Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test Package Insert

Intended Use

The Pinnacle BioLabs COVID-19 Novel Coronavirus (COVID-19)IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus(COVID-19) in human whole blood, serum or plasma. This test is intended to be used as an aid in the diagnosis of infection with Novel Coronavirus. Any reactive specimen with the Novel Coronavirus(COVID-19)IgG/IgM Rapid Test must be confirmed with alternative testing method(s) as this test is currently distributed under an Emergency Use Authorization by the FDA. **For professional use only. This test has not been reviewed by the 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. Not for the screening of donated blood.**

Summary and Explanation of the Test

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. The α and β gene are only pathogenic to mammals. The γ gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronaviruses (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and Novel Coronavirus(COVID-19) (2019) , it's an important pathogen of human respiratory infections. Among them, a COVID-19 was discovered in 2019 due to Wuhan virus pneumonia cases. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea and so on. It can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., and even life-threatening.

Test Principle

The Pinnacle BioLabs COVID-19 Novel Coronavirus (COVID-19)IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant COVID-19 antigen conjugated with colloid gold (COVID-19 conjugates) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band

Test Principle (continued)

(C band). The T1 band is pre-coated with monoclonal anti- human IgG for the detection of IgG anti-COVID-19, T2 band is pre-coated with reagents for the detection of IgM anti-COVID-19 and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. COVID-19 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored T2 band, indicating COVID-19 IgM positive test result.

COVID-19 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored T1 band, indicating a COVID-19 IgG positive test result.

Absence of any test bands (T1 and T2) suggests a negative result. The test card also contains a quality control band C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. The quality control band is a color band of the quality control antibody immune complex. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

Kit Components

- ***25 Individually wrapped test cassette device(s)***
- ***Disposable pipette(s)***
- ***5 mL buffer***
- ***Package insert***
- ***Quick Reference Guide***

Materials Not Provided

- ***Timer***

Storage and Stability

Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse test. The kit should be stored at 2~30°C in cool and dry place, protected from light. After opening the aluminum foil pouch, the test card will become invalid due to moisture absorption. Therefore, it is important that the test is performed and resulted within one hour of opening the individually wrapped foil cassette.

Specimen Collection and Preparation

The kit can be performed using a whole blood (finger-stick) specimen [recommended], or plasma or serum samples prepared from commonly used anticoagulants (EDTA, heparin, sodium citrate). Testing should be performed immediately after specimen collection. **For Serum and Plasma Only:** If the test cannot be performed immediately, the serum and plasma specimen to be tested can be stored at 2 ~ 8 °C for 5 days. For long-term storage, store at -20 °C. Avoid repeated freeze-thaw specimens. Anti-coagulated whole blood specimens should not be stored for more than 72 hours at room temperature; not more than 7 days at 2-8 °C. Before testing, slowly return the refrigerated or frozen specimens to room temperature and mix them carefully. When clearly visible particulate matter is present in the specimen, it should be centrifuged to remove sediment before testing. If the specimen contains a large amount of lipid, hemolysis or turbidity, please do not use it, so as not to affect the result judgment.

Assay Procedure

1. Place the test device on a clean, flat surface. After washing your hands, choose the non-dominant hand and face it palm side up. Remove the cap from the finger-stick device and use the disposable finger-stick device to stick the ring finger. It is recommended to wipe off the first droplet of blood with the provided gauze pad. **For Serum and Plasma Only:** Bring the specimen and test components to room temperature if refrigerated or frozen.

2. Fill the pipette dropper with the blood specimen. Holding the dropper vertically, dispense 1 drop (about 10 μL) of whole blood (include finger blood),serum, plasma into the sample well, making sure that there are no air bubbles. Then add 2 drops (about 70-100 μL) of Sample Diluent immediately.

3. Set up timer for 15 minutes. Read and record results at the 14-15 minute mark. **It is important not to read results after 15 minutes.**

Negative Result

If only the C band is present, the absence of any burgundy color in the both test bands (T1 and T2) indicates that no COVID-19 antibody is detected in the specimen. The result is negative.

Presumptive Positive Result
(Must be verified by HHS approved facility)

In addition to the presence of the C band, if the T1 band is visible, the test indicates the presence of the COVID-19 IgG antibody. The result is a presumptive positive and additional confirmation testing is immediately needed.

