Phamatech COVID-19 IgG/IgM Rapid Test
(Whole Blood / Serum / Plasma)

INSTRUCTIONS FOR USE

Phamatech COVID-19 IgG/IgM Rapid Test is a 10 minute instant point-of-care test device for the qualitative detection of IgG and IgM antibodies specific to COVID-19 in human whole blood, serum or plasma specimens.

IMPORTANT

On March 16, 2020 the FDA updated its Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. The updates include guidance that allows for serological test that identify antibodies (e.g., IgM, IgG) to SARS-CoV-2 from clinical specimens, **like Phamatech COVID-19 IgG/IgM Rapid Test, to be used** in laboratories or by healthcare workers.
Please note the following information:

- This test has not been reviewed by FDA
- 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.
- 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.
- 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.
- This test is not for the screening of donated blood
- This test is for professional use.

INTENDED USE

Phamatech COVID-19 IgG/IgM Rapid Test Cassette is intended to be used in conjunction with other test and/or clinical and epidemiological information:

- For the in vitro qualitative detection of IgM and IgG antibodies specific to 2019n-CoV (detected in China in 2019) in whole blood / serum / plasma collected directly from symptomatic patients. The test may cross react with other viruses not tested for.

- For the presumptive identification of viral infections in patients who may be infected with 2019nCoV (detected in China in 2019) in conjunction with clinical and epidemiological risk factors. The test may cross react with other viruses not tested for.

- To provide epidemiologic information for surveillance of 2019n-CoV.

Testing with Phamatech COVID-19 IgG/IgM Rapid Test should only be performed in conjunction with other laboratory approved testing and/or clinical observations for the presumptive identification of viral infections in patients who may be infected with 2019n-CoV.

All test results are presumptive and should be confirmed by an approved molecular assay. A presumptive negative test does not preclude 2019n-CoV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, a presumptive positive result does not rule out infections caused by other viruses.

SUMMARY AND EXPLANATION

Early January 2020, a novel coronavirus (COVID-19) was identified as the infectious agent causing an outbreak of viral pneumonia in China, where the first cases had their symptom onset in December 2019.[1]
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds that cause respiratory, enteric, hepatic, and neurologic diseases.[2] Six coronavirus species are known to cause human disease.[3] Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.[3] The two other strains — severe acute respiratory syndrome coronavirus (SARS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV) — are zoonotic in origin and have been linked to sometimes fatal illness.[4]
Coronaviruses are zoonotic, which means they can be transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, and cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.[5]
Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, and thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing. [5]

EXPLANATION

In response to the global pandemic caused by 2019n-CoV, Phamatech COVID-19 IgG/IgM Rapid Test was developed as a 10 minute simple point-of-care test using a lateral flow immunoassay that will allow medical personnel with minimal training to perform. The test detects the presence of IgG and IgM antibodies specific to 2019n-CoV (detected in China in 2019) generally available in whole blood / serum / plasma after infection by 2019n-CoV.

PRINCIPLE

Phamatech COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based, lateral flow immunoassay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component.
In the IgG component, anti-human IgG is coated in the IgG test line region on the membrane. During testing, when the specimen is added to the test cassette, it reacts with COVID-19 antigen-coated particles inside the test cassette.

The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG coated in the IgG test line region. If the specimen contains IgG antibodies to COVID-19, a complex will be formed resulting in a colored line that will appear in the IgG test line region. Similarly, anti-human IgM is coated in the IgM test line region and if the specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM on the membrane. A colored line appears in the IgM test line region as a result.
Therefore, if the specimen contains COVID-19 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred and the test has been activated correctly.

REAGENTS
The test contains anti-human IgM and anti-human IgG as the capture reagent, COVID-19 antigen as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

PRECAUTIONS
1. Biohazard. Biological samples such as blood have the potential to transmit infectious diseases. Follow all applicable local, state, and federal regulations.
2. Use routine laboratory precautions. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use the test if the protective pouch is damaged.
4. For research use only. Do not use after the expiration date.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Please ensure that an appropriate amount of samples are used for testing. Too much or too little of sample size may lead to deviation of results.
8. Used tests should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIALS
Materials provided
- Test cassette
- Dropper
- Instruction Insert
- Lancet
- Alcohol Prep Pad

Materials required but not provided
- Specimen collection containers
- Centrifuge (for plasma only)
- Capillary tubes
- Timer
- Pipette

PROCEDURE

SPECIMEN COLLECTION AND PREPARATION FOR TESTING

- Phamatech COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or finger prick), serum or plasma.

