COVID-19 IgM/IgG Rapid Test Training

W.H.P.M., INC.

COVID-19 Background

- According to the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention (CDC), Chinese authorities identified an outbreak caused by a novel—or new—coronavirus. The virus can cause mild to severe respiratory illness. The outbreak began in Wuhan, Hubei Province, China, and has spread to a growing number of other countries—including the United States. The virus is different from six other, previously identified human coronaviruses, including the Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) coronaviruses that have caused previous respiratory disease outbreaks.

Source: OSHA. Osha.gov/SLTC/covid-19/background.html.

SYMPTOMS OF COVID-19

- Infection with SARS-CoV-2, the virus that causes COVID-19, can cause illness ranging from mild to severe and, in some cases, can be fatal. Symptoms typically include fever, cough, and shortness of breath. Some people infected with the virus have reported experiencing other non-respiratory symptoms. Other people, referred to as asymptomatic cases, have experienced no symptoms at all.
- According to the CDC, symptoms of COVID-19 may appear in as few as 2 days or as long as 14 days after exposure.

Exposure To Covid-19

- COVID-19 is believed to spread from person-to-person, primarily through respiratory droplets produced when an infected person coughs or sneezes. The virus is also believed to spread by people touching a surface or object and then touching one's mouth, nose, or possibly the eyes.
- People are thought to be most contagious when they are most symptomatic (i.e., experiencing fever, cough, and/or shortness of breath). Some spread might be possible before people show symptoms; there have been reports of this type of asymptomatic transmission with this new coronavirus, but this is also not thought to be the main way the virus spreads.

Emergency Use Authorization (EUA)

- In instances where there are no FDA-approved or cleared tests available, and other criteria are met, the FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA).
- The EUA for COVID-19 testing is supported by the Secretary of Health & Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19.
- The EUA, permitting use of the test, would remain in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs unless it is terminated or revoked by FDA.

FDA Guidance (Without EUA)

- Due to the Coronavirus Public Health Emergency, the FDA updated its Policy for Diagnostic Tests for COVID-19 on May 4, 2020 (Section D). Included in this update is guidance for screening tests that identify antibodies (e.g., IgM, IgG) to SARS-CoV-2 from clinical specimens.
- ”Unless and until an EUA is issued that authorizes additional testing environments for a specific test, under CLIA, use of that test is limited to laboratories certified to perform high complexity testing, and at the point-of-care when covered by the laboratory’s CLIA certificate for high-complexity testing. This policy does not apply to at-home testing, including at-home specimen collection, due to additional considerations that require FDA review.”

FDA Guidance (Without EUA)

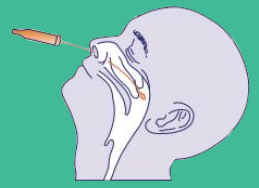
Important Notification

- W.H.P.M.'s COVID-19 IgM/IgG Rapid Test has not been reviewed by the FDA.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Negative results do not rule out SARS-CoV-2 infection, especially in those who have been exposed to the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in those individuals.
- The results from rapid antibody testing should not be used as the sole basis to diagnose or exclude a COVID-19 infection or to determine an individual's infection status.

COVID-19 TEST OPTIONS

Host AntiBody Tests (Serology) – The rapid tests identify the IgM and IgG antibodies present in the patients blood specimen (using whole blood, serum or plasma samples).

Viral Antigen Tests - Expected availability is unknown at present however it is anticipated these will be a visual read or reader type device similar to commonly used influenza tests.

