Artron

COVID-19 IgM/IgG Antibody Test

Instructions For Use

Format: Cassette
Specimen: Serum/Plasma/Whole Blood
Catalog Number: A03-51-322

CE

* Please read the instructions carefully before use

INTENDED USE

Artron COVID-19 IgM/IgG Antibody Test is a rapid, qualitative and convenient immunochromatographic *in vitro* assay for the differential detection of IgM & IgG antibodies to SARS-COV-2 in human serum, plasma or whole blood samples. The device is designed to aid in the determination of recent or previous exposure to SARS-COV-2 virus tracking the status of the disease after SARS-COV-2 infection.

This assay only provides a preliminary result. A positive result does not necessarily mean a current infection, but represents a different stage of the disease after infection. IgM positive or IgM/IgG both positive suggest recent exposure, while IgG positive suggests previous infection, or latent infection. Current infection should be confirmed by Real-Time Reverse Transcriptase (RT-PCR) or viral gene sequencing. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. It is intended for professional use as an aid in diagnosis of SARS-COV-2 infection only.

SUMMARY AND PRINCIPLE OF THE ASSAY

SARS-COV-2 is an acute resolved disease but it can also be deadly, with a 2% case fatality rate. Since late December, 2019, it caused an outbreak of a novel coronavirus disease (COVID-19; previously known as 2019-nCoV), which has subsequently affected over 114 countries and regions worldwide. Severe disease onset might result in death due to massive alveolar damage and progressive respiratory failure. The pathogen has since been identified as a zoonotic coronavirus, similar to SARS coronavirus and MERS coronavirus, and has been named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The 2019 novel coronavirus (SARS-CoV-2) epidemic has been declared a public health emergency of international concern by the World Health Organization, may progress to a pandemic associated with substantial morbidity and mortality. SARS-CoV-2 is genetically related to SARS-CoV, which caused a global epidemic with 8096 confirmed cases in more than 25 countries in 2002–2003.

The principle of Artron COVID-19 IgM/IgG Antibody Test is an antibody-capture immunochromatographic assay for the simultaneous detection and differentiation of IgM & IgG antibodies to SARS-COV-2 virus in human serum, plasma, or whole blood samples. SARS-COV-2 -specific antigens are conjugated to a colloidal gold and deposited on the conjugate pad. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized on two individual test lines (T line 2 and T line 1) of the nitrocellulose membrane. The IgM line (T2) is closer to the sample well and followed by the IgG line (T1). When the sample is added, the gold-antigen conjugate is rehydrated and the SARS-COV-2 IgM and/or IgG antibodies, if any in the sample, will interact with the gold conjugated antigen. The immunocomplex will migrate towards the test window until the test zone (T1 & T2) where they will be captured by the relevant anti-human IgM (T2) and/or anti-human IgG (T1), forming a visible pink line, indicating positive results. If SARS-COV-2 antibodies are absent in the sample, no pink line will appear in the test lines (T1 & T2), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant.
- 25 Capillary tubes for 25 tests.
- Sample buffer 3ml per bottle for 25 tests.
- Instructions for Use

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Alcohol swab
- Safety lancet (for fingerstick whole blood specimens)
- Blood collection device. (for other than fingerstick whole blood specimens)
- Precision pipette capable of delivering 10µl and/or 20µl with disposable tips(for other than fingerstick whole blood specimens)
- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the product seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- This test should be performed at 15 to 30°C (59 to 86°F). If stored refrigerated, ensure that the Test Units are brought to operating temperature before performing testing.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- **Whole Blood** samples may be collected by fingerstick or venipuncture, following routine facility procedures. In summary:
  Fingerstick whole blood:
  - Clean the area of finger to be lanced with the alcohol swab. Allow to dry.
  - Without touching the puncture site, rub down the hand towards the middle or ring finger fingertip.
  - Puncture the skin with a sterile lancet and wipe away the first drop of blood.
  - Gently rub the hand from wrist to the lanced finger to form a full drop of blood over the puncture site.
  - Collect the blood droplet using the included capillary tube.
  - Fingerstick whole blood must be tested immediately after collection.

