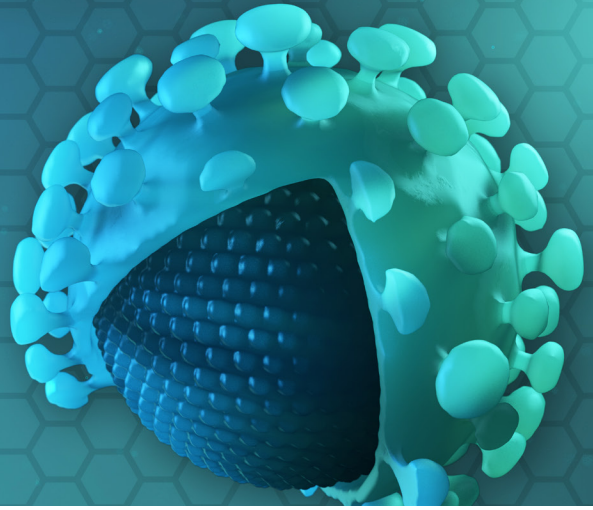
CORONA VIRUS
COVID-19
IgG And IgM Rapid Test



A Rapid Test For The Detection of COVID-19 (Coronavirus) Provided by Premier Biotech
The COVID-19 IgG and IgM Rapid Test provided by Premier Biotech is used for the qualitative detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. The procedure is easy to administer and offers reliable results at 10 minutes that remain valid for 20 minutes. Available now for prompt shipping, contact Thato Internatonal to place an order or request additional information today by calling 888-417-5550

Confident COVID-19 Results
- Fast results in 10 minutes
- Easy to use and highly accurate
- 60 tests/case
- Prompt shipping and delivery

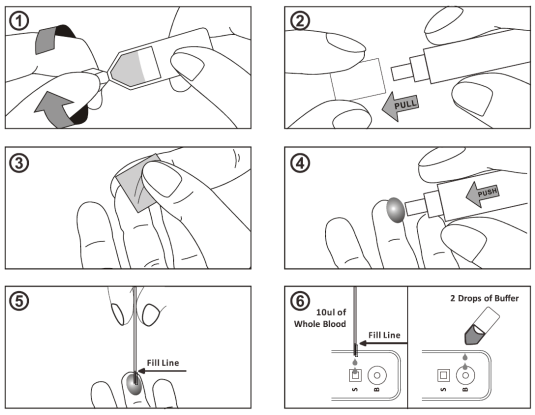
Kit Contents Include:
- Test cassette
- Desiccant, buffer, alcohol swab
- Sterile lancet
- Disposable capillary
- Package insert/procedure guide

The COVID-19 Pandemic
COVID-19 (Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. Elderly, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness.

Procedure Video: Click here

Easy To Use Procedure



Note: Test can also be run with serum/plasma specimens

ALL GREEN HEALTH

For pricing or to place an order - Call 888-863-2287 or e-mail questions@covidtestingkitsusa.com

Product IgG and IgM Rapid Test/Cassette | **SKU:** RT-CV19 | **Pack:** 60/case

All Green Efficiencies Inc. | 960 S Westlake Blvd Ste 207 Westlake Village, CA 91361 | 888-863-2287 | WWW.COVIDTESTINGKITSUSA.COM

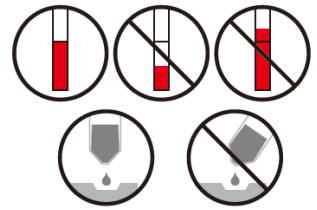
COVID-19 IgG And IgM Rapid Test Cassette Quick Reference Guide

IMPORTANT NOTE:
Each test can be used only **ONE TIME**. Do not attempt to use the test more than once.

Test Procedure

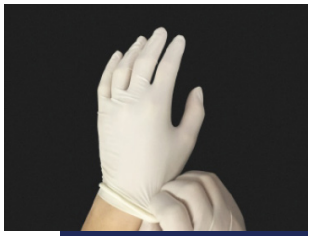
PREPARATION

Blood Volume Check



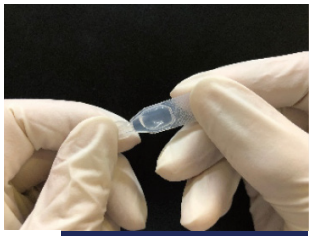
Assay Diluent Volume Check

1 Check the expiry date. If expiry date has passed, use another kit.



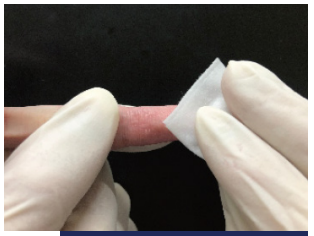
2 Put on the gloves. Use new gloves for each patient.