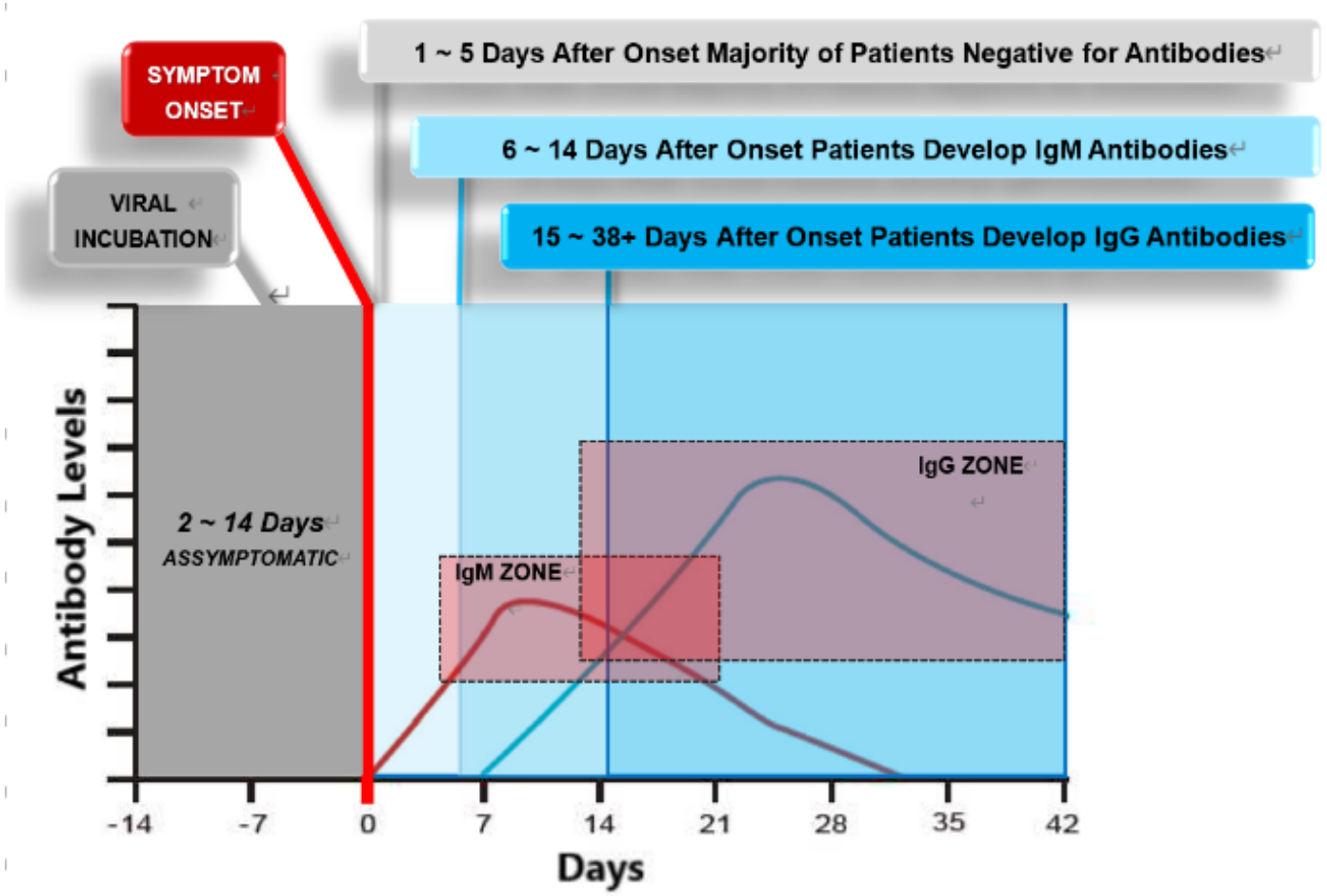


Molecular - This test format requires an instrument. How it works is it detects the presence of a virus by identifying a small section of the virus' genome collected from a patient's nasal swab, then amplifying that portion until there's enough for it to be detected.

