COVID-PRESTO®

CE

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

Ref.: TR-COV-001

INTENDED USE

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test allows the determination of an immunization to SARS-CoV-2 which makes it possible to confirm, even in the absence of symptoms, contact with the virus and a potential acquired protective immunity.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (SARS-CoV-2) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 1-3 weeks after exposure.

TEST PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM), anti-human IgG antibody (test line IgG) and rabbit IgG (control line C) immobilized on a nitrocellulose strip. The Conjugate (recombinant COVID-19 antigens labeled with colloidal gold) is also integrated into the strip.
When a specimen is added to the sample well (S) followed by assay buffer added to the buffer well (B), IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex.
This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.
To serve as a procedural control, a colored line will always change from blue to red in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIAL SUPPLIED

- 25 sealed pouches each containing a test cassette and a desiccant
- 25 single doses of buffer
- 1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Laboratory pipettes
- 10µl micropipette (for fingerstick whole blood only)
- Gloves
- Timer

STORAGE AND STABILITY

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

STORAGE AND STABILITY

- For professional In Vitro diagnostic use only. Do not use after expiration date.
- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not use it if the single tube/pouch are damaged.
- Test is for single use only. Do not re-use under any circumstances.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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.
- Humidity and temperature can adversely affect results.
- Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma. For serum or plasma:

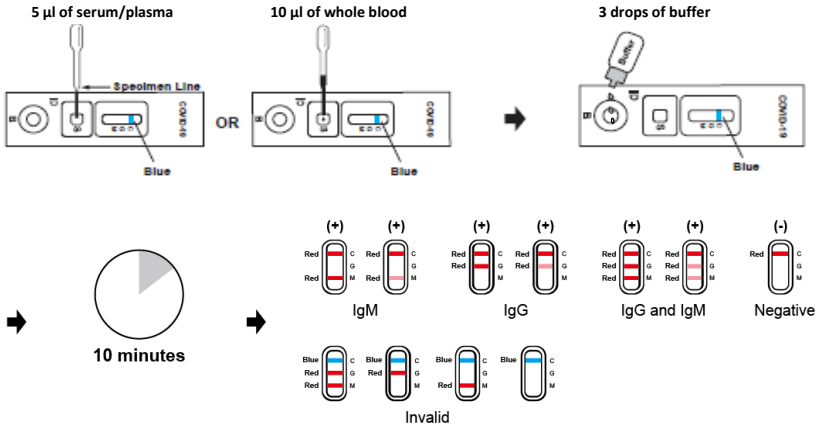
1. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
2. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored 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.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

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

Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

1. Place the test device on a clean and level surface.
2. Perform the test as follow, depending on specimen:
   - For **Serum or Plasma Specimens:** draw **5µl** of serum/plasma specimen with a laboratory pipette and then transfer the specimen into the sample well (S) of the test device. Then add 3 drops of sample buffer to the buffer well (B) immediately. Avoid air bubbles.
   - For **Whole Blood Specimen:** draw **10µl** whole blood specimen with a laboratory pipette and then transfer the specimen into the sample well (S) of the test device. Then add 3 drops of sample buffer to the buffer well (B) immediately. Avoid air bubbles.
   - For **whole blood samples taken at the fingertip** (use of the 10µL micropipette):
     - Using the lancet, prick the side of the fingertip. Form a large drop of suspended blood.
     - Hold the micropipette horizontally and put the tip of the micropipette in contact with the blood. DO NOT PRESS THE PEAR OF THE PIPETTE. The pipette automatically fills up to the black line.
     - Place the micropipette vertically above the well (S) of the cassette and squeeze the bulb to deposit the blood.
       Note: if blood is not expelled from the micropipette, plug the small hole in the middle of the black line with fingers of the other hand then squeeze the bulb.
     - Immediately add 3 drops of buffer to the buffer well (B) of the cassette. Avoid air bubbles.
3. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window or if blood is still present in the specimen well (S), add 1 additional drop of the sample buffer to the buffer well (B).
   The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: The colored line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G. The result is negative.

IgM POSITIVE: The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region M. The result is anti-COVID-19 IgM positive.
IgG POSITIVE: The colored line in the control line region (C) changes from blue to red, and a colored line appears in test line region G. The result is anti-COVID-19 IgG positive.
IgG and IgM POSITIVE: The colored line in the control line region (C) changes from blue to red, and two colored lines appear in test line regions M and G. The result is anti-COVID-19 IgM and IgG positive.

INVALID: Control line is still completely or partially blue, and fails to completely change from blue to red. 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the 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

- Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
- Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
- This test is not intended to be used for the diagnosis of COVID-19 infection, but for the diagnosis of acquired immunization to the COVID-19 virus.
- A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
- A negative result can occur if the quantity of the anti-COVID-19 antibodies that are detected are not present during the stage of disease in which a sample is collected or if their level is below the detection limit of the test.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- Some preliminary data seem to indicate that these antibodies may appear late (D30), especially in the case of pauci / asymptomatic infection.
- COVID-PRESTO® is a TROD ; the final diagnosis of immunization should be made in a medical laboratory.

PERFORMANCE CHARACTERISTICS

COVID-PRESTO® test performance was evaluated at the Orléans Hospital (Infectious Diseases Department - publication of results in progress) from:

- Sensitivity: 144 capillary blood samples obtained from 143 patients who had a positive COVID-19 PCR due to suggestive symptoms (fever and / or cough and / or dyspnea and / or flu-like syndrome)

- Specificity: 72 patients who had a negative COVID-19 PCR drawn due to symptoms which led to the realization of the PCR which turned out to be negative without sign of severity

Sensitivity

Reference method	COVID-19 PCR positive			
Time delay after 1st symptoms	D3-D6	D7-D10	D11-D15	D16-D31
Number of negative samples	20	16	12	0
Number of IgM positive samples	2	6	3	0
Number of IgM and IgG positive samples	0	10	25	38
Number of IgG positive samples	2	5	0	5
Results	**16.7%**	**28.3%**	**70%**	**100%**

Specificity

Reference method	COVID-19 PCR negative
Number of samples	72
Results	**100%**

REFERENCES

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

INDEX OF SYMBOLS

	Consult instruction for use		Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Lot Number	REF	Catalog#
CE	CE mark				

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