ACCUCARE™
Covid 19 ANTIGEN TEST DEVICE
(Endocervical)

INTENDED USE

The Covid 19 Ag card test is a chromatographic immunoassay for the qualitative detection of Coronavirus antigen in nasal and throat swab specimens, as an aid in the diagnosis of infection with Corona Virus

Only for *In vitro diagnostic* use

ORDER INFORMATION

REF	Cont.
CVDC 10	10 Test
CVDC 25	25 Test

INTRODUCTION

Human coronaviruses are common throughout the world. Seven different coronaviruses, that scientists know of, can infect people and make them sick. Some human coronaviruses were identified many years ago and some have been identified recently. Human coronaviruses commonly cause mild to moderate illness in people worldwide. Three newer human coronaviruses, MERS-CoV, SARS-CoV and 2019-nCoV, have been known to frequently cause severe illness. Human coronaviruses can sometimes cause lower-respiratory tract illnesses, such as pneumonia or bronchitis. This is more common in people with cardiopulmonary disease, people with weakened immune systems, infants, and older adults. The Covid 19 Ag card test is an immunochromatographic assay that detects pathogen antigens directly from nasal and throat swabs in 10 minutes.

PRINCIPLE

The Covid 19 Ag card testdetects Coronavirus through visual interpretation of color development on the internal strip. Coronavirus Antigen-specific antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti Coronavirus antibodies which conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient Coronavirus antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Covid 19 Ag card testcontaining Coronavirus Antigen-specific antibodies coated particles and Coronavirus Antigen specific antibodies coated on the membrane.

KIT COMPONENTS

Test Device, Extraction Buffer, Sterile Swab, Extraction Tube, Dropper and product insert.

MATERIALS REQUIRED BUT NOT PROVIDED WITH KIT

1. Pipettes
2. Timer

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. Do not freeze.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

WARNING AND PRECAUSTION

1. For professional in vitro diagnostic use only.

2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.

3. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).

4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.

5. Read the entire procedure carefully prior to testing.

6. Do not eat, drink or smoke in any area where specimens and kits are handled.

7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.

9. Humidity and temperature can adversely affect results.

10. When the assay procedure is completed, dispose the swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, swabs can be treated with 0.5% sodium hypochlorite (i.e., household bleach) for one hour before disposal.

11. Used testing materials should be discarded according to local regulations.

SPECIMEN COLLECTION & PREPARATION

• The Covid 19 Ag card testcan be performed using nasal and throat swab specimens.
• The quality of specimens obtained is of extreme importance. Detection of Coronavirus antigen requires a vigorous and thorough collection technique that provides adequate amount of antigen.
• Use the swab provided in the kit. Alternatively, any plastic-shaft polyester Swab may be used.
Nasal Swabbing:
Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.
It is recommended to collect sample.
Throat Swabbing:
Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.

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• If the test is to be conducted immediately, put the swab into the extraction tube.
• It is recommended that specimens be processed as soon as possible after collection. If immediate testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swabs may be stored for 3 days refrigerated (2-8°C) or no more than 6 month at -20°C. All specimens should be allowed to reach room temperature (15-30°C) before testing.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after expiration date.
3. The test should remain in the sealed pouch until use.
4. Do not use the test if pouch is damaged.
5. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
6. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. The test should be discarded in a proper biohazard container after testing.
8. The test must be carried out within 2 hours of opening the sealed bag.

DIRECTIONS FOR USE

Allow test device, assay buffers, specimen, and/or controls to equilibrate to room temperature (18-30°C) prior to testing. Use a new pipette for each sample/test.

1. Prepare swab specimens:

• Place a clean extraction tube in the workstation. Hold the Extraction Buffer bottle vertically and add 11-13 drops of extraction buffer (approximately 0.5 mL) to the extraction tube. Immediately insert the swab, let stand for 1 minute. Compress the bottom of the tube and rotate the swab 6 times. Best results are obtained when the specimen is vigorously mixed in the solution.
• Press the swab against the side of the tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible.
• Fit the dropper tip on top of the extraction tube.

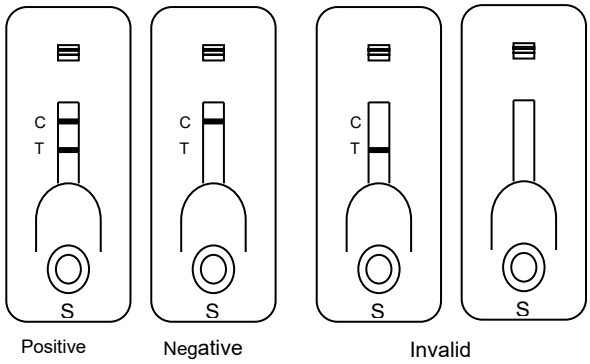
2. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.

3. Add 3 drops (approximately 100 µL) of extracted specimen from the extraction tube to the specimen well (S) of the test cassette then start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result window.

4. As the test begins to work, color will migrate across the membrane.

5. Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 10 minutes.

NOTE: Do not read after 20 minutes; Discard Cassette



INTERPRETATION OF THE RESULTS

POSITIVE: Two bands will appear in the control and test areas, which indicate a positive result for Corona antigen.

NEGATIVE: One color band will appear in the control area only, with no distinct colored line in the test window. This indicates a negative result.

INVALID: A distinct colored line in the Control area should always appear. The test is invalid if no line forms in the control window. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

LIMITATIONS

1. The Covid 19 Ag card testis for professional in vitro diagnostic use, and should only be used for the qualitative detection of Coronavirus. No meaning should be inferred from the color intensity or width of any apparent bands.

2. This test will only indicate the presence of Coronavirus antigen in specimens. Performance with other specimens has not been assessed.

3. Detection of Coronavirus is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar. Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data, available to the physician.

4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.

5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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