3 Open the test pouch and write the patient's ID on the test cassette.



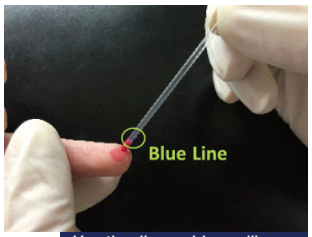
4 Twist off the tab of the buffer vial without squeezing.

5 Carefully pull off the sterile lancet cap.

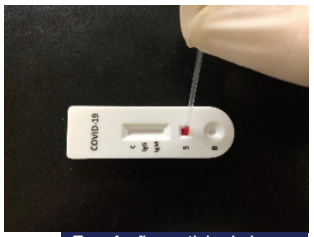


6 To disinfect the finger tip with alcohol swab.

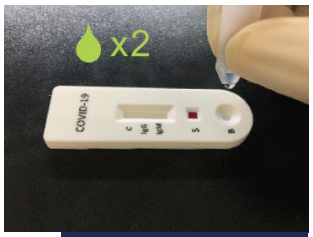
7 Push the sterile lancet firmly onto the chosen site.



8 Use the disposable capillary to draw the whole blood up to the Fill Line.



9 Transfer fingerstick whole blood specimen to the specimen well marked "S".

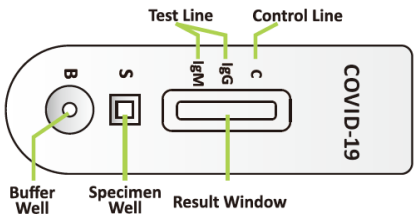


10 Add 2 drops of buffer.

11 Read results at 10-20 minutes.

12 Do not read the results after 20 minutes. Reading too late can give false results.

All the used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.



CASSETTE OVERVIEW

POSITIVE RESULTS

IgG and IgM Antibodies Positive
Three lines appear(C,IgG and IgM)

IgG Antibodies Positive
Two lines appear(C and IgG)

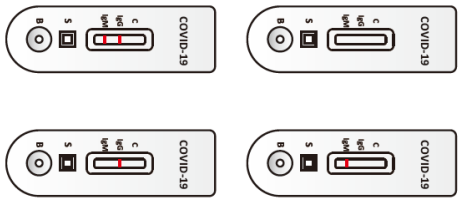
IgM Antibodies Positive
Two lines appear(C and IgM)

NEGATIVE RESULT

Only one colored line appears in the control region (C).

INCONCLUSIVE RESULTS

Control line fails to appear.
Review the procedure and repeat the test with a new test cassette.



To learn more and to view our quick COVID-19 procedure video visit: https://www.dropbox.com/s/95a7jik2boicrp7/Premier%20COVID-19-Rapid-Procedure.mp4?dl=0

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CV19-3/20

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

Package Insert

REF INGM-MC42 English

A rapid test for the qualitative detection of antibodies (IgG and IgM) to SARS-CoV-2 in whole blood, serum, or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections.

【SUMMARY】

COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. Most estimates of the incubation period for COVID-19 range from 1-14 days.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma.

【PRINCIPLE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, 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.

【REAGENTS】

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- To collect Fingerstick Whole Blood Specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- 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 Fingerstick Whole Blood specimen to the test cassette by using a dropper, capillary or micropipette measuring 10ul. The dropper or capillary provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the dropper or capillary.
- 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 2-8°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 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick 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 federal regulations for transportation of etiologic agents.

