COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert

REF BCOV-502 **English**

COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasopharynx.
For professional in vitro diagnostic use only.

INTENDED USE

The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare providers.

Results are for the detection of SARS-CoV-2 Antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The BIOZEK COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel.

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. 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 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored 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 monoclonal anti-SARS-CoV-2 antibody as the capture reagent, and monoclonal anti-SARS-CoV-2 antibody as the detection reagent.

The amount of capture antibody on each test is 100-400ng and the concentration of capture antibody is 0.2-1.5mg/mL. The amount of detection antibody on each test is 80-350ng, the concentration of captured antibody is 0.1%-0.4%.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package 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 mic robiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. 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.
9. The used test cassettes and swabs should be discarded according to local regulations.
10. Humidity and temperature can adversely affect test results.
11. Viral Transport Media (VTM) may affect the test result; extracted VTM specimens for PCR testing cannot be used for the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab).

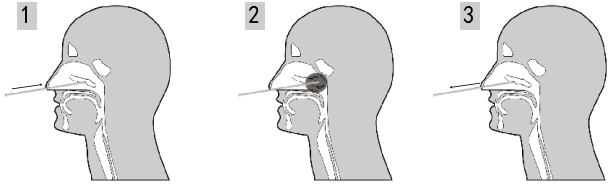
STORAGE AND STABILITY

Store the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) packaged in the sealed pouch and extraction buffer at room temperature or refrigerated (2-30°C). The test and extraction buffer are stable through the expiration date printed on the sealed pouch and buffer label. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use the kit beyond the expiration date. Do not use the kit if the package of the test cassette or buffer is damaged.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Specimen Collection

1. Insert a provided sterile swab into the nostril of the patient carefully, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx gently.
3. Withdraw the sterile swab from the nasal cavity.



Specimen Transport and Storage

1. Swab specimens should be extracted and tested as soon as possible after swab specimen collection.
2. If swab specimens cannot be extracted and tested immediately, it is highly recommended the swab specimen is placed into a dry, and tightly sealed plastic tube for transportation. The nasopharyngeal swab specimens stored in dry and sterile condition are stable for 8 hours at room temperature or 24 hours at 2-8°C.
3. Viral Transport Media (VTM) may affect the test result but if VTM is required, then the **VTM should not contain guanidinium** (e.g. Guanidine Hydrochloride and Guanidine isothiocyanate) and minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less should be considered to avoid excessive dilution of the patient's specimen. Nasopharyngeal swabs stored in VTM are stable for 8 hours at room temperature or 24 hours at 2-8°C.

MATERIALS

Materials Provided

Description		Option 1	Option 2	Option 3
Test Cassettes		30	30	30
Sterile Swabs		30	30	30
Work Station		1	1	1
Package Insert		1	1	1
Extraction Buffer (NaCl 5g/L, Tris 3g/L, Proclin300, 0.02%, BSA 5g/L, TritonX-100 2g/L, pH 8.5)	in pre-filled integrated buffer tube	30	/	/
	in disposable buffer vial	/	/	30
	in 10mL buffer bottle	/	2	/
Extraction Tubes and Tips		/	30	30

Materials Required But Not Provided

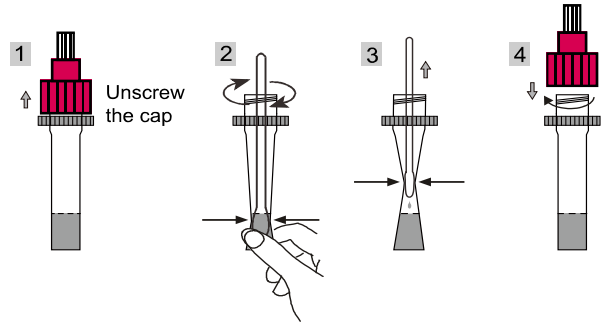
- Timer
- Specimen Transport Tubes

SPECIMEN EXTRACTION

Only the extraction buffer and/or tubes provided in this kit is to be used for specimen extraction.

