

COVID-19 ANTIGEN TEST CASSETTE (SWAB)





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● Designed for qualitative detection of SARS-CoV-2 antigen in swabs



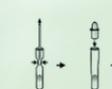
Operation procedure



Nasopharyngeal swab



Transfer 400 uL (about 10 drops) extraction buffer



Rotate about 10 times



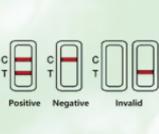
Squeeze the swab tip



Cover the dropper

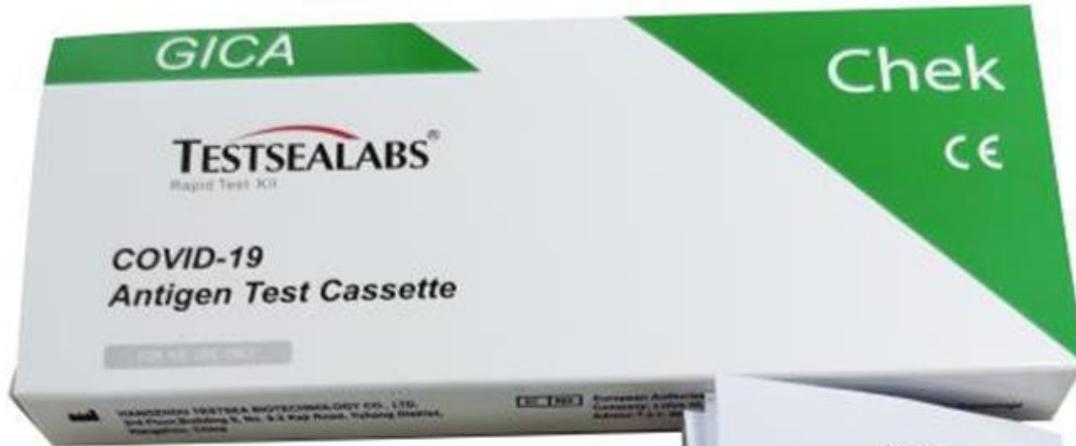


Add 80 uL (about 3-4 drops) to the sample well



Positive Negative Invalid

- 1 CE&ISO Approved from Original Manufacture
- 2 Nasopharyngeal Swab Sample
- 3 Instant Result in 15 minutes, faster than PCR test
- 4 Easy to use, no equipment required, no PCR Lab required
- 5 Room temperature storage(2-30°C)



COVID-19 Antigen Test Cassette
Package Insert

A rapid test for the qualitative detection of COVID-19 antigen in respiratory

[INTENDED USE]
The COVID-19 Antigen Test Cassette is a rapid chromatographic antigen detection of COVID-19 antigen in nasopharyngeal swab specimen of COVID-19 and vesicles.

[PRINCIPLE]
The COVID-19 Antigen Test Cassette is a qualitative membrane strip test detection of COVID-19 antigen in nasopharyngeal swab specimen and vesicles. The test cassette contains anti-COVID-19 antibody immobilized on the test line region and anti-COVID-19 antigen coated particles that have been coated with immobilized anti-COVID-19 antibody. If the specimen contains COVID-19 antigen, a colored line will appear in the region indicating a positive result. If the specimen does not contain COVID-19 antigen, a colored line will always appear at the control line region indicating that specimen is not infected and no false positive along with occurred.

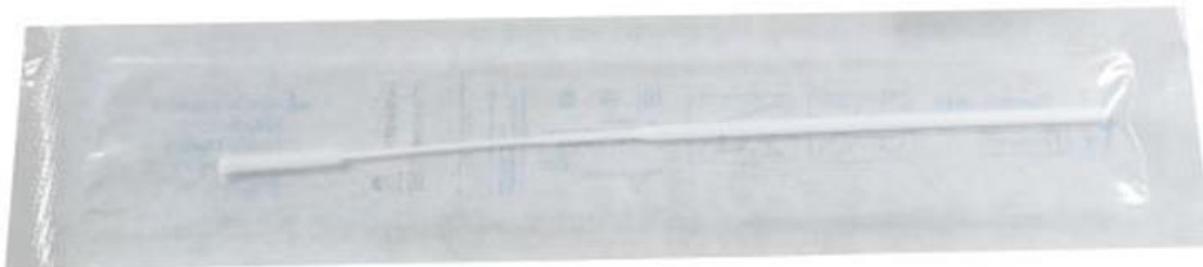
[REAGENTS]
The test contains anti-COVID-19 antibody as the capture reagent, anti-COVID-19 antibody as the detector reagent. A Goat anti-Mouse IgG is employed as the secondary reagent. A Goat anti-Mouse IgG is employed as the secondary reagent.