In addition to the presence of the C band, if the T2 band is visible, the test indicates the presence of the COVID-19 IgM antibody. The result is a presumptive positive and additional confirmation testing is immediately needed.

In addition to the presence of the C band, if both the T1 and T2 bands are visible, the test indicates the presence of both COVID IgG and IgM antibodies. The result is a presumptive positive and additional confirmation testing is immediately needed.

Invalid Result

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands. Repeat the assay with a new device.

Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test Package Insert (continued)

Performance Characteristics

1. Positive Coincidence Rate: The test results of positive quality control are all positive. 2. Negative Coincidence Rate: The test results of negative quality control are all negative. 3. Analytical Specificity: The test results of specimen from non- infected by novel coronavirus should be negative.
4. Analytical Sensitivity: The detection result is positive when detection of a novel coronavirus IgG strongly positive serum 1:50 dilution sensitivity reference : The detection result is positive when detection of a novel coronavirus IgM strongly positive serum 1:50 dilution sensitivity reference.
5. Intra-Assay: There is no different test results of the same quality control in the same batch. 6. Inter-Assay: There is no different test results of the same quality control from different batch.

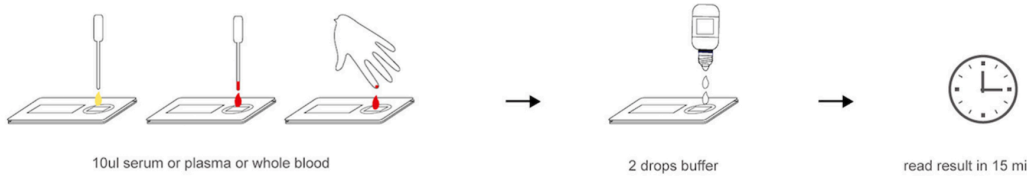
Limitations of the Test

1. The Assay Procedure and the Assay Result Interpretation must be followed strictly when testing. Failure to follow the procedure may give inaccurate results**. 2.** This kit is only used for in vitro diagnosis and is only used for qualitative detection of Coronavirus IgG and/or IgM antibodies in blood samples. **3**.Positive and negative results indicate the presence of IgG and/or IgM antibodies with/without detectable concentrations of Coronavirus in blood samples, but cannot be used as the sole criterion for the determination of Coronavirus infection. Other methods (such as nucleic acid testing) should be used for identification when necessary, and comprehensive judgment should be made based on the test results. All positive results should be deemed presumptive positives and appropriate follow-up testing should be immediately sought.

Warnings and Precautions

1. Before using the kit, please read the instructions carefully and control the reaction time strictly. 2. Inadequate blood supply may deliver inaccurate results. Be sure to deliver adequate blood supply to the sample well. It is strongly encouraged to use the accompanying pipette, ensuring 10 µL is delivered to the sample well of the cassette. 3. Do not allow the product to get wet. 4. Do not dilute the specimen for testing. 5. Dispose of kit in accordance with infectious disease protocol. 6. Special Statement from the US Food and Drug Administration: For professional use only. This test has not been reviewed by the 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. Not for the screening of donated blood.

Sample Collection



Results Interpretation

Excluding the pipette bulb, ensure the pipette is filled half way up the conduit with no bubbles or visible air.

Failure to deliver adequate blood supply to the sample well may lead to inaccurate results. The following guide shows sample collection from WB/S/P.

If using the device outside of a clinical laboratory setting, it is recommended to use the included pipette. To deliver adequate blood supply, exclude the bulb and draw 50% up the remainder of the conduit, pursuant to the image to the left.

References

1. Catherine I. Paules MD; Hilary D. Marston, MD, MPH; Anthony Fauci, MD. Coronavirus Infections - More than the common cold. JAMA 2020; 323 (8)

2. Prof Roujian Lu MSc, Xiang Zhao Md, Juan Li PhD, et al. Genomic characterization and epidemiology of 2019 Novel Coronavirus implications for virus origins and receptor binding. The Lancet, Volume 395 Issue 10224.

3. B. Coutard, C. Valle, X. de Lamballerie, et al. The spike glycoprotein of the new coronavirus 2019- nCOV contains a burin-like cleavage site absent in CoV of the same clade. Antiviral Research, Volume 176. April 2020.

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

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