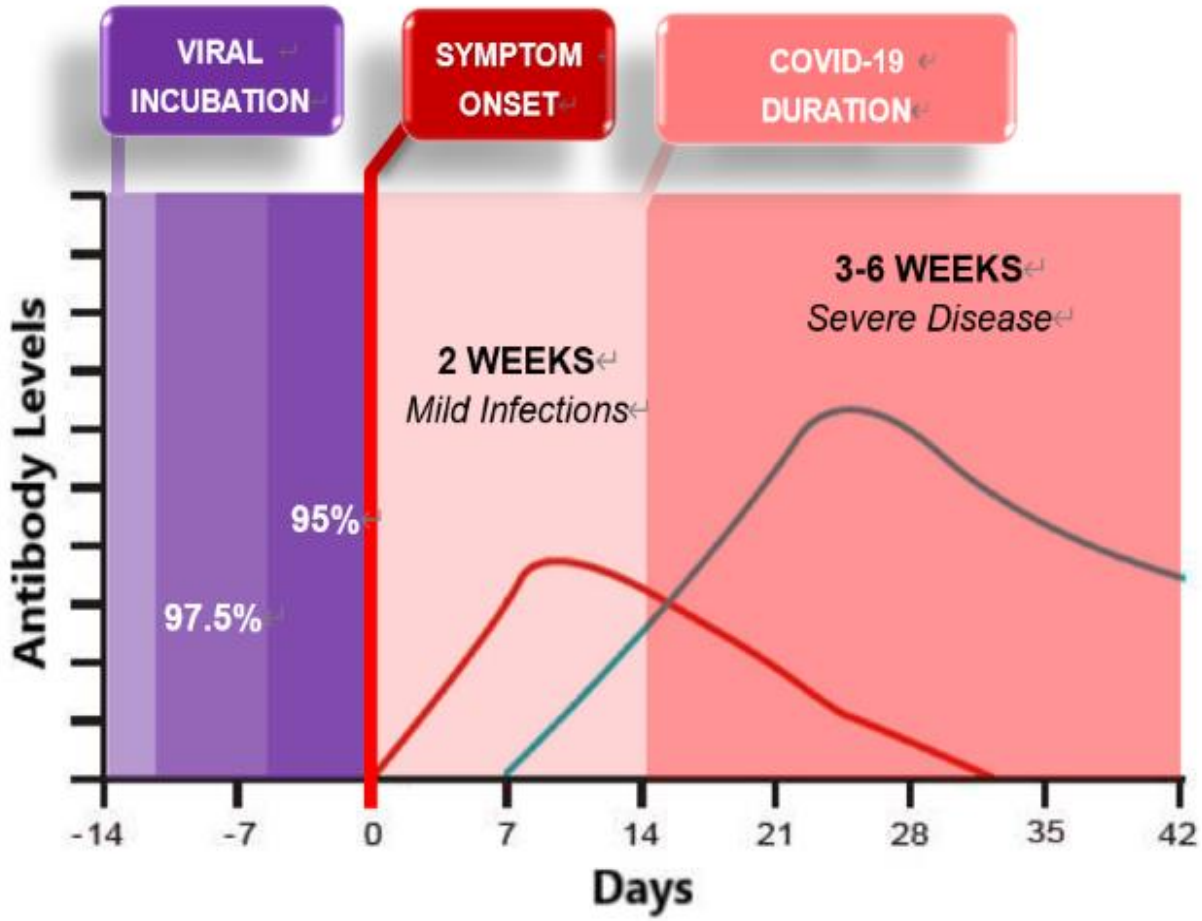
Testing For Antibodies

- The human immune system is an incredibly effective defense mechanism in fighting and protecting the body against disease. When a patient is infected by the SARS-CoV-2 virus, the immune system will begin to form IgM antibodies as the first line of defense. While IgM antibodies are effective in the fight against infection, as the immune system mounts a more direct defense against the infection the body will begin to form specialized IgG antibodies.
- IgG antibodies are highly specific to the disease in question, they will appear in a later stage of the infection and remain in the body for some time after the infection has been defeated. The COVID-19 IgM/IgG Antibody Test is designed to quickly detect and differentiate both the IgM and IgG antibodies produced by the immune system during a COVID-19 infection.
- Antibodies present at 7+ days.