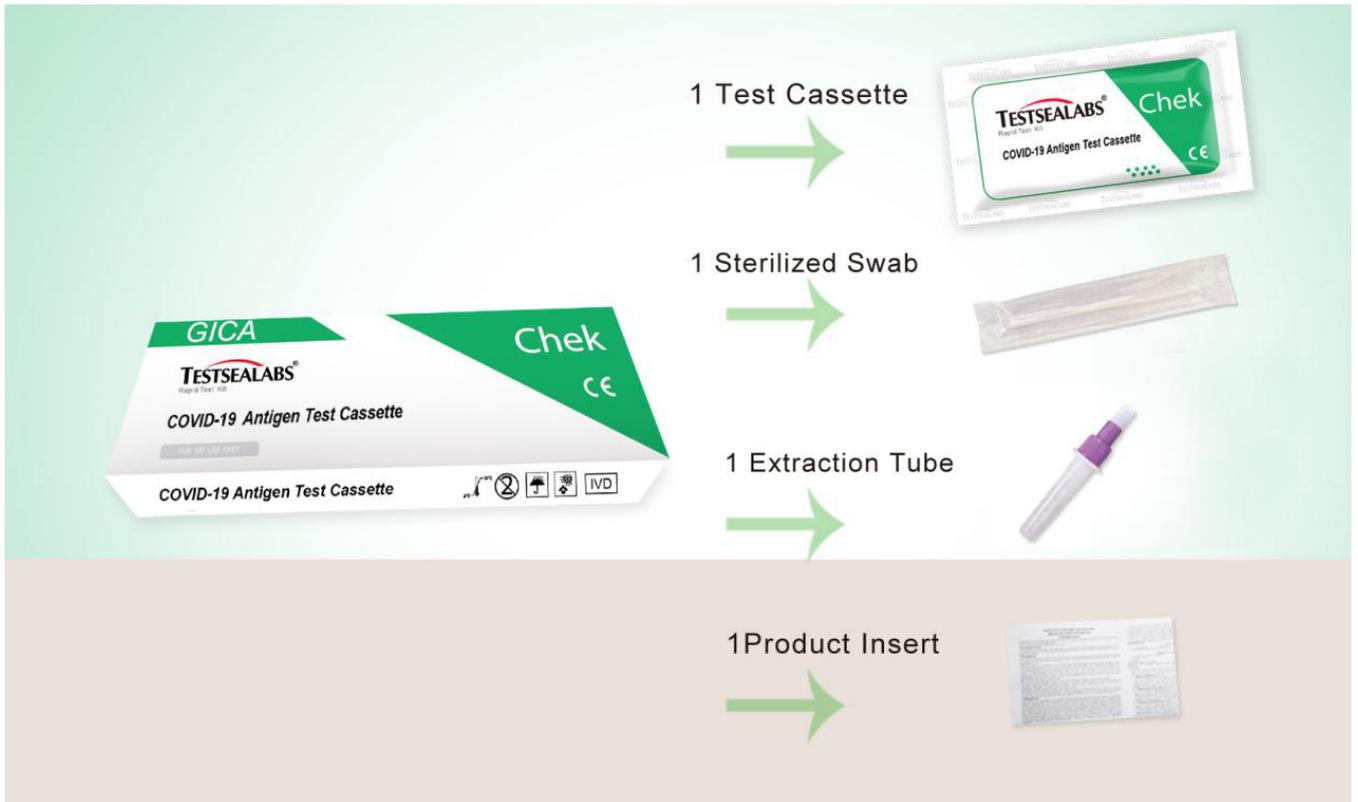
[PRECAUTIONS]

- 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 are tested.
- Handle all specimens as if they contain infectious agents.
- Observe established procedures for proper disposal of specimens and follow the standard procedures for proper disposal of specimens and specimens are delayed.
- Wear protective clothing such as laboratory coats, disposable gloves and face mask.
- Follow standard biosecurity guidelines for handling and disposal of test specimens.
- Humidity and temperature can adversely affect results.

