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

REF BNCP-402 **English**

A rapid test for the qualitative detection of Nucleocapsid IgG/IgM antibodies and Receptor Binding Domain (RBD) IgG/IgM antibodies against to COVID-19 in human whole blood, serum or plasma specimens.

For professional in vitro diagnostic use only.

INTENDED USE

The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette is an *in vitro* diagnostic test for the qualitative detection of Nucleocapsid IgG/IgM antibodies and Receptor Binding Domain (RBD) IgG/IgM antibodies against to SARS-CoV-2 in human whole blood (venipuncture or fingerstick), serum or plasma specimens from patients suspected of SARS-COV-2 infection with severe symptoms for at least 10 days by a healthcare provider. The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation. Results from the BIOZEK COVID-19 IgG/IgM Rapid Test Cassette should not be used as the sole basis for diagnosis.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Nucleocapsid IgG/IgM antibodies and Receptor Binding Domain (RBD) IgG/IgM antibodies against to COVID-19 in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region, if the specimen contains IgG antibodies to COVID-19. A red line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to COVID-19, the conjugate-specimen complex reacts with anti-human IgM. A red line appears in IgM test line region as a result.

Therefore, if the specimen contains COVID-19 IgG antibodies, a red line will appear in IgG test line region. If the specimen contains COVID-19 IgM antibodies, a red line will appear in IgM test line region. If the specimen does not contain COVID-19 antibodies, no red line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a red line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-human IgM (220-350ng/test) and anti-human IgG (220-350ng/test) as the capture reagent, COVID-19 antigen (180-270ng/test) as the detection reagent. Goat anti-mouse IgG (180-270ng/test) is employed in the control line system.

The composition of buffer: Na_2HPO_4 5g/L, NaCl 5g/L, Casein-Na 3g/L, Proclin 300 0.02%.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. For professional in vitro diagnostic use only. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
8. The used test should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

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

The buffer should be stored at room temperature or refrigerated (2-30°C). **DO NOT FREEZE.** Unopened buffer is stable through the expiration date printed on the label. Do not use the buffer beyond the expiration date. It is suggested not to use the buffer, beyond 6 months after opening the vial.

SPECIMEN COLLECTION AND PREPARATION

- The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood Specimens**:
  - 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** or droppers provided:
    - Touch the end of the capillary tube to the blood until filled to approximately 20μL. Avoid air bubbles.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. 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 7 days, for long term storage, serum/plasma 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

MATERIALS

Materials Provided

Description	Quantity
Test Cassettes	30
Droppers	30
Buffer	2
Package Insert	1

Materials Required But Not Provided

- Specimen Collection Containers
- Lancets (for fingerstick whole blood only)
- Capillary Tubes
- Centrifuge
- Timer
- Pipette

DIRECTIONS FOR USE

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

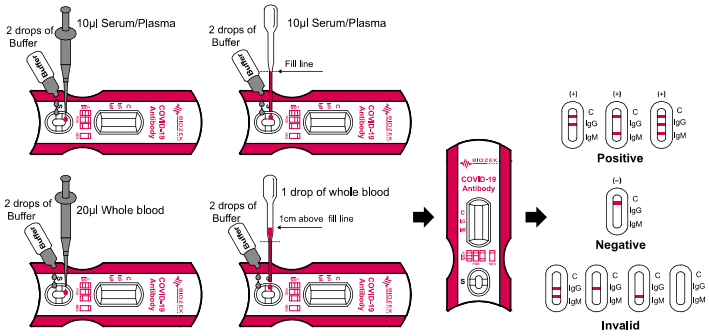
1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

   For **Serum or Plasma** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen to the **fill line** (approximately 10μL), and transfer the specimen to the specimen well (**S**), then add **2 drops of buffer** (approximately 80 μL), and start the timer.
   - To use a pipette: To transfer **10 μL** of specimen to the specimen well(**S**), then **add 2 drops of buffer** (approximately 80 μL), and start the timer.

   For **Venipuncture Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20μL) of specimen to the sample well(**S**). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
   - To use a pipette: To transfer **20 μL** of whole blood to the specimen well(**S**), then **add 2 drops of buffer** (approximately 80 μL), and start the timer.