  Venous whole blood:
  - Collect venous whole blood in a tube with anticoagulant.
  - Whole blood samples should be tested immediately after sample collection.
- **For Serum samples,** collect blood in a tube without anticoagulant and allow it to clot.
- **For Plasma samples,** collect blood in a tube containing anticoagulant.
  - Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Allow sample to attain room temperature (without heating) prior to use.

TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface. The opened test kit should be better used within 4hours.

2. **For fingerstick or venous whole blood:**
Using a capillary tube, collect the fingerstick whole blood or whole blood (20μl) till to the black line.
For serum/plasma:
Using a pipette, collect the serum/plasma (10μl).


or


3. Add the collected serum/plasma/whole blood to upper area (close to test window) of sample well on the test device without air bubbles (hold the capillary tube/ pipette vertically and gently touch the end against the pad within the sample well for transferring).

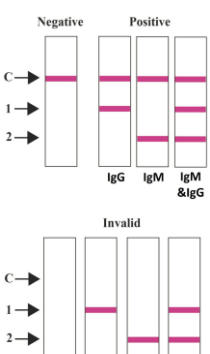

or


4. Wait for 20-30 seconds; add 2 drops (around 90μl) of the sample buffer to the Sample Well of the test device.

5. Read the results after 15-30 minutes. Strong positive specimens may produce positive result in as little as 1 minu

DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a negative result for SARS-COV-2 infection.

Positive
Pink colored bands appear at the control region (C) and T1 and /or T2 region.
1) IgM and IgG Positive, visible bands at T2 and T1, indicating positive result for a recent SARS-COV-2 exposure.
2) IgM positive, a visible band at T2 region, indicating positive result for a current or recent SARS-COV-2 exposure.
3) IgG positive, a visible band at T1 region, indicating a positive result for a previous or latent SARS-COV-2 infection.

Invalid
No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- The test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.
- Shelf life: 18 months

LIMITATIONS

- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- The reagent can only be used to determine the immune status of the body to SARS-COV-2 after infection, but not directly to diagnose current SARS-COV-2 infection.
- Although the test demonstrates superior accuracy in detecting antibodies against SARS-COV-2 virus, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.

PERFORMANCE CHARACTERISTICS

- Analysis of Sensitivity and Specificity

  Inactive COVID-19 IgM/IgG sensitivity panel including 3 SARS-COV-2 IgM positive sera(Strong, moderate and weak), 3 SARS-COV-2 IgG positive sera, and one negative serum was applied to validate the analysis sensitivity of Artron COVID-19 IgM/IgG Antibody Test and parallelly refer with the testing results of CE approved commercial Wondfo SARS-COV-2 Antibody Test(W195). Artron COVID-19 IgM/IgG Antibody Test could identify all the positive samples and showed the similar sensitivity with reference CE approved commercial Wondfo SARS-COV-2 Antibody Test to COVID-19 IgM/IgG Sensitivity Panel. No false positive or negative results were observed.

  Artron COVID-19 IgM/IgG Antibody Test showed no cross reaction with seromarkers associated with unrelated medical conditions: CRP, RF, HIV, HBV serum markers (HBsAg, anti-HBc IgG/IgM), HCV, herpes simplex virus IgG (HSV), cytomegalovirus IgG/IgM, mycoplasma IgM, Dengue Virus IgG/IgM and negative samples also included 50 health sera from blood donors and 20 health whole blood samples from blood donors.

- Interference Study

  Analytes commonly found in OTC, prescription and/ or abuse drugs, chemical analytes, and pH did not interfere Artron COVID-19 IgM/IgG Antibody Test.

- Repeatability and Reproducibility

  Tests showed positive results with all positive samples and showed negative results with negative samples. There was no significant difference observed to the same sample when repeatedly testing 10 tests in the same batch. No appreciable intra and inter lot variation were observed among different tests for each lot, different lots, different operators at different test sites in different time for the same sample.

The results demonstrated that the repeatability and reproducibility of Artron COVID-19 IgM/IgG Antibody Test are satisfactory.

