SARS-CoV-2 Antigen Assay (SCAA)

Catalog Number: AU2023-01

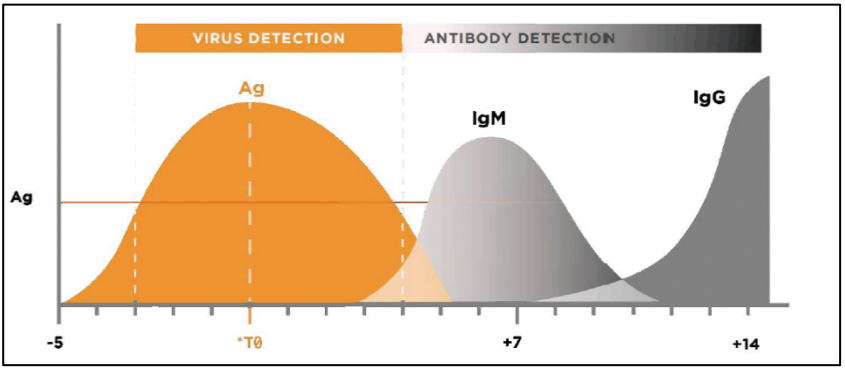
For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use (Expected Usage)

Used for in vitro qualitative detection of SARS-CoV-2 antigens in human swabs samples (Nasopharyngeal swab and oropharyngeal swab). It can only be used as a supplementary test indicator for suspected cases with negative PCR test of SARS-CoV-2 or used in conjunction with PCR testing in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by SARS-CoV-2 infection. It is not suitable for screening of the general population. Limited to medical institutions.

2. Advantage of the Antigen Test:

- Antigen detection window period is earlier than antibody detection.
- It will be tested immediately when the body is infected with the SARS-CoV-2, no need to wait for the body to produce the immune response about less than 7 days.
- Antigen test is faster than PCR test.
- Antigen test requires no other equipment
- Easy to use and operate.
- The test can be completed in 20 minutes.



3. Features

- Detections of human swabs (Nasopharyngeal swab and oropharyngeal swab)
- Sensitivity: 90%; Specificity: >98%;
- Minimum detection limit: <0.5ng/ml (Virus culture); <1pg/ml (recombinant antigen)
- Instant Result in 20 minutes
- Store at: 4°C to 30°C

4. Kit Contents

Contents	AU2023-01
Cassette Device	25 devices (each sealed foil pouch contains: 1 device, 1 disposable dropper, 1 desiccant)
Sample Diluent	25 bottles
Collection Swaps	25 sterile single use specimen collection swaps
Instruction Manual	1 each

5. Storage and Stability

- The kit should be stored at 4°C - 30°C until ready to use.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

6. Precautions

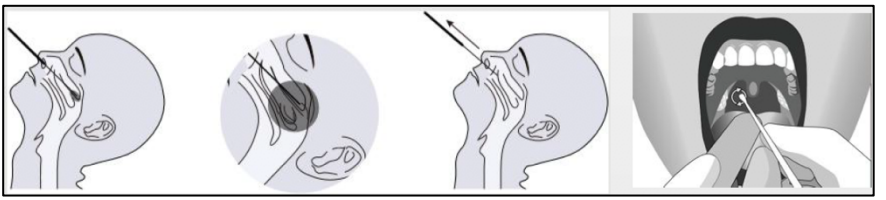
- For professional use only.
- Use the test device only once.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Collection Tubes from different lots.
- Do not open the Test Cassette foil pouch until you are ready to perform the test.
- Do not spill solution into the reaction zone.
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.

- All samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15 - 30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Evaluate the test result after 10 minutes and not beyond 20 minutes.
- Store and transport the test device always at 2°C - 30°C (36°- 86°F).

7. Sample Collection and Storage

Collection method of Nasopharyngeal swab specimen:

- The operator holds the swab by the right hand and holds the head of the subject fixedly by the left hand.
- Putting the sab downing backwards the bottom of the nasal cavity and penetrate slowly and gently.
- Do not overexert to avoid traumatic hemorrhage.
- When the tip of the swab touching the posterior parries of the paranasal cavity, letting the swab remain in the place for a few seconds (about 3-seconds) and rotating the swab gently for one cycle and then remove the swab slowly.



Nasopharyngeal Specimen collection *Oropharyngeal Specimen collection*

Collection method of Oropharyngeal swab specimen:

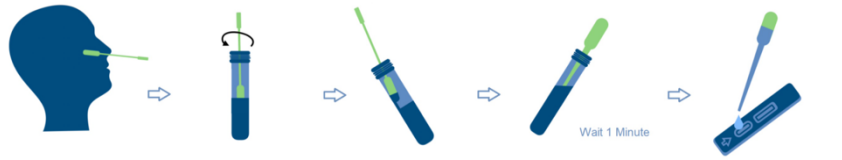
- The head of the person to be collected is slightly tilted and his mouth is wide open, exposing the pharyngeal tonsils on both sides.
- Wipe the swab across the root of the tongue.
- Wipe the pharyngeal tonsils on both sides of the person to be collected back and forth with a little force or at least 3 times, and then wipe up and down the posterior pharyngeal wall for the least 3 times.

Sample Treatment:

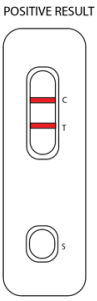
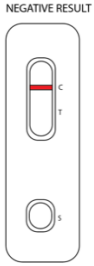
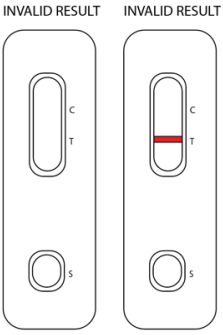
- Dip the swab after sample collection into the sample diluent solution tube, make the solution fully permeate the swab
- Rotate and squeeze the swab 5 times, then pull out the swab, and take the remained liquid as the sample to be tested.

Assay Procedure:

- Apply 3 full drops of the sample diluent solution (60-70ul) vertically into the sample well of the test cassette.
- The results are observed after 20 minutes and sowed on clinical significance after 20 minutes.



8. Interpretation of Results

	**Positive:** The colored line in the control line region (C) appears and a colored line appears in test line region (T). The result is positive for SARS-CoV-2 antigen.
	**Negative:** The colored line in the control line region (C) appears. No line appears in test line region (T).
	**Control line (C) fails to appear.** Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

9. Note

The intensity of the color in test regions may vary depending on the concentration of antigen present in the sample. The antigen level cannot be determined by this qualitative test. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

10. Quality Control

1. Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

2. External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

11. Limitations of the Test

1. This product is only used for testing individual swab.

2. Negative results do not rule out the possibility of Novel Coronavirus infection.

3. The results of this product are for clinical reference only and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory examination (especially etiological examination), treatment response and epidemiology.

4. This reagent is a qualitative reagent, which cannot determine the exact concentration of antigen.

12. Notice

1. Must strictly follow the instructions for operation and interpretation of the results.

2. The product is qualitatively tested, and the result cannot be used as a quantitative basis.
should be tested using reagents within the validity period.

3. The reagent, straw for single person one-time use, cannot be reused.

4. Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antigen in the sample.

5. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

6. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

Who we are

Attogene is a biotechnology company located in Austin, Texas. Our focus is to enhance health and wellness by offering and developing customer focused Life Science Products domestically and internationally.

Our mission is to:

- Enhance detection technologies
- Enable rapid responses
- Enable impactful research discoveries

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