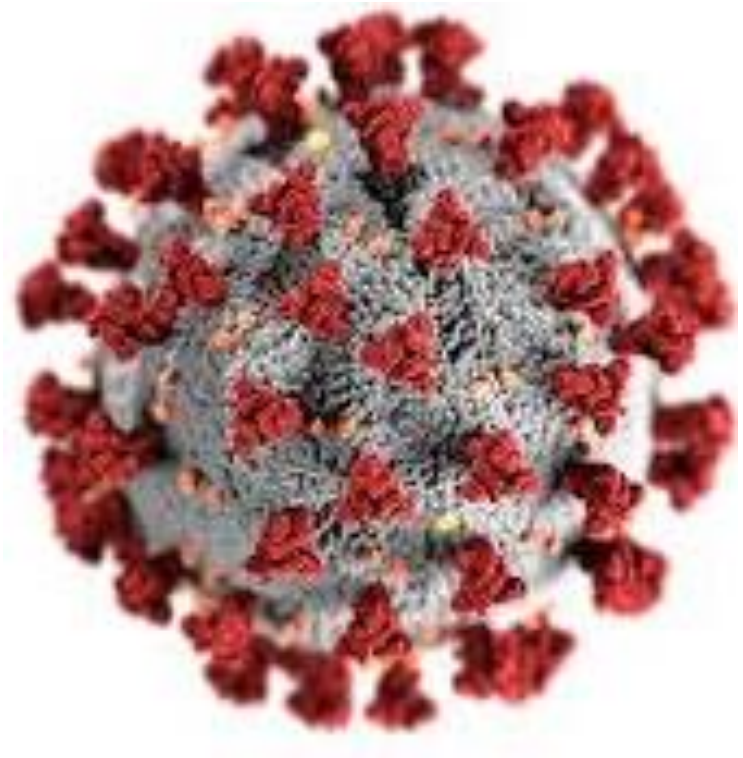
Antibody Detection Timeline



Antibody Detection Timeline



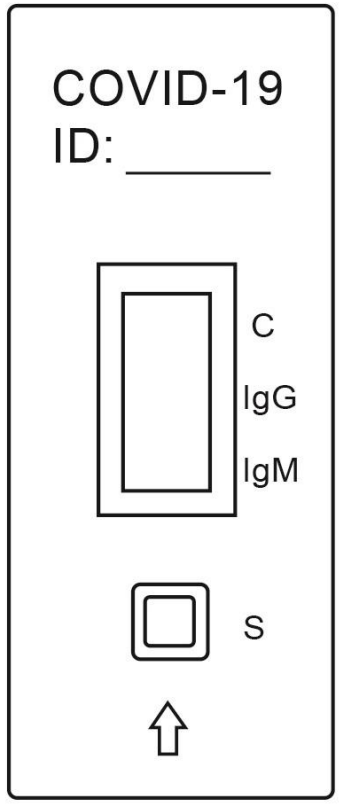
W.H.P.M.'s Test



COVID-19 IgM/IgG Rapid Test:

- Serology Antibody Test
- Whole Blood/Serum/Plasma
- Results in 15 Minutes
- Increased Screening with IgM & IgG Antibody Detection
- Sensitivity 93.5% • Specificity 100% • Accuracy 97.9%
- Highly portable – can be used at Point of Care (i.e. small labs, clinics, patient bedside, etc.)

DEVICE FORMAT



3 MM CASSETTE

Important Notes

Prior To Testing

- Read Instructions for Use and Quick Guide thoroughly before performing test.

Storage & Stability

- Test devices should be stored at 4ºC-30ºC and should be kept away from direct sunlight or heat sources. Do not freeze.
- Test device should be used within 1 hour of opening pouch. If temperature is higher than 30ºC or room has high humidity, then test device should be used immediately.

Specimen Type

- Whole Blood
- Serum
- Plasma

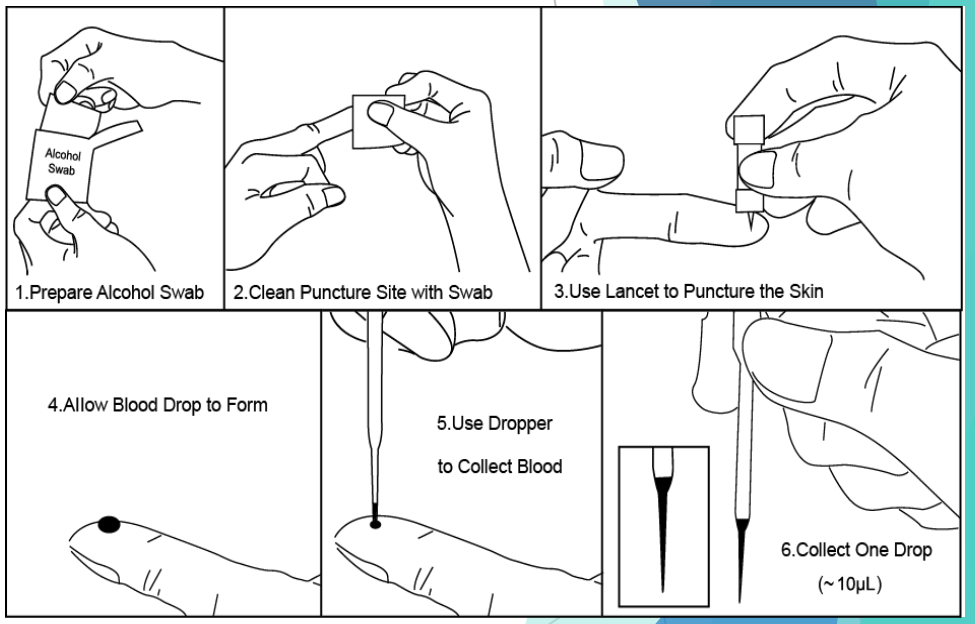
Specimen Collection

- Proper specimen collection and handling is critical to the performance of this test. Specimens should be tested as soon as possible after specimen collection.
- Any materials of human origin should be considered as infectious and handled using standard biosafety procedures.

Specimen Collection

- **Whole Blood – Fingerstick**

1. Following laboratory procedures, clean the finger of the person being tested with an alcohol swab.
2. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
3. Use a lancet to puncture the skin just slightly off the center of the finger and allow blood drop to form.
4. Use dropper provided to collect fingerstick whole blood sample.