[STORAGE AND STABILITY]
Store as packaged in the sealed pouch at room temperature or refrigerate up to 30 days. Stable to the expiration date printed on the sealed pouch. The test must be used within the expiration date. Do not use beyond the expiration date.

[SPECIMEN COLLECTION AND PREPARATION]
1. Swab Specimen collection



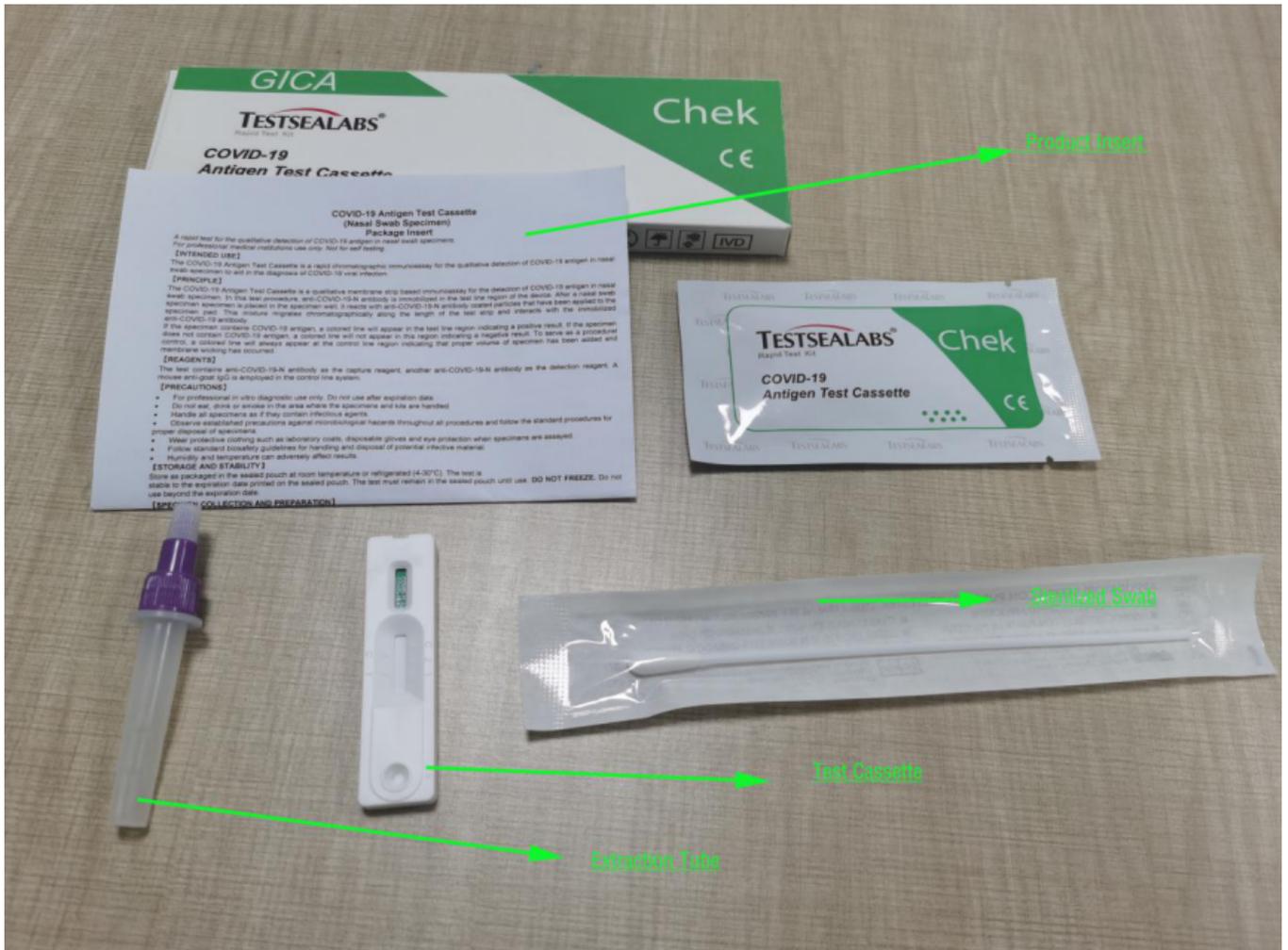


?INTENDED USE?