Swab specimen extraction with pre-filled integrated buffer tube (Option 1)

1. Unscrew the cap of the extraction tube with extraction buffer inside.
2. Place the swab specimen into the extraction buffer, for better mixture and extraction to release antigen, rotate the swab for approximately 10 seconds while pressing the swab head against the inner wall of the tube at least 5 times to release the antigen.
3. Remove the swab while squeezing the swab head against the inner wall of the tube to get maximum solution left inside the extraction tube. Dispose of the used swab in your biohazard waste.
4. Tighten the cap onto the sample extraction tube. Use extracted sample solution as final sample for testing as soon as possible.

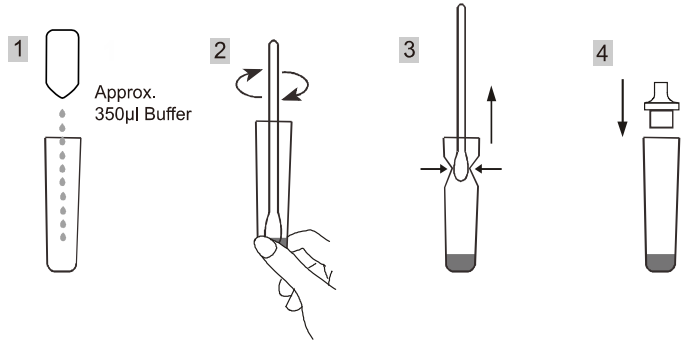


Swab specimen extraction with extraction buffer and tube separately (Option 2&3)

(Extraction buffer in 10mL buffer bottle or disposable buffer vial)

1. Place the extraction tube in the workstation and add approx. **350μL Extraction Buffer** into the extraction tube as following:
   Extraction buffer in 10mL bottle: Add **10 drops** of extraction buffer into the tube.
   Extraction buffer in disposable buffer vial: Tear to open the small disposable vial and add the **Entire Extraction Buffer** into the tube.
2. Place the swab specimen into the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inner wall of the tube 5 times to release the antigen.
3. Remove the swab while squeezing the swab head against the inner wall of the tube to get maximum solution left inside the extraction tube. Dispose of the used swab in your biohazard waste.
4. Fit the tip onto the top of the extraction tube. Use extracted sample solution as final sample for testing as soon as possible.

NOTE: For extraction buffer in 10mL bottle, it is suggested not to use the extraction buffer beyond 3 months after opening the extraction buffer bottle.



Viral Transport Media (VTM) specimen extraction

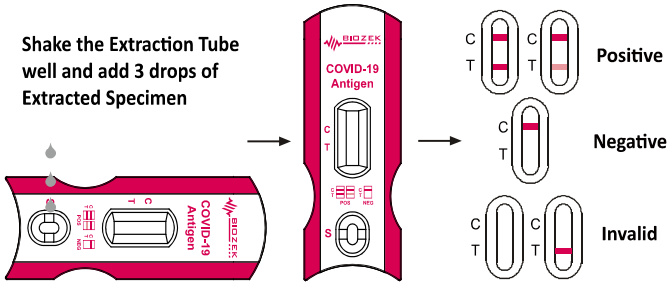
1. VTM should not contain guanidinium.
2. When using Viral Transport Media (VTM) specimen, it is important to ensure that the VTM containing the swab specimen has been balanced to room temperature (15-30°C).
3. Using a pipette to transfer 350μL VTM specimen into the specimen extraction tube with approx.350μL extraction buffer inside, shake to mix it well for extraction. Use extracted sample solution as final sample for testing as soon as possible.

NOTE: The storage of the extracted specimen is stable for 2 hours at room temperature or 24 hours at 2-8°C.

DIRECTIONS FOR USE

Allow the test, extracted sample solution and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed 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. Shake the extracted sample solution to mix it well. Invert the sample extraction tube and add **3 drops of the Extracted Sample Solution** (approx.100μL) to the specimen well(**S**) of the cassette. Start the timer.
3. Wait for the colored line(s) to appear and read the result at **15 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of COVID-19 antigens in the sample.