【MATERIALS 】

Materials provided

Test cassettes	Droppers/ Capillary
Buffer	Package insert
Lancets (for fingerstick whole blood only)	

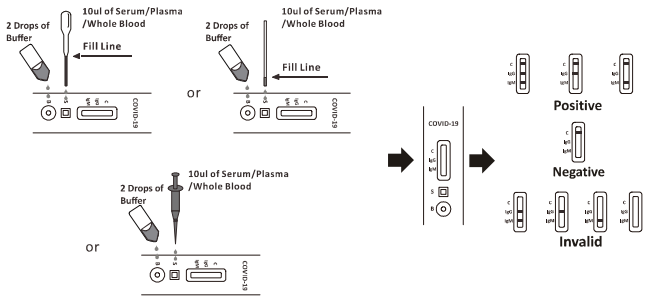
Materials required but not provided

Specimen collection containers	Centrifuge (for plasma only)
Micropipette	Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - For Serum or Plasma or Whole Blood Specimens:
     - To use a dropper or capillary: Hold the dropper or capillary vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
     - To use a micropipette: Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

IgG and IgM POSITIVE:* **Three lines appear**. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-COV-2 infection.

IgG POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.

IgM POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s). Negative results are not definitive. Refer to Limitations of use.

INVALID: **Control line 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 cassette. If the problem persists, discontinue using the test kit immediately and contact Premier Biotech.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
2. Results from the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used as the sole basis to diagnose or exclude SARS-COV-2 infection or to inform infection status.
3. In the early onset of fever, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. 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.
8. 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.
9. 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.
10. Not for the screening of donated blood.

【EXPECTED VALUES】

Primary SARS-COV-2 infection is characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection. Secondary SARS-COV-2 infection is characterized by the elevation of SARS-COV-2-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Cassette was compared with clinical diagnosis(Confirmed). The study included 446 specimens for IgG and 456 specimens for IgM.

IgG Results

Method		*Clinical Diagnosis(Confirmed)*		Total Results
	Results	Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Positive	75	2	77
	Negative	0	369	369
Total Results		75	371	446

Diagnostic Sensitivity: 100.0% (95%CI: 96.1%~100.0%)*
Diagnostic Specificity: 99.5% (95%CI: 98.1%~99.9%)*
Accuracy: 99.6 %(95%CI: 98.4%~99.9%)* *Confidence Interval

IgM Results

Method		*Clinical Diagnosis(Confirmed)*		Total Results
	Results	Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Positive	78	3	81
	Negative	7	368	375
Total Results		85	371	456

Diagnostic Sensitivity: 91.8 %(95%CI: 83.8%-96.6%)*
Diagnostic Specificity: 99.2 %(95%CI: 97.7%~99.8%)*
Accuracy: 97.8 %(95%CI: 96.0%~98.9%)* *Confidence interval

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV and HAMA positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor. It is possible to cross-react with samples positive for MERS-CoV antibody. 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.

Interfering Substances

The following potentially interfering substances were added to COVID-19 negative specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL	Albumin: 2 g/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL	Ethanol: 1%
Ascorbic Acid: 2g/dL	Creatine: 200mg/dl	Bilirubin: 1g/dL
Hemoglobin: 1000mg/dl	Oxalic Acid: 60mg/dL	Uric acid: 20mg/ml

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

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2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.
5. US Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff. Issued March 16, 2020. Docket Number FDA-2020-D-0987.

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Number: RP5800960
Effective date: 2020-03-25

ALL GREEN HEALTH

Coronavirus (COVID-19) Disease/Testing Frequently Asked Questions

Q: What are IgG and IgM antibodies?

A: Immunoglobulin G (IgG), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections. Immunoglobulin M (IgM), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection.

Q: How quickly after exposure will there be sufficient antibody to be detected?

A: In general, IgM antibodies appear about a week after infection and IgG antibodies appear about two weeks after infection. It is important to recognize that people have their own unique immune response and thus detection time can vary significantly from person to person.

IgM antibodies: Data is still being collected but at the point, this document was written the best information available suggests that IgM antibodies to SARS-CoV2 are detectable between 3-10 days after first symptoms.

IgG antibodies: Data is still being collected but at the point, this document was written the best information available suggests that IgM antibodies to SARS-CoV2 are detectable between 14-21 days after first symptoms.

Q: What is PCR testing and what does PCR stand for?

A: PCR (Polymerase Chain Reaction) is laboratory test to diagnose the COVID-19 infection based on viral RNA. The test involves a nasopharyngeal swab that looks like a long Q-tip and draws mucus from the back of the patient's nasal cavity where it meets the throat. The swab is then inserted into a vial and is shipped to a laboratory where lab techs or machines use reagents to extract the viral RNA. An enzyme, Reverse Transcriptase is used to convert the RNA into DNA and the DNA is replicated many times to make it detectable.

Q: What testing methodology is better, PCR or serology/antibody testing?

