COVID-19 Rapid Test Kit

Catalogue Number: RAPG-COV-019

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

TEST KIT DESCRIPTION AND INTENDED USE

The Biopanda COVID-19 Rapid Test Kit is a qualitative lateral flow immunochromatographic assay for the detection of IgM and IgG antibodies to SARS-CoV-2 in human whole blood, serum or plasma samples.

It is intended for use as a tool to assist in the diagnosis of SARS-CoV-2 infections. It is also intended as a tool for carrying out serological epidemiological investigations, particularly of asymptomatic infections.

This test is for *in vitro* diagnostic use only by a trained healthcare professional.

COVID-19: BACKGROUND INFO

In late December 2019, a cluster of pneumonia cases of unknown cause was reported by health authorities in Wuhan, China. A subsequent investigation, launched in early January 2020, identified a novel coronavirus (SARS-CoV-2) as the infectious agent responsible. This coronavirus is thought to be zoonotic in origin.

Coronaviruses are a group of enveloped RNA viruses that cause diseases in mammals and birds. In humans, coronaviruses usually cause mild respiratory tract infections such as the common cold. Two other strains—severe acute respiratory syndrome coronavirus (SARS-COV) and Middle East respiratory syndrome coronavirus (MERS-COV)—are also zoonotic in origin and have caused serious outbreaks.

Typical symptoms include fever, cough and shortness of breath. In rare but severe cases, the disease can progress to pneumonia, multiple organ failure, and death. The elderly, and those with underlying health conditions (such as heart disease, high blood pressure or diabetes) are most at risk of developing serious illness.

TEST PRINCIPLE

The COVID-19 Rapid Test is a qualitative lateral flow immunoassay for the simultaneous detection of IgM and IgG antibodies to SARS-CoV-2 in whole blood, serum or plasma specimens.

The test cassette contains recombinant SARS-CoV-2 antigen conjugated to coloured particles. When a specimen is added to the sample well of the cassette, any IgM and IgG present in the specimen will bind to the antigen conjugate, forming coloured coronavirus antigen-antibody complexes. This mixture migrates laterally along the membrane to the test region. In this test region, anti-human IgM and anti-human IgG have been immobilised onto the membrane. These capture any IgM and IgG complexes that have formed, resulting in the appearance of coloured lines.

Therefore, if the specimen contains SARS-CoV-2 IgM antibodies, a coloured line will appear in the IgM test line region. If the specimen contains SARS-CoV-2 IgG antibodies, a coloured line will appear in the IgG test line region. A coloured line should always appear in the control line region, indicating that the proper volume of specimen and buffer has been added to allow the assay to run. Note that the presence of the control line does not guarantee that a sufficient volume of blood was added.

KIT CONTENTS

- Foil wrapped test cassettes
- Disposable sample droppers
- Buffer
- Lancets (if ordered with kit)
- Alcohol pads (if ordered with kit)
- Package insert

STORAGE AND HANDLING

Store the kit at between 2-30^{o}C in a cool, dry place away from direct sunlight. **DO NOT FREEZE**. Do not store in a refrigerator. The test cassettes are stable up to the expiry date printed on the foil pouch as long as the pouch has not been opened.

Do not open the foil pouch until you are ready to run the test. Do not touch the sample well or results window of the cassette.

PRECAUTIONS

- This kit is for *in vitro* diagnostic use only and should only be used by trained healthcare 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 (RT 15-30°C) before running the test.
- Keep the cassette 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.
- Used tests and unused samples should be discarded according to local standard biosafety procedures.

SAMPLE COLLECTION AND STORAGE

The Biopanda COVID-19 Rapid Test can be performed using whole blood, serum, or plasma.

To collect finger-prick **Whole Blood** Samples:

- Ask the patient to wash their hands with soap and warm water, then warm up their fingers by rubbing their hands together for 30 seconds.
- Clean the finger-prick site with an alcohol pad. Allow to dry.
- Massage the selected finger down towards the tip of the finger, then puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently massage the punctured finger again to form a second drop of blood. It is recommended to allow a large drop of blood to form.
- See the 'TEST PROCEDURE' section below for further instructions.