***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of COVID-19 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear in the control region (C). 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local Biozek products distributor.

QUALITY CONTROL

Internal Quality Control

An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

Positive and negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.[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 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection and processing are critical. Failure to follow the procedure may give inaccurate results.
2. The performance of the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) should be evaluated following the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result; extracted VTM specimens for PCR testing cannot be used for this cassette.
3. The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal 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 SARS-CoV-2 antigens can be determined by this qualitative test.
4. The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
5. The results obtained from the testing should be considered with other clinical findings from other laboratory tests and evaluations.
6. 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 and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following condition: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
8. 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.
9. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
11. Positive results of COVID-19 may be obtained due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

EXPECTED VALUES

The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is not less than 95%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been evaluated with swab specimens obtained from symptomatic patients tested by the Regional Health Offices. RT-PCR is used as the reference method for the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated positive results. Specimens were considered negative if RT-PCR indicated negative results.

Nasopharyngeal Swab Specimens

BIOZEK COVID-19 Antigen Rapid Test Cassette		RT-PCR		Total Results
		Positive	Negative	
COVID-19 Antigen	Positive	25	0	25
	Negative	5*	42	47
Total Results		30	42	72
Diagnostic Sensitivity		93.3%**		
Diagnostic Specificity		100%		

*3 out of 5 samples tested weak positive when the transport medium was used for testing due to dilution of the material on the swab into transport medium.

**Combination of the results obtained with transport medium and manufacturer extraction buffer

Specificity Testing with Various Viral Strains

The BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been tested with the following viral strains. No discernible line at either of the test-line regions has been observed at the listed concentrations:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 TCID50/mL
Adenovirus type 7	1.58 x 10^5 TCID50/mL
Human Coronavirus OC43	2.45 x 10^6 LD50/mL
Influenza A H1N1	3.16 x 10^5 TCID50/mL
Influenza A H3N2	1 x 10^5 TCID50/mL
Influenza B	3.16 x 10^6 TCID50/mL
Human Rhinovirus 2	2.81 x 10^4 TCID50/mL
Human Rhinovirus 14	1.58 x 10^6 TCID50/mL
Human Rhinovirus 16	8.89 x 10^6 TCID50/mL
Measles	1.58 x 10^4 TCID50/mL
Mumps	1.58 x 10^4 TCID50/mL
Parainfluenza Virus 2	1.58 x 10^7 TCID50/mL
Parainfluenza Virus 3	1.58 x 10^8 TCID50/mL
Respiratory syncytial virus	8.89 x 10^4 TCID50/mL

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Limit of Detection

Limit of detection (LOD) is evaluated by diluting a recombine COVID-19 to the following concentrations: 100ng/mL, 10ng/mL, 1ng/mL, 500pg/mL, 200pg/mL, 100pg/mL and 50pg/mL. Limit of detection for the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is 100pg/mL for recombine COVID-19 protein.

Precision

Intra-Assay and Inter-Assay

Within-run and Between-run precision have been determined by using three specimens of COVID-19 standard control. Three different lots of the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) have been tested with negative SARS-COV-2 antigen weak and SARS-COV-2 antigen strong. Ten replicates of each level have been tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-Reactivity

The following organisms have been tested at 1.0 x10^8 org/mL and all found to be negative when tested with the BIOZEK COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab):

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Nesseria subllava	*Streptococcus sp group F*

Interfering Substance

Following interfering substances are spiked with negative and SARS-COV-2 weak antigen positive specimens. No substances show any interference.

Analytes	Concentration
Whole Blood	20μL/mL
Mucin	50μL/mL
Budesonide Nasal Spray	200μL/mL
Dexamethasone	0.8mg/mL
Flunisolide	6.8ng/mL
Mupirocin	12mg/mL
Oxymetazoline	0.6mg/mL
Phenylephrine	12mg/mL
Rebetol	4.5μg/mL
Relenza	282ng/mL
Tamiflu	1.1μg/mL
Tobryamycin	2.43mg/mL

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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Number: 199016701-A
Effective Date: 2020-10-6