A: PCR or molecular testing identifies the virus DNA and is much better for diagnosing active infection, especially in early stages. Serology testing identifies the antibodies produced by the immune system in response to a virus. It is ideal for return to work testing or to help indicate when patients have recovered from infection. It is not ideal for diagnosing early symptomatic or pre-symptomatic infection.

Q: What are some use cases for antibody testing?

A: 1. Return to work testing for employees.
2. Testing for healthcare workers, medical professionals and responders on the front-line holding high-risk positions of exposure to the virus. Antibody testing can help detect antibodies that may give a person immune protection.
3. Testing for purposes of identifying the true number of people infection in a population. This can be accomplished by testing individuals that did not have access to molecular testing while they were symptomatic or by testing people who were infected but never showed symptoms (known as asymptomatic). Antibody testing can help by increasing our under standing of how prevalent asymptomatic infection is in the community or workplace.

Q: What are the types of In Vitro Diagnostic tests for SARS-CoV-2?

A: Molecular Tests: These tests detect SARS-CoV-2 nucleic acids from human specimens. The CDC SARS-CoV-2 Real-Time RT-PCR Diagnostic Panel test is a molecular test.

Antigen Tests: These tests detect SARS-CoV-2 antigens in clinical specimens.

Serological Tests: These tests detect SARS-CoV-2 antibodies (e.g., IgM, IgG) in clinical specimens. Premier Biotech's IVD testing kit is a serological testing kit.

Q: What is COVID-19 and SARS-CoV-2?

A: Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus2 (SARS-CoV-2).

Q: What is the clinical classification of COVID-19?
A: COVID-19 is clinically divided into 4 groups: mild, moderate, severe and critical. All 4 groups can spread the virus and should be isolated from healthy individuals to decrease the likelihood of spreading the virus.

Q: Is the test from Premier Biotech available for home use?
A: Not at this time—all tests must be done at a testing site. The FDA sees the public health value in expanding testing that may include home collection, and they are actively working with test developers on this goal for possible use in the future.

Q: Can the test be used with decomposed samples?
A: No, the tests are to be used with freshly obtained samples.

Q: How much sample is required to run the test?
A: 10ul

Q: How long does it take to interpret results using the serology test?
A: Results can be read at 10 minutes and remain valid for 20 minutes.

Q: Has there been any clinical evaluations conducted using the test distributed by Premier Biotech?
A: Yes—Clinical trials were completed in three institutions: Hubei, CDC, Jiangsu. Additional on-going clinical studies are being conducted in the U.S. including studies conducted by Stanford University. Results from those studies will continue to be published.

Q: Do you know at what day of the illness the IgM/IgG rapid tests were run on the people in the studies?
A: Results from other similar rapid tests have stated it takes 8-10 days to develop the antibodies. Some studies suggest that IgM could be found 3-4 days after the onset of symptoms, but this varies from person to person. The Health Commission of China suggest on-going testing with PCR and antibodies tests. For suspected people, PCR +, quarantined; PCR – Ab +, quarantined; PCR – Ab –, retested 2-3 days later.

Q: Are there any anticoagulants that are compatible with the test for locations interested in collecting in advance prior to receipt of the test kits?
A: Anticoagulants such as EDTA, Citrate, Heparin or Oxalate should be used for whole blood storage.

Q: What is the sensitivity rate of the test?
A: False Positive = 2.5% for IgM and 3.7% for IgG | False Negative= 1.8% for IgM and unobserved for IgG.

Q: What color of collection tube should be used?
A: Primarily the pumpkin color. If you don't have access to that then the green/lime one or the lavender one.

Q: Where should positive tests be reported?
A: Healthcare providers should immediately notify their local or state health department in the event of the identification of a PUI for COVID-19. Additional information can be found on the CDC website:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

Q: Does Premier Biotech offer confirmation tests?
A: Not at this time.

Q: What are a few other good resources to learn more about COVID-19 (symptoms, testing, support)?
A: The Centers for Disease Control and Prevention (CDC) has an extensive COVID-19 FAQ resource available here:
https://www.cdc.gov/coronavirus/2019-ncov/faq.html
For additional information regarding Premier Biotech's rapid serology test and support, visit us online at:
https://premierbiotech.com/innovation/covid-19/


the sterile lancet firmly onto
the chosen site.
Use the di
draw the v
Fill Line.
The all used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
Test Line
Buffer Well
Specimen Well
Result Wi
Overview of the