For **Serum** samples**:**

Blood should be collected with a plain tube by venipuncture. The serum should be separated from the cells by centrifugation after clot formation.

Plasma samples:

K2-EDTA, Heparin, Sodium citrate and Potassium Oxalate can be used as an anticoagulant for collecting the blood. Separate plasma from the cells 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. If necessary, serum and plasma samples may be stored at 2-8°C for up to 7 days. For long-term storage, samples should be kept at below -20°C. Venous whole blood 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. Finger-prick blood samples should be tested immediately.

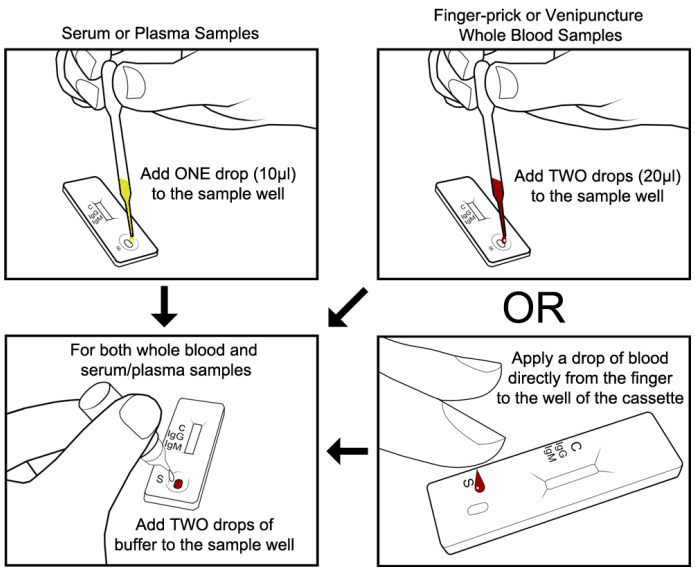
Bring samples to RT prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be repeatedly frozen and thawed.

TEST PROCEDURE (See illustration overleaf)

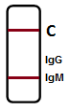
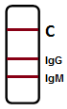
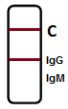
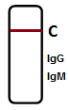
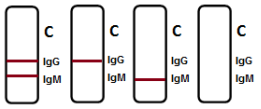
1. Allow the test cassette, sample, and buffer to reach RT prior to testing. Remove the test cassette from the sealed pouch and use within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.
   - For **whole blood finger-prick samples:**
     Holding the sample dropper vertically, draw up the finger-prick blood. Add **two** drops (approximately 20µl) of this blood specimen to the sample well (S) of the test cassette, then immediately add 2 drops of buffer (approximately 80 µl) and start the timer.
     You can also apply a drop of blood directly from the finger to the cassette by allowing a drop of blood to fall into the sample well, or by touching the blood drop on the finger against the sample well.
   - For **venous whole blood samples:**
     Using a dropper, or a pipette for better precision, add 20µl of whole blood to the sample well (S) of the test cassette, then immediately add 2 drops of buffer (approximately 80 µl) and start the timer.
   - For **serum or plasma samples:**
     Using a dropper, or a pipette for better precision, add 10 µl of serum or plasma to the sample well (S) of the test cassette, then immediately add 2 drops of buffer (approximately 80 µl) and start the timer.
3. Wait for the coloured line(s) to appear. Results can be read at **5-10 minutes** if IgM and/or IgG lines have already appeared. A reading time of 15 minutes is recommended to allow for weakly positive lines to form. Do not interpret the results after 20 minutes have elapsed.

