARS-CoV2 antibody and Goat anti-Mouse IgG onto the membrane.
- Assemble the membrane, label pad, absorbent pad and sample pad on the plastic backing.
- Use the cutter to cut the plastic backing into strips of selected size. And/or lay the strip into the plastic cassette.
- Pack the cassette and a desiccant packet into a pouch and seal the pouch.
- Test the cassette according to the QC procedure and release the finished product.