



SARS-CoV-2 Serologic Assay (SCSA)

Catalog Number: AU2019-XX

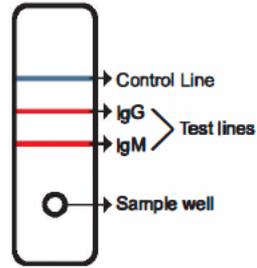
For Research Use Only. Not for use in Diagnostic Procedures.

I. Intended Use

The SARS CoV-2 IgG/IgM rapid test is a lateral flow chromatographic immunoassay for the qualitative detection of IgM/IgG anti-SARS CoV-2 antibody which may be found in samples such as serum, plasma, whole blood or cell culture media. This product is suitable for screening for the presence of SARS CoV-2 reactive antibody in a **Research Use Only** Fashion.

2. Introduction

The SARS CoV-2 serologic assay (detecting IgM/IgG) is a rapid lateral flow chromatographic immunoassay. The test cassette contains 1) a burgundy colored conjugate pad containing recombinant SARS CoV-2 antigen and rabbit IgG conjugated with colloid gold, 2) a nitrocellulose membrane strip containing two test lines (M and G) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-SARS CoV-2 antigen, G band is pre-coated with reagents for the detection of IgG anti-SARS CoV-2 antigen, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Anti-SARS CoV-2 antigen IgM if present in the specimen will bind to the SARS CoV-2 antigen gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored M band, indicating a SARS CoV-2 antigen IgM positive test result. Anti-SARS CoV-2 IgG if present in the specimen will bind to the SARS CoV-2 antigen conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a SARS CoV-2 IgG positive test result. Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.



3. Kit Contents

Contents	AU2019-01	AU2019-05	AU2019-10	AU2019-25
Cassette device (1 device per pouch)	1 device	5 devices	10 devices	25 devices
Sample Diluent	1 bottle	5 bottles	10 bottles	25 bottles

4. Storage and Stability

- The kit should be stored at 2°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.

5. Required Materials Not Supplied

- Specimen collection container - For specimen collection use
- Timer - For timing use
- Centrifuge - For preparation of clear specimens

6. Precautions

- For Research Use Only (RUO).
- 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).

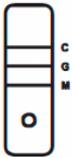
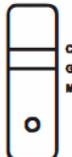
7. Specimen Collection and Storage

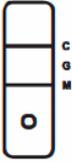
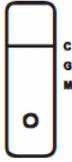
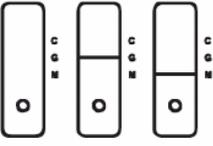
- The Novel Coronavirus IgG/IgM Combo Rapid Test can be performed using whole blood (from venipuncture or finger stick), serum, plasma or cell culture media.
- To collect finger, stick whole blood specimens:
- Wash the hand then allow to dry. Massage the hand without touching the puncture. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Finger stick Whole Blood specimen to the test device by using a capillary tube or hanging drops. NOTE: Finger sticks can typically be purchased at local stores that carry glucose meters.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2°C -8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2°C -8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

8. Procedure

- Remove the samples and required reagents from storage conditions.
- Remove the reagent card from the packaging bag and lay flat on the dry surface.
- Add samples:
 - Serum/plasma or cell culture media samples: Add 10 μ L serum, plasma or cell culture media samples to the sample hole (S) respectively and 3 drops sample buffer added vertically.
 - Whole blood samples: Add 20 μ L whole blood samples to the sample hole (s) and 2-3 drops sample buffer added vertically.
- After adding samples, the positive samples can be detected within 15 minutes. after the test confirmation, the reaction time (calculated from after adding the sample) for more than 15 minutes will affect the observation of the test results. therefore, it is recommended that the final observation and record the test results within 15 minutes.

9. Interpretation of Results

<p>POSITIVE RESULT</p> 	<p>IgG and IgM Positive: *The colored line in the control line region (C) appears and two-colored lines should appear in test line region C and T (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of SARS CoV-2 antigen reactive antibody.</p>
<p>POSITIVE RESULT</p> 	<p>IgG Positive: *The colored line in the control line region (C) appears and a colored line appears in test line region G. The result is positive for SARS CoV-2 antigen reactive IgG antibody.</p>

<p>POSITIVE RESULT</p> 	<p>IgM Positive: *The colored line in the control line region (C) appears and a colored line appears in test line region M. The result is positive for SARS CoV-2 antigen reactive IgM antibody.</p>
<p>NEGATIVE RESULT</p> 	<p>The colored line in the control line region (C) appears. No line appears in test line regions G or M.</p>
<p>INVALID RESULT</p> 	<p>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.</p>

10. Note

The intensity of the color in test regions (G and M) may vary depending on the concentration of IgG/IgM present in the sample. The IgG/IgM 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.

11. Quality Control

- 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.

12. Limitations of the Test

1. This product is only used for testing individual serum, plasma, cell culture media or whole blood samples.
2. Negative results do not rule out the possibility of the presence of antibody against SARS CoV-2.
3. The results of this product are for Research reference only and should NOT be used for clinical diagnosis and treatment decisions. This kit is not meant to be used for clinical management of patients in any way. This kit may be validated in a clinical setting with known positive and negatives to be internally considered in combination with their symptoms, signs, medical history, other laboratory examination (especially etiological examination), treatment response and epidemiology to help validate its utility.
4. The reference value of serological antibody detection in sample with impaired immune function or exposed to immunosuppressive compounds may be a limitation in detection of IgG/IgM.
5. The target of this product is the SARS CoV-2 IgM/IgG antibody, which does not directly reflect the presence of the SARS-CoV-2 in the sample, It is for Research Use Only but may be validated in a clinical lab setting for the purpose of its utility in disease analysis according to document IIE-COVID19-Guidance document published by the United States FDA.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>

13. Notice

1. This product is used for Research Use Only.
2. Must strictly follow the instructions for operation and interpretation of the results.

3. The product is qualitatively tested, and the result cannot be used as a quantitative basis should be tested using reagents within the validity period.
4. The reagent, and device is for one sample, one-time use and cannot be reused.
5. Because the sample titer is different, the red lines of the test line will show different shades of color. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.
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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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