Specimen Collection Cont.

- **Whole Blood – Venous Blood**

1. Draw blood following laboratory procedure for obtaining venous blood.
2. Depending on use, collect sample in a tube containing heparin or EDTA.
3. Be sure the tube of blood is well mixed before sampling.
4. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).

Specimen Collection Cont.

- **Serum**

1. By venipuncture collect the blood specimen into a red top collection tube (not containing any anticoagulants in a Vacutainer).
2. Allow the blood to clot.
3. Separate the serum by centrifugation.

- **Plasma**

1. By venipuncture collect blood specimen into a collection tube (containing EDTA or citrate, respectively, in a Vacutainer) following standard laboratory procedures.
2. To separate the plasma use centrifugation.
3. Carefully withdraw the plasma into a new pre-labeled tube.

Specimen Collection Cont.

Serum and Plasma Stability

- Test specimens as soon as possible after collection. In the event specimens will not be tested immediately they should be stored at 2-8°C for up to 3 days.
- For longer storage specimens should be frozen at -20°C. Avoid more than 4 freeze-thaw cycles for frozen samples. Prior to testing, bring frozen specimens to room temperature 18 to 30°C (64 to 86°F) and mix gently.
- If particulate matter is visible, specimens should be clarified by centrifugation before testing.
- To avoid interference on a result interpretation, do not use samples demonstrating gross lipemia, gross hemolysis or turbidity.

Test Preparation

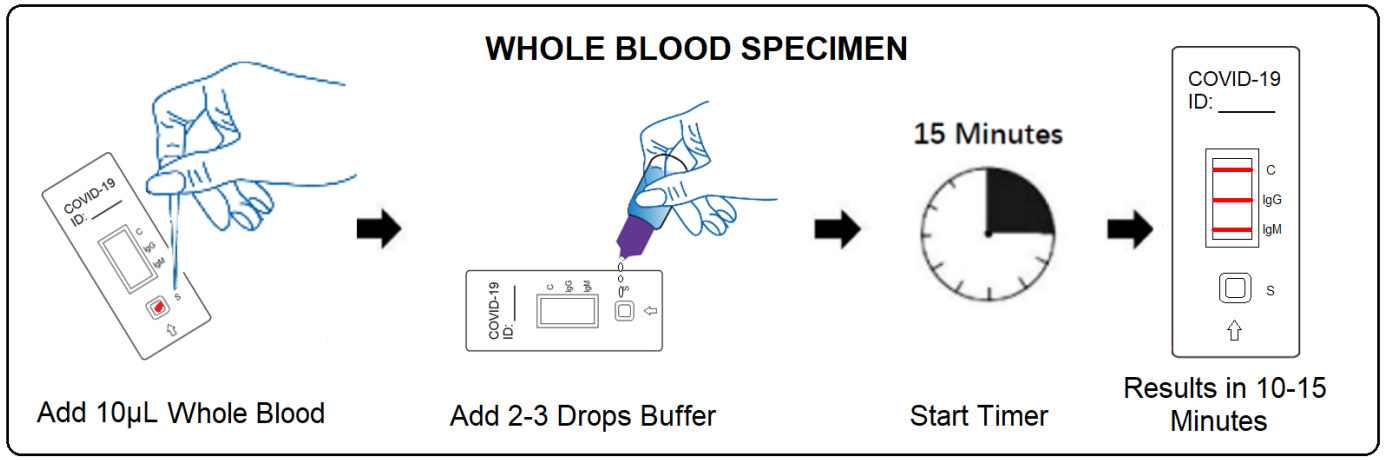
1. Prior to beginning test, ensure clinical specimens and test materials are at room temperature.
2. Check the expiration on each individual reagent and outer kit box before using the test. Do not use expired tests.
3. Do not use device if pouch is perforated or desiccant is missing.
4. Use Universal Biological Precautions when handling any clinical specimen.

Test Procedure

1. For frozen samples, bring the specimens and test components to room temperature, and once thawed mix specimen well. Fresh samples can start testing immediately.
2. When ready to proceed, open the test device pouch and remove the device. Place the test device on a flat, clean surface.
3. Label the test device with specimen ID #.
4. Using a transfer pipette, transfer whole blood, serum or plasma to sample well. Be careful not to exceed the sample well.