   For **Fingerstick Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approximately 20μL) of specimen to the sample well(**S**). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
   - To use a capillary tube: Fill the capillary tube and transfer **approximately 20μL of fingerstick whole blood specimen** to the specimen well (**S**) of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

   NOTE: It is suggested not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

IgG POSITIVE:* Two red lines appear. One red line should always appear in the control line region (C) and another red line should be in the IgG line region (IgG).

IgM POSITIVE:* Two red lines appear. One red line should always appear in the control line region (C) and another red line should be in the IgM line region (IgM).

IgG and IgM POSITIVE:* Three red lines appear. One red line should always appear in the control line region (C) and another two red lines should be in the IgG line region (IgG) and IgM line region (IgM).

***NOTE:** The red color intensity in the IgG line and IgM line regions may vary depending on the concentration of COVID-19 antibodies presence in the specimen. Therefore, any shade of red color in the IgG line and IgM regions should be considered positive.

NEGATIVE: **One red line appears in the control line region (C)**. No red line appears in the IgG line region (IgG) or IgM line region (IgM).

INVALID: **No red line appears in the control region (C)**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedures and repeat the testing with a new cassette. If the problem persists, discontinue using the test kit immediately and contact BIOZEK local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A red line appearing in the control region (C) is an 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.[1]

LIMITATIONS

1. The test procedure and the interpretation of test result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of Nucleocapsid IgG/IgM antibodies and Receptor Binding Domain (RBD) IgG/IgM antibodies against to SARS-CoV-2 in whole blood, serum or plasma specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. 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.
3. The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/ Serum/Plasma) will only indicate the presence of Nucleocapsid IgG/IgM antibodies and Receptor Binding Domain (RBD) IgG/IgM antibodies against to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist, It is recommended to re-sample the patient a few days later or test with a molecular diagnostic device to rule out infection in these individuals.
6. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
7. The results can be negative, despite the specimen having the target antibodies for the reason that the antibodies, even though available, but are not in sufficient concentration to be detected by the test unit. Since there is no measuring units for such antibodies, no specific point can be provided for the limit of detection.
8. In the early infection, anti-SARS-COV-2 antibodies concentrations may be below detectable level. Therefore it is not recommended to use the test in early onset stage of COVID-19 suspected symptom.
9. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
10. Results from immunosuppressed patients should be interpreted with caution.
11. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity

Table 1: Related to disease stage IgG Result

Disease Stage		Result
BIOZEK COVID-19 IgG/IgM Rapid Test Cassette	< 10/14 days with severe symptoms	51.5%
	> 10 days with mild symptoms	85.7%
	> 10 days with severe symptoms	**98.7%**

Table 2: Related to disease stage IgM Result

Disease Stage		Result
BIOZEK COVID-19 IgG/IgM Rapid Test Cassette	< 10/14 days with severe symptoms	46.5%
	> 10 days with mild symptoms	28.6%
	> 10 days with severe symptoms	**51.7%**

Diagnostic Specificity

	Result
BIOZEK COVID-19 IgG/IgM Rapid Test Cassette	98.0%

Analytical Specificity

Cross-Reactivity

The BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, Anti-Measles, HAMA, RF, non-specific IgG, non-specific IgM, anti-EV71, anti-Parainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the BIOZEK COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride:	100 mg/dL	Ascorbic Acid:	20 mg/dL
Bilirubin:	60 mg/dL	Total cholesterol :	15 mmol/L
Hemoglobin:	1000 mg/dL		

Precision

Repeatability

Within-run precision has been determined by using 3 replicates of three specimens: a negative, a IgG positive, and a IgM positive. The negative, IgG positive, and IgM positive values were correctly identified >99% of the time.

Reproducibility

Between-run precision has been determined by 3 independent assays on the same three specimens: a negative, a IgG positive, and a IgM positive. Three different lots of the BIOZEK COVID-19 IgG/IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, IgG positive, and IgM positive specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

INDEX OF SYMBOLS

	Consult Instructions For Use	Σ 30	Contains sufficient for 30 tests		Do not use if package is damaged
IVD	*in vitro* diagnostic medical device		Manufacturer		Do not re-use
2°C 30°C	Temperature limit 2-30 C	REF	Catalogue number		

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WARNING STATEMENT

- 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 or other interference factors.
- Not for the screening of donated blood.

BIOZEK medical

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Effective Date: 2021-XX-XX