- Diagnostic Sensitivity and Specificity
  Total 147 sera/plasma and 27 fingerstick whole bloods from SARS-COV-2 infected patients and 123 non-SARS-COV-2 infected sera and 51 non-SARS-COV-2 infected whole bloods were tested. Among all chosen samples, Artron COVID-19 IgM/IgG Antibody identified out total 145 SARS-COV-2 IgM&/or IgG positive include 121 IgM positive and 93 IgG positive from 174 SARS-COV-2 infected patients samples; the diagnostic sensitivity was 83.33%; 12 false positive from total 174 non-SARS-COV-2 sera or whole bloods were observed, the diagnostic specificity was 93.10%. For positive serum or plasma samples, 118 IgM &/or IgG positive results from 147 SARS-COV-2 sera/plasma showed the sensitivity for serum/plasma testing was 80.27%; 7 false positive results from 123 non-SARS-COV-2 sera showed the specificity for serum/plasma testing was 94.31%. For whole blood samples, 27 IgM &/or IgG positive results from 27 SARS-COV-2 fingerstick whole bloods, showed the sensitivity was 27/27; 5 false positive results from 51 non-SARS-COV-2 whole bloods showed the specificity was 46/51.

Table 1 Artron COVID-19 IgM/IgG Antibody Test results

RT-PCR	Artron COVID-19 IgM/IgG Antibody Test										
	Sera/plasma					Whole blood					Total
	IgM (+)	IgG (+)	IgM & IgG (+)	IgM & IgG (-)	Subtotal	IgM (+)	IgG (+)	IgM & IgG (+)	IgM & IgG (-)	Subtotal	
Positive	49	18	51	29	147	3	6	18	0	27	174
Negative	4	1	2	116	123	2	1	2	46	51	174
Total	53	19	53	145	270	5	7	20	46	78	348

Table 2 Diagnostic sensitivity and specificity for Serum/Plasma& whole blood

RT-PCR	Artron COVID-19 IgM/IgG Antibody Test		
	Positive	Negative	Total
Positive	145	29	174
Negative	12	162	174
Total	157	159	348

Diagnostic sensitivity: 145/(145+29)×100%=83.33%
Diagnostic specificity: 130/(130+12) ×100%=93.10%
Overall agreement: (145+162)/348×100%=88.22%

Table 3 Diagnostic sensitivity and specificity for Serum/Plasma

RT-PCR	Artron COVID-19 IgM/IgG Antibody Test		
	Positive	Negative	Total
Positive	118	29	147
Negative	7	116	123
Total	125	145	270

Diagnostic sensitivity: 118/(118+29)×100%=80.27%
Diagnostic specificity: 116/(116+7) ×100%=94.31%
Overall agreement: (118+116)/270×100%=86.67%

All the 123 SARS-COV-2 RT-PCR negative and 147 SARS-COV-2 RT-PCR positive serum/plasma samples were tested additionally with approved SARS-COV-2 IgM/IgG CLIA Chemiluminescence Immunoassay (CLIA). The sensitivity and specificity of Artron COVID-19 IgM/IgG Antibody Test to IgM and IgG were calculated based on the detection results of COVID-19 IgM/IgG CLIA reagent for SARS-COV-2 IgM and IgG respectively.

Table 4 IgM to SARS-COV-2 Detection results

IgM results of CLIA COVID-19 IgM/IgG	IgM results of Artron COVID-19 IgM/IgG Antibody Test		
	Positive	Negative	Total
Positive	100	6	106
Negative	6	158	164
Total	106	164	270

Diagnostic sensitivity: 100/(100+6)×100%=94.33%
Diagnostic specificity: 158/(158+6) ×100%=96.34%
Overall agreement: (100+158)/270×100%=95.56%

Table 5 IgG to SARS-COV-2 Detection results

IgG results of CLIA COVID-19 IgM/IgG	IgG results of Artron COVID-19 IgM/IgG Antibody Test		
	Positive	Negative	Total
Positive	69	12	81
Negative	3	186	189
Total	72	198	270

Diagnostic sensitivity: 69/(69+12)×100%=85.19%
Diagnostic specificity: 186/(186+3) ×100%=98.41%
Overall agreement: (69+186)/270×100%=94.44%

BIBLIOGRAPHY

- Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization.13 March 2020.
- Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). World Health Organization. 16-24 February 2020.
- The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19). Chinese Center for Disease Control and Prevention. CCDC Weekly, 2(8):113-122, 2020.
- A novel coronavirus outbreak of global health concern. Wang C et al. Lancet, 395(10223): 470-473, 2020

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