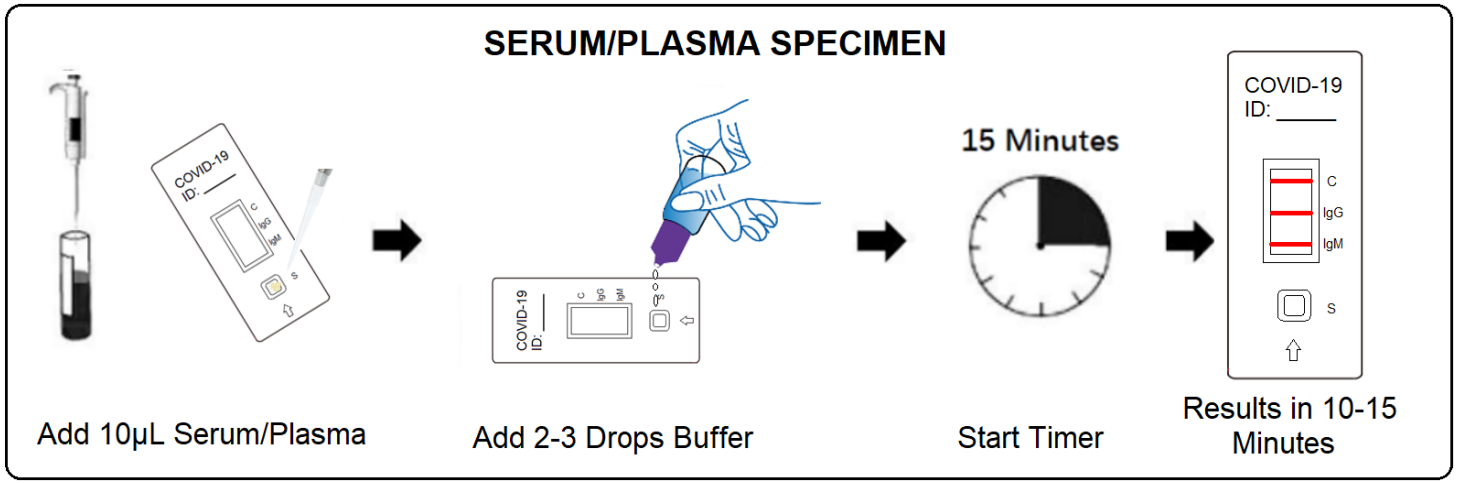
Test Procedure – Whole Blood

- To use a pipette: Hold the pipette vertically, draw the specimen into the pipette and transfer 1 drop of whole blood (approximately 10µL) to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.
- To use a micropipette: Pipette and dispense 10µL of whole blood to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.



Test Procedure – Serum/Plasma

- To use a pipette: Hold the pipette vertically, draw the specimen up into the pipette and transfer one small drop (approximately 10µL) of the specimen to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer. Avoid trapping air bubbles in the SAMPLE WELL.
- To use a micropipette: Pipette and dispense 10µL of serum or plasma to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.



