BIOSYNEX

BIOSYNEX COVID-19 Ag BSS

Ref : SW40006

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RAPID DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGENS IN NASOPHARYNGEAL OR NASAL 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 (N) protein antigen of SARS-CoV-2 in nasopharyngeal or nasal swab specimens. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections.

2 I SUMMARY

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 (N) of SARS-CoV-2 in nasopharyngeal (NP) or nasal (NS) swab specimens. 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 (N) 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 tubes
Buffer	Nozzles
Sterile Swabs (CE 0197)	Workstation
Package insert	

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. Change gloves before each new sample collection/test.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Inadequate humidity and temperature conditions may adversely affect the results. Samples can be collected outside. However, the test procedure and result interpretation must be performed in a place free of excessive humidity and at a temperature between 15°C and 30°C.
- 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.
- When collecting a nasopharyngeal or nasal swab sample, use the 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. Do not use if the pouch is damaged.
- Swabs, tubes and test device are for single use only.
- To reduce the risk of hand or airborne contamination:
  a. Change gloves before collecting a new sample and performing a new test
  b. Do not take out the components from the kit after collecting a sample without removing gloves and disinfecting your hands
  c. Perform the sample collection and the test procedure in well-ventilated rooms.

6 I STORAGE AND STABILITY

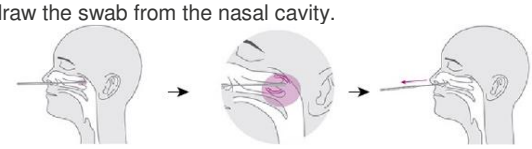
- The kit can be stored at room temperature or refrigerated (2-30°C).
- Do not freeze any of the test kit components.
- Do not use test device and reagents after expiration date.
- Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

7 I SAMPLE COLLECTION AND STORAGE

Use the swab supplied in the kit.
If necessary, let the patient blow his/her nose.
Only the sample collection can be performed outdoors. The test procedure should be performed indoors at 15-30°C.
Specimens should be tested as soon as possible after collection

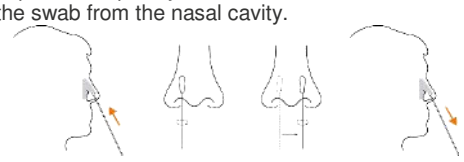
Nasopharyngeal swab specimen collection

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.



Nasal swab specimen collection

1. Carefully insert the swab into one nostril, up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that the sample is adequately collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity.



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, especially in the case of viscous samples. Remove the swab. The extracted solution will be used as the test sample. It can be stored for up to 30 minutes at room temperature (15-30°C).

9 I SPECIMEN TRANSPORT AND STORAGE

Do not return the swab to the original paper packaging.
For best performance, direct NP or NS swabs should be tested as soon as possible after collection. If immediate testing is not possible, it is recommended that the NP or NS 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 or stored 3 hours at 2-8°C. If the storage conditions between sample collection and testing are not respected, dispose of the sample. A new sample must be collected for testing.

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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. 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 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. It is recommended to perform a new test.

NOTES:

1. The intensity of color in the test (T) and control (C) lines regions may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test (T) and control (C) lines regions should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. The most likely reasons for control line failure are: insufficient sample volume or an overly viscous sample, incorrect procedural techniques (incorrect swab extraction, temperature and humidity conditions for performing the test), the use of tests that have been open for more than one hour or are expired.

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. Validated control standards are not supplied with this test but are available separately under the following references: SW40009 (positive control swab) and 6060001 (negative control swab). These are the only controls that can be used with the test. It is recommended that positive and negative controls are 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.
7. The antigen detected by the test is the N protein. The different variants of the virus described so far in some countries (United Kingdom, South Africa, Brazil ...) concern mutations of the Spike protein and therefore have no impact on the functionality of the test.
8. The use of specimens stored in transport medium or saline may adversely affect the results. Use only freshly collected samples using the provided swabs.

14 I PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

Nasopharyngeal swab

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 (NP)	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 (NP)	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%

Nasal swab

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 249 samples (109 confirmed positive and 140 negative samples).

		PCR		
		Positive	Negative	Total Results
BIOSYNEX COVID-19 Ag BSS (NS)	Positive	106	0	106
	Negative	3	140	143
Total Results		109	140	249

Sensitivity: 97,2% (95%CI*: 92,1-99,4%)
Specificity: 100% (95%CI*: 100%-100%)
Accuracy: 98,8% (95%CI*: 96,5-99,8%)

*Confidence Intervals

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	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
	Manufacturer	LOT	Lot number		Expiry
DIL	Buffer				

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