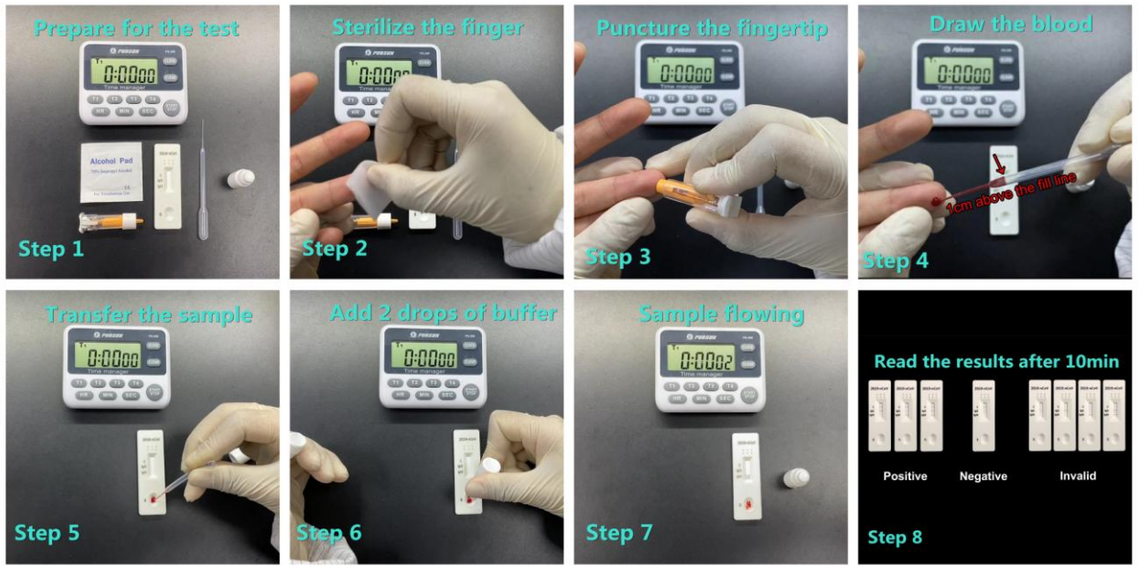
To collect Finger prick Whole Blood Specimens (when ready to perform the test):
- Wash the patient's hand with soap and warm water or clean with an alcohol prep pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip. Select the middle or ring finger for puncture.
- Remove the cap of the lancet by twisting. Place the lancet over the finger and push down to puncture the skin. 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.
- Collect the blood from the finger using the dropper provided or by using a capillary tube.
- Transfer the blood specimen to the sample well on the test device

To collect Whole Blood using Venipuncture and preparation of Serum and Plasma:
- Collect blood using general guidelines for venipuncture.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing Preparation
- Testing should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.

- Whole blood collected by finger prick 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.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

RUNNING THE TEST (WHOLE BLOOD FROM FINGER PRICK)



RUNNING THE TEST (ALL SAMPLE)

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen to the **fill line** (approximately 10µL), and transfer the specimen to the specimen well (**S**), then add **2 drops of buffer** (approximately 80 µL), and start the timer.
- To use a pipette: Transfer **10 µL** of specimen to the specimen well (**S**), then **add 2 drops of buffer** (approximately 80 µL), and start the timer

For **Venipuncture Whole Blood** specimen:

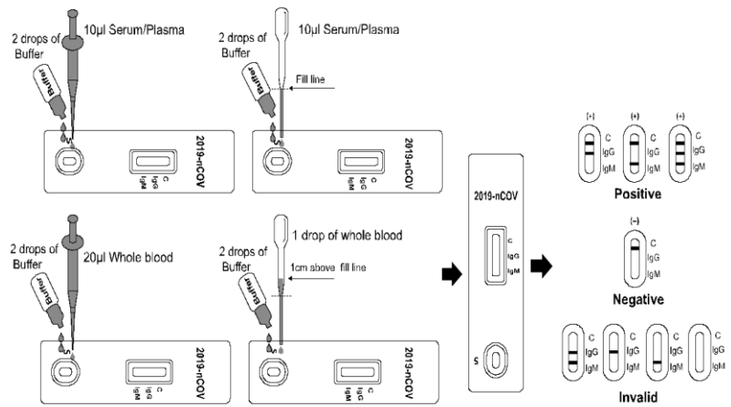
- To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20µL) of specimen to the sample well (**S**). Then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a pipette: Transfer **20 µL** of whole blood to the specimen well (**S**), then **add 2 drops of buffer** (approximately 80 µL), and start the timer

For **Finger prick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically over the finder, draw 1 drop of blood and transfer **1 full drop** (approx. 20µL) of specimen to the sample well (**S**). Then add **2 drops of buffer** (approximately 80 µL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer **approximately 20µL of finger prick whole blood specimen** to the specimen well (**S**) of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

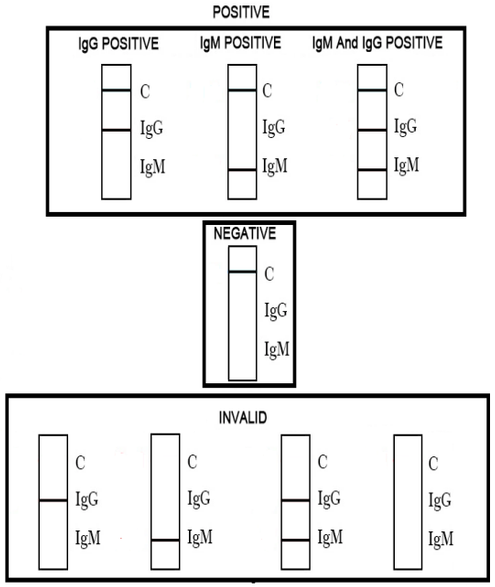
IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and the IgM line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the IgG region and the IgM region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

- All test results are presumptive and should be confirmed by an approved molecular assay.
- 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.
- 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.
- 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.



QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Phamatech COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to COVID-19 can be determined by this qualitative test.
2. Phamatech COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to COVID-19 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of COVID-19 infection.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
6. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

PERFORMANCE CHARACTERISTICS

Clinical Performance

The clinical performance of "Phamatech COVID-19 IgG/IgM Rapid Test" was evaluated in Shanghai, China with clinical samples derived from blood samples collected from 2019n-CoV infectious patients and 2019n-CoV non-infectious patients confirmed by PCR.

The study included testing of 20 known positive samples and 50 known negative samples.

Of the 20 known positive samples, the IgG test yields a 100% agreement of 20 out of 20, while the IgM test yields an 85% agreement of 17 out of 20.

Of the 50 known negative samples, the IgG test yields a 98% agreement of 49 out of 50, while the IgM test yields a 96% agreement of 48 out of 50. The data are illustrated in the table below.

Sensitivity and Specificity

IgG Result

Method		PCR		Total Results
COVID-19 IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	20	1	21
	Negative	0	49	49
Total Result		20	50	70

IgG test results yields 20 positive results from 20 known positive samples.
IgG test results yields 49 negative samples from 50 known negative samples.
Relative Sensitivity: 100% (95%CI*: 86.0%-100%)
*Confidence Interval
Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)
Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

IgM Result

Method		PCR		Total Results
COVID-19 IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

IgM test results yields 17 positive results from 20 known positive samples.
IgM test results yields 48 negative samples from 50 known negative samples.
Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)
*Confidence Interval
Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)
Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

Cross-reactivity

"Phamatech COVID-19 IgG/IgM Rapid Test" (Whole Blood/Serum/Plasma) has been tested against anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using Phamatech COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.
- Triglyceride: 50 mg/dL - Ascorbic Acid: 20mg/dL - Hemoglobin 1000mg/dL
- Bilirubin: 60mg/dL - Total cholesterol : 6mmol/L

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Number: COVID-19V1-03102020
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