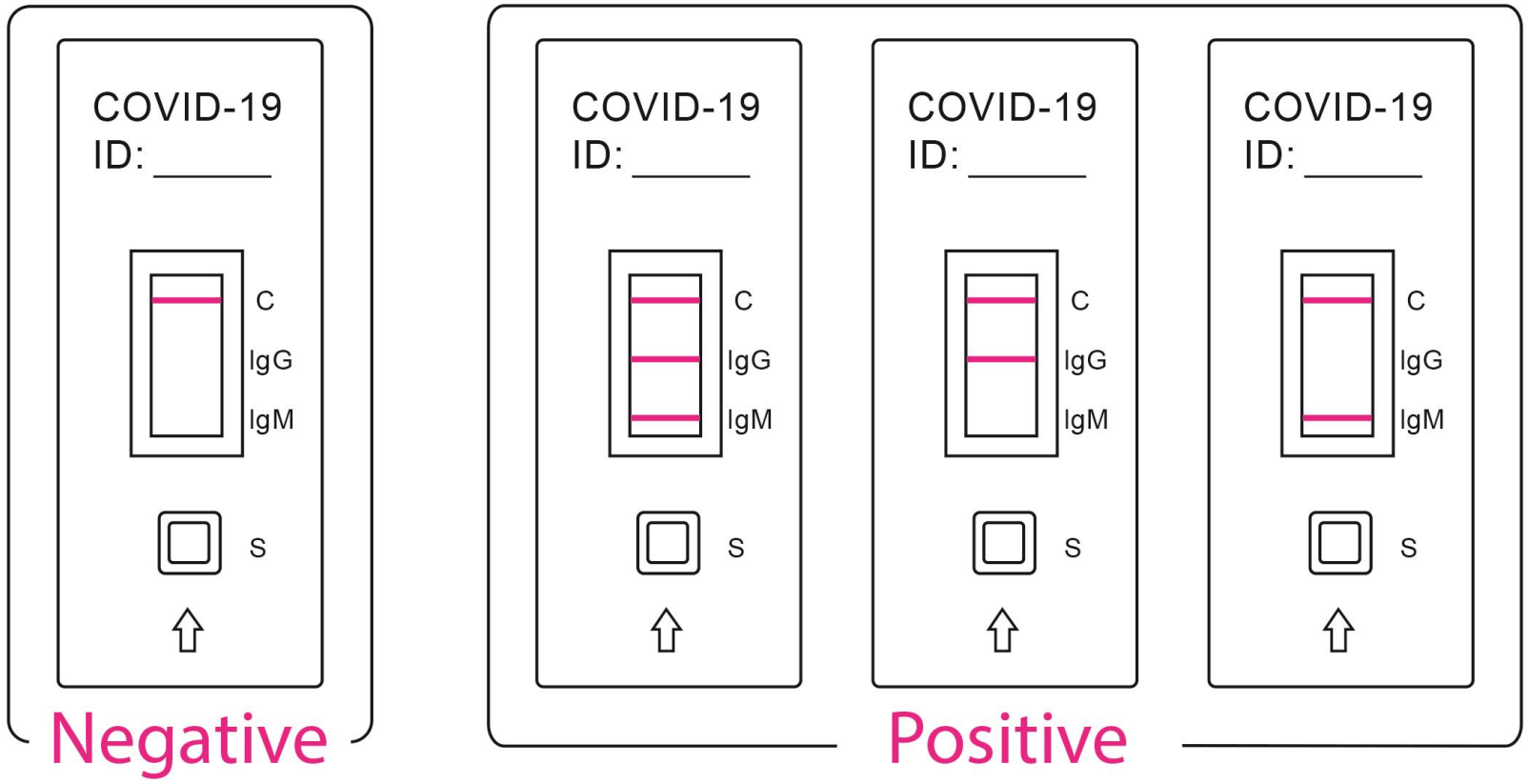
INTERPRETING RESULTS

- **READ TIME:** Read the results at 10 to 15 minutes, do not interpret results after 15 minutes.
- **LINE VISIBILITY:** Any IgM or IgG line regardless of the intensity is considered a line.
- **ANY LINE IS A LINE:** The intensity of the IgM and IgG should NOT be compared to the control line.
- **NEGATIVE:** Test is **NEGATIVE** for both COVID-19 IGM and IgG antibodies if: Only control line (C) is visible.
- A negative result is a presumptive negative. Negative result does not exclude possible infection with SARS-CoV-2 virus. As with any test, providers must consider the patient's likelihood of exposure and the possibility of false laboratory results when making treatment or other patient management decisions. Professional Health Care Providers should follow all relevant CDC guidance, as well as local and state regulations to determine the appropriate course of action for result confirmation and prescribed treatment.
- ***WARNING: Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.***

Interpreting Results Cont.

- **POSITIVE:** Test is **POSITIVE** for COVID-19 if:
- A. Control line (C), IgM (Line 1), and IgG (Line 2), are visible.
- B. Control line (C) and IgM (Line 1) are visible.
- C. Control line (C) and IgG (Line 2) are visible.
- A Positive result is a presumptive positive. Healthcare providers who have obtained a presumptive positive patient for COVID-19 should contact their local or national health department immediately for consultation and guidance.
- ***WARNING: Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.***
- Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

