BZ COVID-19 IgM/IgG

In vitro diagnostic medical devices

INTENDED USE

BZ COVID-19 IgM/IgG is a rapid, qualitative and convenient immunochromatographic in vitro assay for the differential detection of IgM & IgG antibodies to SARS-COV-2 virus in human serum, plasma or whole blood samples.

SUMMARY AND PRINCILE OF THE ASSAY

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). The origin of this virus is unknown, but it has been transmitted from person to person. It spreads mainly through drops that cough and sneeze. Common symptoms include fever, cough, and breathing difficulties. In most cases, minor symptoms develop, but some also progress to pneumonia and multi-organ failure

The principle of BZ COVID -19 IgM/IgG is an antibody - capture immunochromatographic assay for the simultaneous detection and differentiation of IgM & IgG antibodies to SARS -COV-2 virus in human serum, plasma, or whole blood samples. SARS-COV-2 virus-specific antigens are conjugated to a colloidal gold and deposited on the conjugate pad. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized on two individual test lines (2 and 1) of the nitrocellulose membrane. The IgM line (2) is closer to the sample well and followed by the IgG line (1). When the sample is added, the gold-antigen conjugate is rehydrated and the SARS - COV -2 IgM and /or IgG antibodies, if any in the sample, will interact with the gold conjugated antigen.

The immunocomplex will migrate towards the test window until the test zone (1 & 2) where they will be captured by the relevant anti-human IgM (2) and/or anti-human IgG (1), forming a visible pink line, indicating positive results. If SARS-COV-2 antibodies are absent in the sample, no pink line will appear in the test lines (1 & 2), indicating a negative result.

PACKAGE CONTENTS

Test Cassette with Desiccant (25 tests)
Sample buffer 1 ea for 25 tests
Instruction for Use

OPTIONS CONTENTS

Disposable pipette (20ul) 25ea
Alcohol swab
Safety lancet

MATERIALS REQUIRED (BUT NOT PROVIDED)

Alcohol swab
Safety lancet (for fingerstick whole blood specimens)
Blood collection device (for other than fingerstick whole blood specimens) Precision pipette capable of delivering 10ul and / or 20ul with disposable tips (for other than finger stick w hole blood specimens) Gloves.
Clock or timer.

WARNINGS AND RECAUTIONS

For professional in vitro diagnostic use only.
Do not reuse.
Do not use if the product seal or its packaging is compromised.
Do not use after the expiration date shown on the pouch.
Do not mix and interchange different specimens
Wash hands thoroughly after finishing the tests.
Clean up spills thoroughly with appropriate disinfectants.
Handle all specimens as if they contain infectious agents.
Observe established precautions against microbiological hazards throughout testing procedures
Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, regional or national regulations. Keep out of children’ s reach.

SPECIMEN PREPARATION

Whole Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
In summary:

Fingerstick whole blood
Clean the area of finger to be lanced with the alcohol swab.
Allow to dry.
Without touching the puncture site, rub down the hand towards the middle or ring finger fingertip.
Puncture the skin with a sterile lancet and wipe away the first drop of blood.
Gently rub the hand from wrist to the lanced finger to form a full drop of blood over the puncture site
Collect the blood droplet using the included capillary tube.
Fingerstick whole blood must be tested immediately after collection.

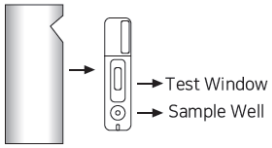
Venous whole blood:
Collect venous whole blood in a tube with anticoagulant.
Whole blood samples should be tested immediately after sample collection.

For Serum samples, collect blood in a tube without anticoagulant and allow it to clot.

For Plasma samples, collect blood in a tube containing anticoagulant. Whole blood is collected in a tube with anticoagulant (Heparin, sodium citrate and EDTA) and centrifuged supernatant is used as a plasma sample.
Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
The blood may be stored at 2℃ to 8℃ for up to three days if the tests cannot be performed immediately.
Allow sample to attain room temperature (without heating) prior to use

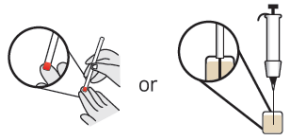
TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a flat, dry surface. The opened test kit should be better used within 4hours

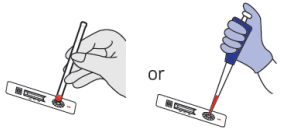


2. For fingerstick or venous whole blood:
Using a capillary tube, collect the fingerstick whole blood or whole blood (20ul) till the black line.

For serum/plasma:
Using a pipette, collect the serum/plasma (10ul).



3. Add the collected serum /plasma / whole blood to upper area (close to test window) of sample well on the test device without air bubbles (hold the capillary tube/pipette vertically and gently touch the end against the pad within the sample well for transferring).

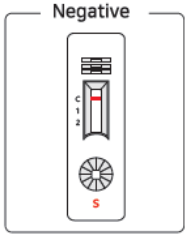


4. Wait for 20-30 seconds; add 2 drops (around 90ul) of the sample buffer to the sample well of the test device.
5. Read the results after 1 0 -1 5 minutes. Strong positive

RESULT INTERPRETATIONS

Negative

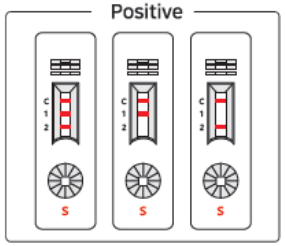
A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 infection.



Positive

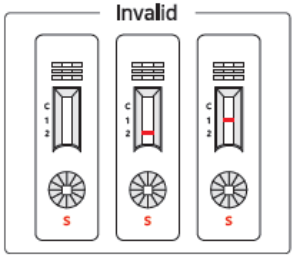
Pink colored bands appear at the control region (C) and 1 and /or 2 region.

1) IgM and IgG positive, visible bands at 2 and 1, indicating positive result for a recent SARS-COV-2 exposure.
2) IgM positive, a visible band at 2 region, indicating positive result for a current or recent SARS-COV-2 exposure.
3) IgG positive, a visible band at 1 region, indicating a positive result for a previous or latent SARS-COV-2 exposure.



Invalid

No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.



STORAGE AND STABILITY

The test device in the sealed pouch should be stored at 2-30℃.

Do not freeze the test device. The bottle containing the buffer should be stored at 2-30℃. The test device should be kept away from direct sunlight, moisture and heat. Shelf life: 18 months

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

LIMITATIONS

1. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis when serum or plasma used.
2. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
3. This test detects the presence of SARS-CoV-2 IgM /IgG in specimen and does not detect SARS - CoV-2 antigen.
4. A definitive clinical diagnosis should not be made based on the result of this test, but should only be made by a qualified physician after all clinical and laboratory findings have been

DESCRIPTION OF SYMBOL USED

Symbol	Description	Symbol	Description
REF	Catalogue number	⚠	Caution
LOT	Batch code		Manufacturer
	Use-by date		Consult instructions for use
	Upper limit of temperature		

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