Testsealabs® COVID-19 Antigen Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in nasal swab specimen to aid in the diagnosis of COVID-19 viral infection.

?Specification?

1pc/box (1 test device+ 1 Sterilized Swab+1 Extraction Buffer+1 Product Insert)

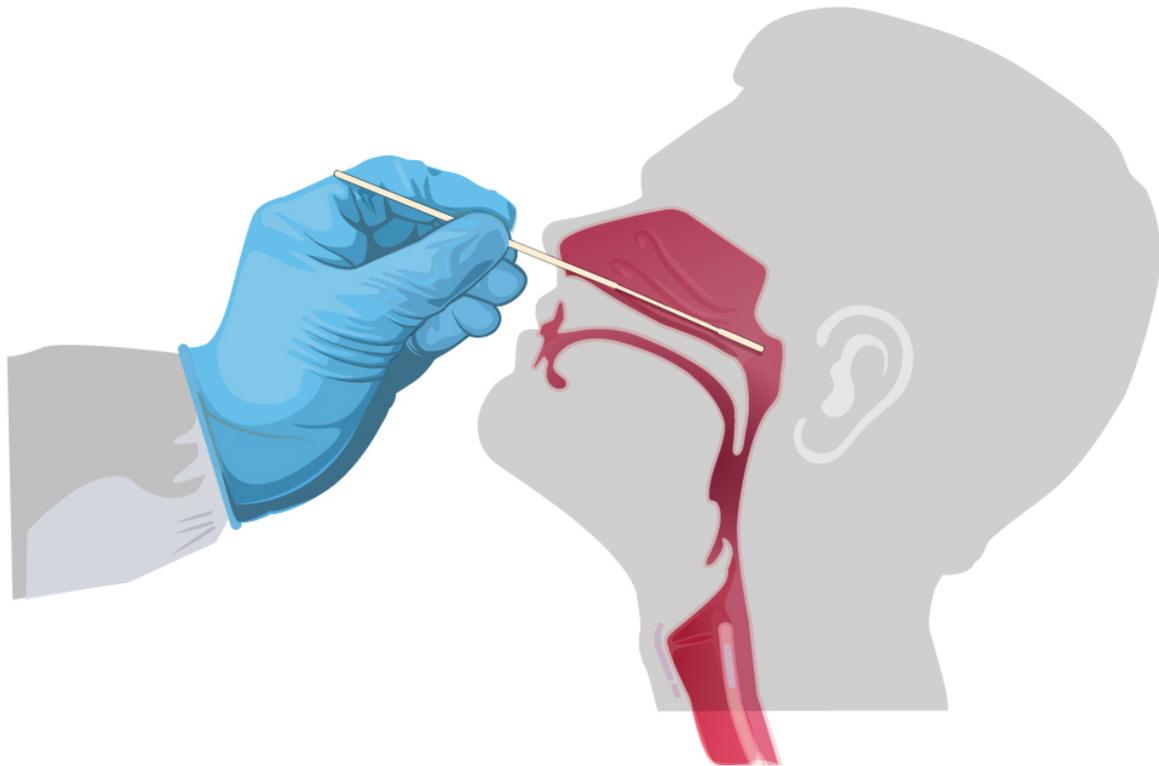


?MATERIALS PROVIDED?

1. Test Devices
2. Extraction Buffer
3. Sterilized Swab
4. Package Insert

?SPECIMENS COLLECTION?

