BIOSYNEX® COVID-19 Ag+ BSS

Ref : SW40010 – SW40010F

RAPID DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGENS IN NASOPHARYNGEAL SWABS.
For professional *in vitro* diagnostic use only.

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1 I INTENDED USE

BIOSYNEX® COVID-19 Ag+ BSS test is a rapid *in vitro* lateral flow assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.

2 I 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.

3 I PRINCIPLE OF THE TEST

The BIOSYNEX® COVID-19 Ag+ BSS test is a qualitative membrane based immunoassay that uses highly sensitive monoclonal antibodies to detect the nucleocapsid protein of SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip contains colloidal-gold conjugated particles with monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2. The secondary antibodies for nucleocapsid protein of SARS-CoV-2 are coated on the membrane. When the sample is added to the sample well, the conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result.
An internal procedural control is included in the assay, in the form of a colored line appearing in the Control (C) area, indicating that the proper volume of sample has been added and membrane wicking has occurred.

4 I KIT CONTENTS

Materials Provided

- Test cassettes
- Extraction buffers
- Sterile Swabs (CE 0197)
- Package insert
- Extraction tubes
- Nozzles
- Workstation

Materials required but not provided

- Timer

5 I PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not interchange or mix components from different kit lots.
- When collecting a nasopharyngeal swab sample, use the nasopharyngeal swab supplied in the kit.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- The test device should remain in the sealed pouch until use.
- Swabs, tubes and test device are for single use only.

6 I STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- Do not freeze any of the test kit components.
- Do not use test device and reagents after expiration date.
- Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

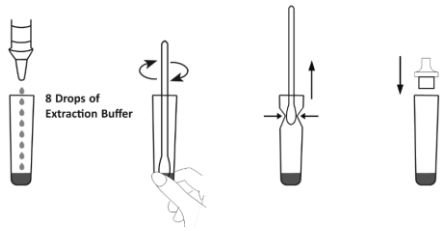
7 I SAMPLE COLLECTION AND STORAGE

Use the nasopharyngeal swab supplied in the kit:

1. Carefully insert the swab horizontally into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.
4. Specimens should be tested as soon as possible after collection.

8 I SAMPLE PREPARATION PROCEDURE

1. Insert the extraction tube into the workstation. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2. Hold the extraction buffer bottle upside down vertically, then squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 8 drops (approx. 300 µL) of the extraction buffer into the extraction tube.
3. Insert the swab into the extraction tube.
4. Rotate the swab for approximatively 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
5. Remove the swab while squeezing the head of the swab against the inside of the extraction tube to expel as much liquid as possible from the swab. The extracted solution will be used as test sample.
6. Discard the swab in accordance with your biohazard waste disposal protocol.



9 I SPECIMEN TRANSPORT AND STORAGE

Do not return the nasopharyngeal swab to the original paper packaging.
For best performance, direct nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible:

- the nasopharyngeal swab can be stored at room temperature in an airtight container for not more than 24 hours.
- The extracted sample in the extraction tube can be stored at room temperature for 24 hours or at 2-8°C for 2 days.

10 I TEST PROCEDURE

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

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. Fit the nozzle on top of the sample extraction tube.
3. Hold the sample extraction tube upside down, and add 3 drops (approx. 80 µL) of test sample into the sample well (S) of the test cassette.
4. Start the timer and wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 15 minutes.

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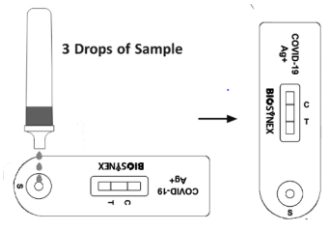

11 I INTERPRETATION OF RESULTS

POSITIVE: *
Two lines appear. One colored line appears in the controle line region (C) and another colored line appears in the test line region (T). A positive result indicates that SARS-CoV-2 antigen was detected in the specimen.

