ttle containing the buffer should be stored at 2-30ºC.
t device should be kept away from direct sunlight, moisture and heat.

ONS

ty and temperature can adversely affect results.
structions for the use of the test should be followed during testing procedures.
is always a possibility that false results will occur due to the presence of interfering nces in the specimen or factors beyond the control of the manufacturer, such as al or procedural errors associated with the testing.
gh the test demonstrates superior accuracy in detecting antibodies against COVID-19 a low incidence of false results can occur. Therefore, other clinically available tests are d in case of questionable results. As with all diagnostic tests, a definitive clinical sis should not be based on the results of a single test, but should only be made by the ian after all clinical and laboratory findings have been evaluated.

RAPHY

l management of severe acute respiratory infection (SARI) when COVID-19 disease is cted, Interim guidance, World Health Organization, 13 March 2020.
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se Center for Disease Control and Prevention. The Epidemiological Characteristics of an eak of 2019 Novel Coronavirus Diseases (COVID-19), CCDC Weekly, 2(8):113-122,

C et al. A novel coronavirus outbreak of global health concern. Lancet, 395(10223): 470-2020.

CTURER CONTACT INFORMATION

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A03-51-322 VER. 20-02 Revision: March 2020

Artron

Coronavirus Diseases 2019 (COVID-19) IgM/IgG Antibody Test

Instructions For Use

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

* Please read the instructions carefully before use

TENDED USE

ron Coronavirus Diseases 2019 (COVID-19) IgM/IgG Antibody Test is a rapid, qualitative and venient immunochromatographic *in vitro* assay for the differential detection of IgM & IgG bodies to COVID-19 virus in human serum, plasma or whole blood samples obtained from ent with COVID-19 infection. The device is designed to aid in the determination of recent or vious exposure to COVID-19 virus tracking the status of the disease after COVID-19 Virus ction.

s assay only provides a preliminary result. A positive result does not necessarily mean a rent infection, but represents a different stage of the disease after infection. IgM positive or /IgG both positive suggest recent exposure, while IgG positive suggests previous infection, or nt infection. Current infection should be confirmed by Real-Time Reverse Transcriptase (RT-R) or viral gene sequencing. The test is intended for professional use.

MMARY AND PRINCIPLE OF THE ASSAY

ce late December, 2019, an outbreak of a novel coronavirus disease (COVID-19; previously wn as 2019-nCoV) was reported in Wuhan, China, which has subsequently affected 26 ntries worldwide. In general, COVID-19 is an acute resolved disease but it can also be deadly, a 2% case fatality rate. Severe disease onset might result in death due to massive alveolar age and progressive respiratory failure. The pathogen has since been identified as a zoonotic navirus, similar to SARS coronavirus and MERS coronavirus, and has been named as severe e respiratory syndrome coronavirus 2 (SARS-CoV-2). The 2019 novel coronavirus (SARS-2) epidemic has been declared a public health emergency of international concern by the d Health Organization, may progress to a pandemic associated with substantial morbidity and ality. SARS-CoV-2 is genetically related to SARS-CoV, which caused a global epidemic with confirmed cases in more than 25 countries in 2002–2003.

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

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

KAGE CONTENTS

ouch contents: Test Cassette, Desiccant.
0 capillary tubes (20 µl) for 100 tests.
ml sample buffer for 100 tests.
st instruction.

ERIALS REQUIRED (BUT NOT PROVIDED)

cohol swab.

- Lancet and blood collection device.
- Pipette
- 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.

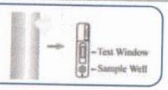
SPECIMEN PREPARATION

- **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.

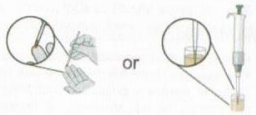
  Venous whole blood:
  - Collect venous whole blood in a tube with anticoagulant.
  - Whole blood samples should be tested immediately after sample collection.
- **For Serum samples,** collect blood in a tube without anticoagulant and allow it to clot.
- **For Plasma samples,** collect blood in a tube 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 2°C to 8°C 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

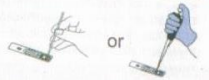
1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface.



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



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).

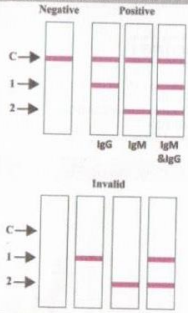


4. Wait for 20-30 seconds; add 2 drops (around 90µl) of the sample buffer to the sample well of the test device.

5. Read the results after 15-20 minutes. Strong positive specimens may produce positive result in as little as 1 minute.

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 COVID-19 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 possible COVID-19 infection.
2) IgM positive, a visible band at T2 region, indicating positive result for a possible COVID-19 infection.
3) IgG positive, a visible band at T1 region, indicating a positive result for a possible COVID-19 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 2-30°C. Do not freeze the test device.