Biopanda Reagents

CE

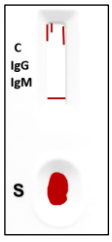


INTERPRETATION OF RESULTS

	Two coloured lines appear: one in the control region (C), and one in the IgM region. **Result: IgM POSITIVE ONLY*** **The patient may have an early, active infection.**
	Three coloured lines appear: one in the control region (C), one in the IgM region, and one in the IgG region. **Result: IgM and IgG POSITIVE*** **The patient may have an active infection, or are recovering from an infection.**
	Two coloured lines appear: one in the control region (C), and one in the IgG region. **Result: IgG POSITIVE ONLY*** **The patient may have been infected in the past, or are recovering from a recent infection.**
	One coloured line appears in the control region (C). No other lines visible. **Result: NEGATIVE** **The patient may not be infected, or may be in the very early stages of infection before antibodies can be detected.**
	No coloured line appears in the control region (C) **Result: TEST INVALID**

It is most likely that insufficient blood or buffer was added to the sample well. Review the procedure and repeat the test with a new test cassette. Disregard any results that do not have a control line. If the problem persists, contact your local distributor.

***NOTE:** The intensity of the colour in the test line regions will vary depending on the titre of the antibodies present in the specimen. Any shade of colour in the test line region should be considered positive.*



Lines can appear outside of the marked IgM, IgG and C regions as a result of adding too much sample or buffer. These result from the formation of a second migratory front, or rundown of the mixture from the top of the cassette.

As long as a Control line has appeared, the presence of these extraneous lines should not affect the performance of the test, and should be ignored.

CROSS-REACTIVITY

The Biopanda COVID-19 Rapid Test has been tested with samples containing anti-Adenovirus antibody, Influenza A virus antibody, Influenza B virus antibody, anti-HCV antibody, anti-HIV antibody, anti-RSV antibody, and anti-Syphilis antibody. No cross-reactivity was observed.

SENSITIVITY AND SPECIFICITY

The Biopanda COVID-19 Rapid Test was assessed using samples from patients whose COVID-19 disease status were confirmed by PCR. To determine specificity, samples were taken from 60 patients who tested negative for COVID-19. The specificity of the IgM and IgG components are presented separately:

IgM Specificity: 96.7% (95%CI*: 88.5%-99.6%) *Confidence Interval

IgG Specificity: 98.3% (95%CI: 91.1%-99.9%)

To determine sensitivity, samples were taken from 203 hospitalised patients of varying severity of illness, who were confirmed positive by PCR. Samples were taken at a range of times from onset of symptoms. 36 samples were also taken from asymptomatic patients who did not require hospital treatment.

Days from onset when sample was taken	No. of samples	IgM positive	IgG positive	Combined positive (sensitivity)	
Asymptomatic †	36	20 (55.6%)	16 (44.4%)	25 (**69.4%**)	95%CI: 51.9%-83.7%
2-10 days	106	85 (80.2%)	21 (19.8%)	86 (**81.1%**)	95%CI: 72.4%-88.1%
11-20 days	62	55 (88.7%)	54 (87.1%)	58 (**93.5%**)	95%CI: 84.3%-98.2%
21+ days	35	15 (42.9%)	35 (100%)	35 (**100%**)	95%CI: 90.0%-100.0%

† Most of these asymptomatic patients were picked up during screening, and remained asymptomatic throughout the course of their illness.

As expected for an antibody test, the sensitivity increases depending on when the sample is taken relative to the time of infection.

LIMITATIONS OF THE TEST

1. The Biopanda COVID-19 Rapid Test is for *in vitro* diagnostic use only.
2. This test will only indicate the presence of IgM and IgG antibodies to SARS-CoV-2 in the specimen. Neither the quantitative value nor the rate of change of the titre of IgM or IgG antibodies to SARS-CoV-2 can be determined by this qualitative test.
3. A negative result does not rule out the possibility of infection. A false-negative result can occur if the test is performed when the antibody titre is below the minimum detection limit, or if the antibodies have not yet appeared at the time of sample collection.
4. The level of antibody response can vary significantly between patients. Some patients, particularly those with asymptomatic or mild illness, can develop a very weak antibody response, which will not be detectable using this test.
5. As IgM is by nature less specific than IgG, a false-positive IgM result can arise.
6. If used as a method for diagnosing COVID-19, a definitive diagnosis should not be based on results from this test alone. IgM especially should not be used as the sole criterion for diagnosis. The results must be considered with other clinical information available to the physician.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	For *in vitro* diagnostic use only
	Consult instructions for use	LOT	Lot number of kit
	Storage temperature	Σ	No. of tests in kit

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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