**NOTE: The intensity of color in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen*

NEGATIVE:
One colored line appears in the control line region (C). A negative result indicated that SARS-CoV-2 antigen is not present in the specimen or in present below the detectable level of the test.

INVALID:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure. Review the procedure and repeat the test with a new cassette.

12 IQUALITY CONTROL

Internal controls

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls

Control standards are not supplied with this test. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

13 I LIMITATIONS

1. The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. BIOSYNEX® COVID-19 Ag+ BSS only indicates the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
2. BIOSYNEX® COVID-19 Ag+ BSS is for professional *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigen is nasopharyngeal swab. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined with this qualitative test.
3. The accuracy of the test depends on the quality of the swab sample. False negative results may result from improper sample collection of storage.
4. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
5. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
6. A negative result does 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.
7. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
8. Positive test results do not rule out co-infections with other pathogens.
9. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
10. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.

14 I PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The BIOSYNEX® COVID-19 Ag+ BSS has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the BIOSYNEX® COVID-19 Ag+ BSS. Specimens were considered positive if PCR indicated a positive result.

		PCR		Total Results
		Positive	Negative	
BIOSYNEX COVID-19 Ag+ BSS	Positive	57	0	57
	Negative	2	499	501
Total Results		59	499	558

Sensitivity: 96.6% (95%CI*: 88.3-99.6%)
Specificity: 100% (95%CI*: 99.3%-100%)
Accuracy: 99.6% (95%CI*: 98,7-100%)

*Confidence Intervals

Cross Reactivity

The BIOSYNEX® COVID-19 Ag+ BSS has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type 1, Parainfluenza Virus Type 2, Parainfluenza Virus Type 3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, *Bordetella pertussis*, *Haemophilus parainfluenzae*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Neisseria meningitides*, *Streptococcus* sp. group A, *Streptococcus* sp. group B, *Streptococcus* sp. group C, *Candida albicans*, Human Metapneumovirus (hMPV), *Legionella pneumophila*, *Mycobacterium tuberculosis*, *Mycoplasma pneumoniae*, *Pneumocystis jirovecii*(PJP)-S *cerevisiae* Recombinant, *Pseudomonas aeruginosa*, *Staphylococcus epidermis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus salivarius*, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens. The results showed no cross reactivity.

Limit of detection

The detection limit (LOD) of BIOSYNEX® COVID-19 Ag+ BSS was established using limiting dilutions of a viral sample inactivated. The material (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15×10^7 $TCID_{50}$/mL. The Estimated LOD is 750 $TCID_{50}$/mL.

Interfering Substances

No positive or negative interference has been demonstrated with the following substances: Ambroxol Hydrochloriden, Nasal antibioitic (Mupirocin Ointment), Mometasone furoate nasal spray, Oxymetazoline Hydrochloride Spray, Nin Jiom Pei Pa Kao cough syrup, Beclomethasone Dipropionate Nasal Aerosol, Dextromethorphan Hydrobromide Oral Solution, Triamcinolone Acetonide Nasal Spray, MucosolvanAmbroxol Hydrochloride Oral Solution, Azelastine Hydrochloride Nasal Spray, Nasal cleansing solution, NaCl, Propionate Nasal Spray, Hyland's 4 Kids Cold Cough Liquid Safe Natural Relief, Physiological Seawater Nasal Spray, Durham's Canker-Rid, Tobramycin Eye Drops, Listerine mouthwash, Whole blood (4%), Scope mouthwash, Mucin.

SYMBOLS

	Attention, see instruction for use	Σ	Tests per kit	REF	Catalog number
IVD	For *in vitro* diagnostic use only	2°c 30°c	Store between 2-30°C		Do not reuse
	Do not use if package is damaged	LOT	Lot number		Expiry
	Manufacturer	DIL	Buffer		

IFU_SW40010_SW40010F_EN_V01202011R03
Date of revision: 11/2020

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