BIOSYNEX COVID-19 Ag BSS

Ref : SW40006

EN

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

CE

1 I INTENDED USE

BIOSYNEX COVID-19 Ag BSS test is a rapid *in vitro* immunochromatographic 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 immunassay 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
- Buffer
- Sterile Swabs (CE 0197)
- Package insert
- Extraction tubes
- Nozzles
- Workstation

Materials required but not provided

- Clock, timer or stopwatch

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.

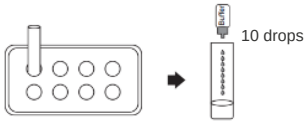
7 I SAMPLE COLLECTION AND STORAGE

Use the nasopharyngeal swab supplied in the kit:

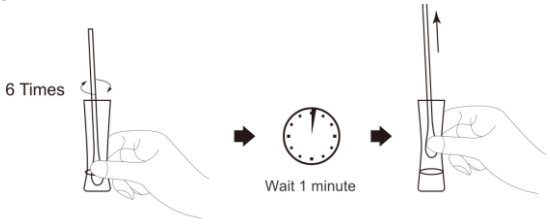
1. Carefully insert the swab horizontally into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal 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. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.



3. Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times to fully extract the sample from the swab. Remove the swab. The extracted solution will be used as test sample.



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, it is recommended that the nasopharyngeal swab is placed in a clean, unused tube labeled with the patient information and sealed tightly at room temperature (15-30°C) for up to 1 hour following sample collection. If greater than a 1 hour delay occurs between sample collection and testing, dispose of the sample. A new sample must be collected for testing.

10 ITEST 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. Insert the nozzle into the sample extraction tube.
3. Reverse the sample extraction tube, and add 4 drops (about 100 µL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for the colored band(s) to appear. The result should be read at 15

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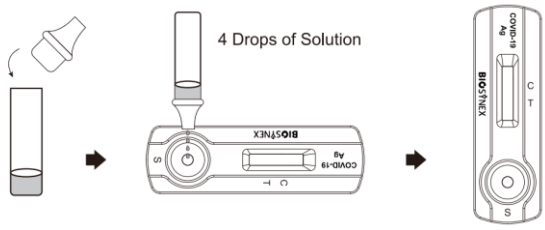
minutes. Do not interpret the result after 20 minutes.



11 I INTERPRETATION OF RESULTS

POSITIVE:

The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.

NEGATIVE:

The presence of only control line (C) within the result window indicates a negative result.

INVALID:

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. 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.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

12 I QUALITY CONTROL

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. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the 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 test is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the BIOSYNEX COVID-19 Ag BSS test depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
3. 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.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not rule out co-infections with other pathogens.
6. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

14 I PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The BIOSYNEX COVID-19 Ag BSS test has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method.
The study included 248 samples (103 confirmed positive and 145 negative samples).

		PCR		
		Positive	Negative	Total Results
BIOSYNEX COVID-19 Ag BSS	Positive	99	0	99
	Negative	4	145	149
Total Results		103	145	248

Sensitivity: 96% (95%CI*: 93,6-98,4%)
Specificity: 100% (95%CI*: 100%-100%)
Accuracy: 98% (95%CI*: 96,4-99,6%)

*Confidence Intervals

The sensitivity of BIOSYNEX COVID-19 Ag BSS test has also been calculated based on the Ct of the positive clinical specimens.

		PCR Positive			PCR Negative	Total Results
		0≤Ct≤20	21≤Ct≤30	31≤Ct≤35		
BIOSYNEX COVID-19 Ag BSS	Positive	24	45	30	0	99
	Negative	1	1	2	145	149
Total Results		25	46	32	145	248

Sensitivity 0≤Ct≤20: 96%
Sensitivity 21≤Ct≤30: 98%
Sensitivity 31≤Ct≤35: 94%

Cross Reactivity

No crossreactivity was observed with specimens positive for human coronavirus (229E, OC43, NL63 & HKU1), influenza A & B virus, RSV A & B, Adenovirus, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, *Legionella pneumophila* and Parainfluenza (1-4).

Limit of detection

The limit of detection of the assay is 1.15 x 10^2 $TCID_{50}$/mL (Median Tissue Culture Infectious Dose) obtained from an inactivated viral sample by heating at 65°C for 30 minutes.

Interfering Substances

No positive or negative interference has been demonstrated with the following substances: human blood (with EDTA anticoagulant), Mucin, Antiviral Drugs (Oseltamivir phosphate, Ribavirin), Antibiotics (Levofloxacin, Azithromycin, Meropenem, Tobramycin), nasal sprays or drops (Phenylephrine, Oxymetazoline, Alkalol nasal wash, 0. 9% NaCl), nasal corticosteroids (Beclomethasone, Hexadecadrol, Flunisolide, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone propionate).

SYMBOLS

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

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