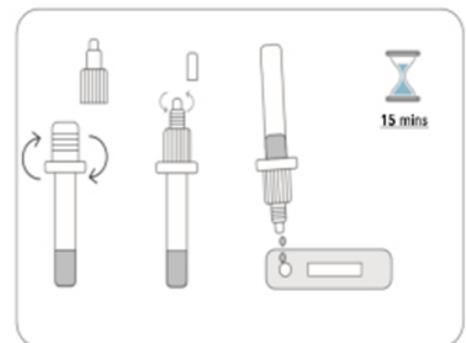
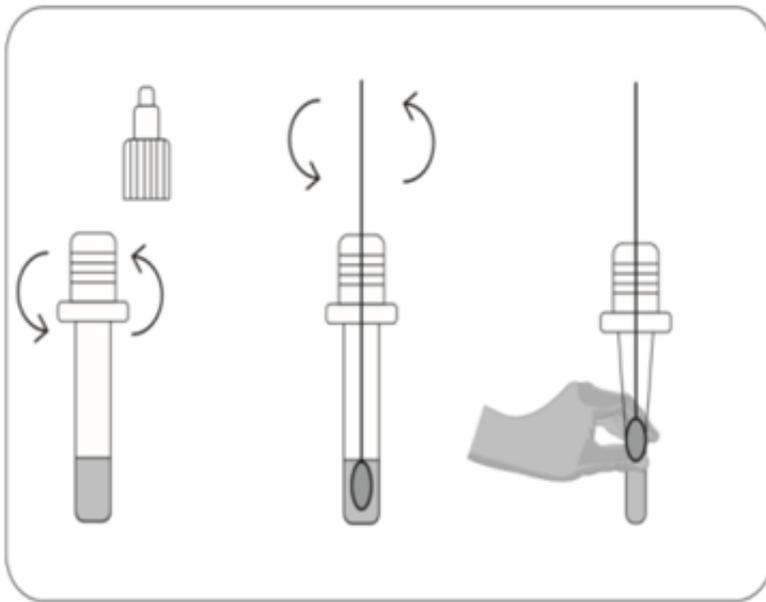
Insert mini tip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.



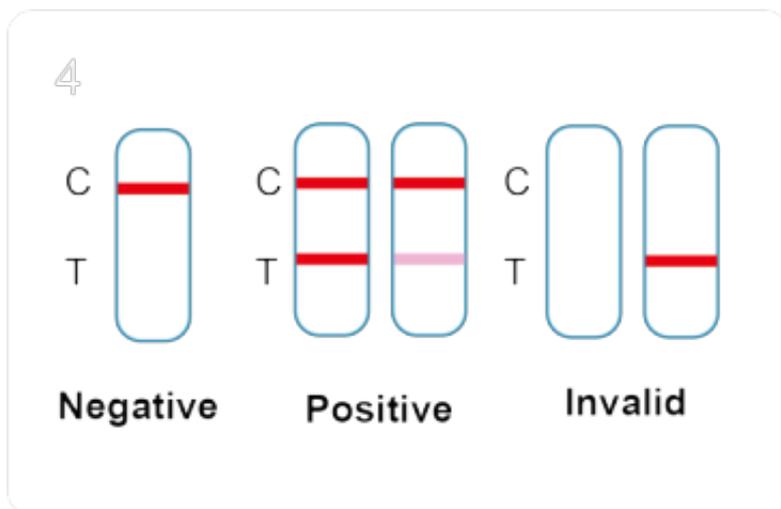
?HOW TO TEST?

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30° (59-86°) prior to testing.

1. Unscrew the cap of the specimen extraction buffer. Use the Nasopharyngeal Swab to pick up fresh sample. Place the Nasopharyngeal Swab into the extraction buffer and shake and mix completely.
2. Take the test cassette from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 2 drops of the sample into the sample hole vertically.
3. Read the result after 15 minutes. If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.



?INTERPRETATION OF RESULTS?



Positive: Two lines appear. One line should always appear in the control line region(C), and another

one apparent colored line should appear in the test line region.

*NOTE: The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

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

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.