COVID-19 Rapid Test

Catalogue Number: RAPG-COV-019

Please read this manual carefully before operating to ensure proper use.

TEST KIT DESCRIPTION

The Biopanda COVID-19 Rapid Test qualitatively detects IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma samples. This test applies lateral flow immuno-chromatography and is a tool to assist in the diagnosis of SARS-CoV-2 infections.

SUMMARY

In early January 2020, a novel coronavirus (SARS-CoV-2) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, 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 and 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 immuno-competent 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]

Common signs of infection include respiratory symptoms, fever, 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, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

PRINCIPLE

The COVID-19 Rapid Test Cassette is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, serum or plasma specimens. 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. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates laterally along the membrane chromatographically by capillary action and reacts with the anti-human IgG in the IgG test line region, if the specimen contains IgG antibodies to SARS-CoV-2. A coloured line will appear in the IgG test line region as a result of this. Similarly, anti-human IgM is coated in the IgM test line region and if the specimen contains IgM antibodies to SARS-CoV-2, the conjugate-specimen complex reacts with anti-human IgM. A coloured line appears in the IgM test line region as a result. Therefore, if the specimen contains SARS-CoV-2 IgG antibodies, a coloured line will appear in the IgG test line region. If the specimen contains SARS-CoV-2 IgM antibodies, a coloured line will appear in the IgM test line region. If the specimen does not contain SARS-CoV-2 antibodies, no coloured line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS

- 10 x Foil wrapped cassettes and desiccant.
- 10 x Disposable sample droppers
- 1 x Buffer Tube
- 1 x Product insert

STORAGE AND STABILITY

Store the kit between 2-30ºC and ensure the kits are not frozen or stored in direct sunlight. The test is valid until the expiration date printed on the foil wrapping.

PRECAUTIONS

Follow these instructions for the best results:

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- Blood samples may be potentially infectious and should be handled with standard biosafety procedures.
- Protective clothing such as laboratory coats, disposable gloves, and eye protection should be worn when working with assays.
- Ensure the test kit is at room temperature before running the test.
- Keep the test inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Test kits that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test to ensure quality controlled testing.
- Used tests and unused samples should be discarded according to local standard biosafety procedures.

SAMPLE COLLECTION AND PREPARATION

- The Biopanda COVID-19 Rapid Test can be performed using whole blood, serum, or plasma.
- To collect Fingerstick **Whole Blood** Samples:
- 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 by using a capillary tube: Touch the end of the capillary tube to the blood until filled to approximately 20µl. Avoid air bubbles.
- For **serum/plasma** samples: Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples.
  Testing should be performed immediately after sample collection. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 7 days. For long-term storage, samples 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 samples 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 for transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

TEST PROCEDURE

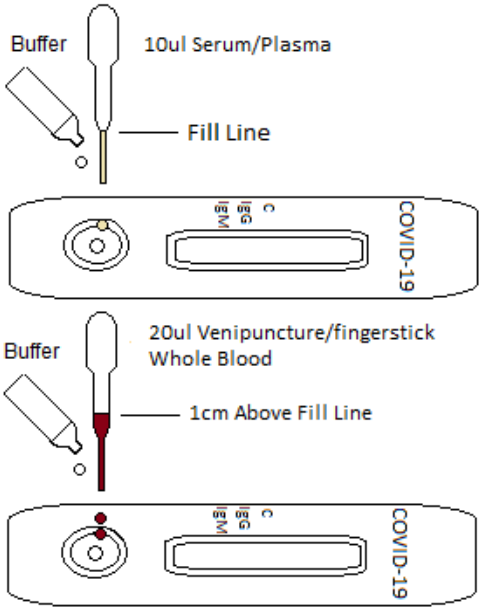
1. Allow the test, specimen, and buffer to reach room temperature (15-30°C) prior to testing. Remove the test cassette from the sealed pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

❖ For **<u>Serum or Plasma</u> specimens**:
Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well of the test cassette, then add 2 drops of buffer (approximately 80µl) and start the timer. Avoid trapping air bubbles in the sample well. See illustration below.

❖ For **<u>Whole Blood (Venipuncture)</u> specimens:**
Hold the dropper vertically and transfer 1 drop of whole blood (approximately 20µl) to the specimen well, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.

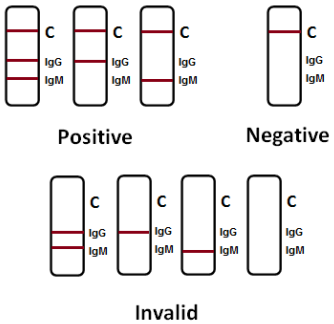
❖ For **<u>Whole Blood (Fingerstick)</u> specimens:**
To use a capillary tube: Fill the capillary tube and transfer approximately 20µl of fingerstick whole blood specimen to the specimen well of the test cassette, then add 2 drops of buffer (approximately 80 µl) and start the timer. See illustration below.

3. Wait for the coloured line(s) to appear. Read the results at **10 min**, do not interpret the results after 20 min.



INTERPRETATION OF RESULTS

IgG POSITIVE:*Two lines appear. One coloured line should be in the control line region (C), and a coloured line appears in the IgG test line region. The result is positive for SARS-CoV-2 specific-IgG antibodies.
IgM POSITIVE:*Two lines appear. One coloured line should be in the control line region (C), and a coloured line appears in the IgM test line region. The result is positive for SARS-CoV-2 specific-IgM antibodies.
IgG and IgM POSITIVE:*Three lines appear. One coloured line should be in the control line region (C), and two coloured lines should appear in IgG test line region and IgM test line region.
***NOTE:** The intensity of the colour in the test line regions will vary depending on the titre of SARS-CoV-2 antibodies present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.
NEGATIVE: One coloured line appears in the control region (C). No apparent coloured line appears in the IgG or IgM test region (T).
INVALID: Control line fails to appear. Insufficient sample 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.



LIMITATIONS

1. The Biopanda COVID-19 Rapid Test is for *in vitro* diagnostic use only. This test should be used for the detection of IgG and IgM antibodies to SARS-CoV-2 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 SARS-CoV-2 can be determined by this qualitative test.
2. The Biopanda COVID-19 Rapid Test will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 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 SARS-CoV-2 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.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

The Biopanda COVID-19 Rapid Test was compared with PCR. The results show that the Biopanda COVID-19 Rapid Test has a high sensitivity and specificity.

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

Relative Sensitivity: >99.9% (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
Biopanda COVID-19 Rapid Test	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

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

The Biopanda COVID-19 Rapid Test has been tested with 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

Specimens spiked with the following compounds have been tested using the Biopanda COVID-19 Rapid Test and no interference was observed:
Triglyceride: 50mg/dL
Ascorbic Acid: 20mg/dL
Hemoglobin: 1000mg/dL
Bilirubin: 60mg/dL
Total cholesterol: 6mmol/L

BIBLIOGRAPHY

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Thank you for purchasing Biopanda's COVID-19 Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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