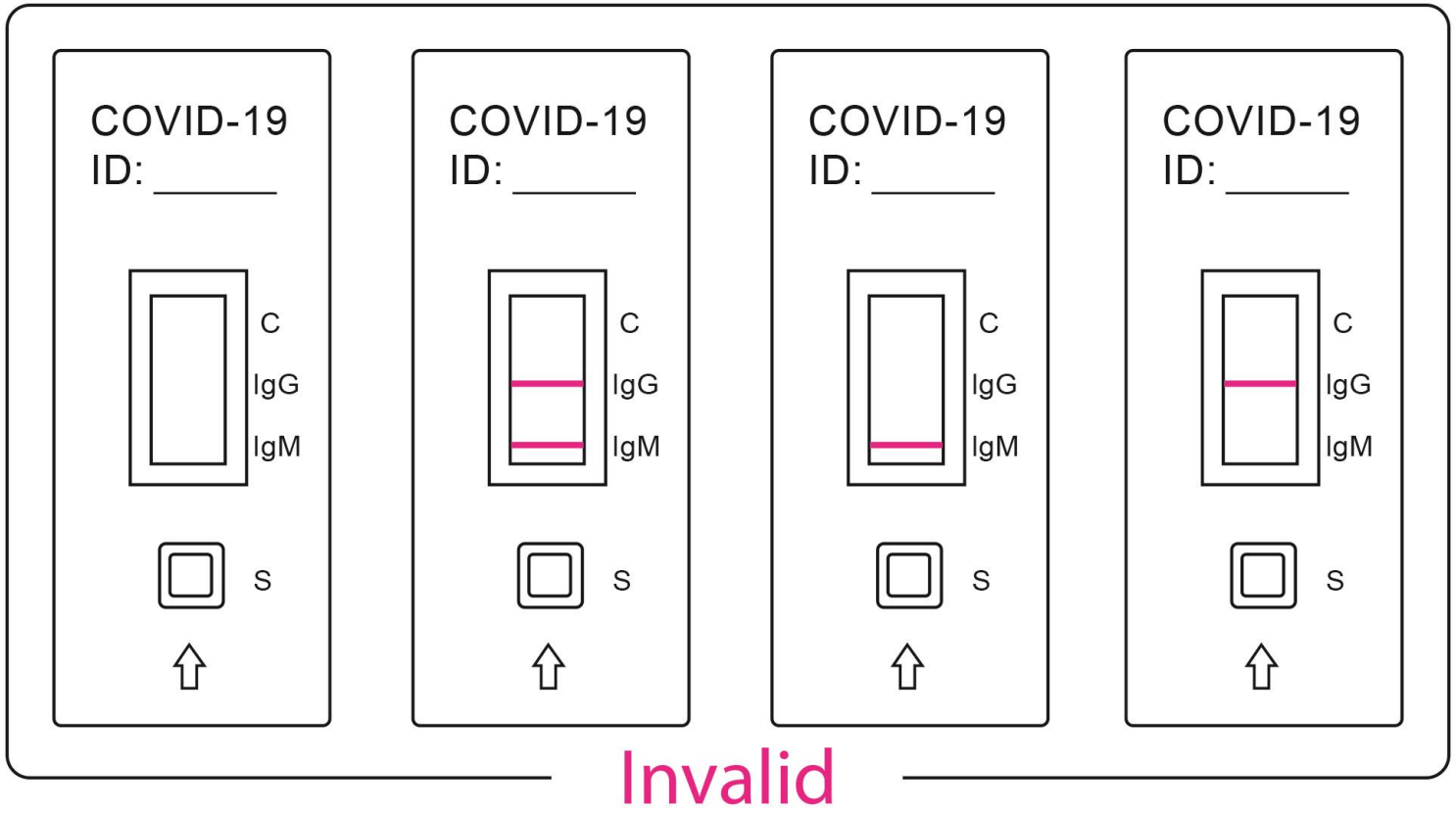
Interpreting Results Cont.



Interpreting Results Cont.

- **INVALID**: Test is **INVALID** if: Control line (C) is **NOT VISIBLE** regardless of the IgM (Line 1), and IgG (Line 2) result.
- An INVALID test result indicated that there may be a problem with the testing procedure of the COVID-19 IgM/IgG Rapid Test. In the event of an INVALID result it is recommended that the Health Care Provider conduct the test again using a new COVID-19 IgM/IgG Rapid Test cassette. If issues persist, please contact laboratory administrators and/or customer service.
- ***WARNING: Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.***
- ***WARNING: THIS TEST HAS NOT BEEN REVIEWED BY FDA.***

Interpreting Results Cont.



LIMITATIONS

1. The COVID-19 IgM/IgG Rapid Test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The test line intensity does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. Do not compare the line intensity of the test line to the control (C) line.
2. When using the COVID-19 IgM/IgG Rapid Test false positive results for IgM and IgG antibodies may arise due to a cross-reactivity from pre-existing antibodies, previous infections (such as other coronaviruses), or other possible causes.
3. If the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is less than the detection limit of the assay, a negative or non-reactive result may occur.
4. It is recommended that patient be re-sampled a few days later or tested with an alternative test device/method if symptoms persist and the result from the COVID-19 IgM/IgG Rapid Test was negative or non-reactive.
5. The test procedure and the interpretation of result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the whole blood, serum, or plasma specimen from individual subjects. Proper sample collection is critical for optimal test performance. Failure to follow the procedure correctly may yield inaccurate results.
6. The results obtained using the COVID-19 IgM/IgG Rapid Test should only be interpreted in conjunction with clinical findings, presented symptoms, and the results from other evaluations and laboratory tests.

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