BIOSYNEX

Ref : SW40010

BIOSYNEX COVID-19 Ag+ BSS

EN

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* lateral flow assay for the qualitative detection of nucleocapsid (N) protein antigen from SARS-CoV-2 in nasopharyngeal (NP) or nasal* (NS) 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 immunoassay that uses highly sensitive monoclonal antibodies to detect the nucleocapsid (N) protein of SARS-CoV-2 in nasopharyngeal (NP) or nasal* (NS) swab. The test strip contains conjugated particles with monoclonal antibodies against the N protein of SARS-CoV-2. The secondary antibodies for N 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
- Prefilled extraction buffers
- Sterile Swabs (CE 0197 or CE 0123)
- Nozzles
- Workstation
- Package insert

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. 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.
- Do not interchange or mix components from different kit lots.
- When collecting a 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

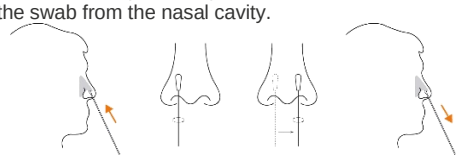
Use the swab supplied in the kit.
If necessary, let the patient blow his/her nose.
Only the sample collection can be performed outdoors. The test procedure should be performed indoors at 15-30°C.
Specimens should be tested as soon as possible after collection.

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 2-3 cm until resistance is met.
2. Roll the head of the swab at least 5 times along the nasal wall.
3. Using the same swab, repeat this process for the other nostril.
4. Withdraw the swab from the nasal cavity.



8 I SAMPLE PREPARATION PROCEDURE

1. Insert the prefilled extraction tube into the workstation. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2. Open the aluminum foil of the prefilled tube.
3. Insert the swab into the prefilled 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, especially in the case of viscous samples.
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.
6. Discard the swab in accordance with your biohazard waste disposal protocol.

9 I SPECIMEN TRANSPORT AND STORAGE

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

- the 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 4 drops (approx. 100 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.

11 I INTERPRETATION OF RESULTS

POSITIVE:**
Two lines appear. One colored line appears in the control 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 (T) and control line (C) regions may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test line (T) and control line (C) regions should be considered positive.*

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 is present below the detectable level of the test.

BIOSYNEX SWISS SA
Rue de Romont 29-31
CH-1700 FRIBOURG - Suisse
Tel CH : 026 552 51 52
Fax : +33 3 88 78 76 78
Tel FR : +33 3 88 78 78 87
client.pro@biosynex.com
Tel clients Export : +33 3 88 77 57 52
export@biosynex.com
www.biosynex.com

INVALID:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Review the procedure and repeat the test with a new cassette.

The most likely reasons for control line failure are: insufficient specimen volume, overly viscous specimen, incorrect operating procedure (incorrect swab extraction, temperature and humidity conditions for performing the test) or the use of tests that have been open for more than one hour or are expired.

12 I QUALITY 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. but are available separately under the following references: SW40012 (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 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 or 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.
11. 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.
12. The extraction buffer has the ability to kill the virus, but it cannot inactivate 100% of the virus.

14 I PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

Nasopharyngeal swab NP

The BIOSYNEX COVID-19 Ag+ BSS test has been evaluated with specimens obtained from patients. RT-PCR was used as the reference method. The study included 662 samples.

		PCR		
		Positive	Negative	Total Results
BIOSYNEX COVID-19 Ag+ BSS (NP)	Positive	77	0	77
	Negative	2	583	585
Total Results		79	583	662

Sensitivity: 97.5% (95%CI*: 91.1-99.7%) *Confidence Intervals
Specificity: 100% (95%CI*: 99.4-100%)
Accuracy: 99.7% (95%CI*: 98.9-100%)

The sensitivity of the 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≤29	30≤Ct≤35		
BIOSYNEX COVID-19 Ag+ BSS (NP)	Positive	22	45	10	0	77
	Negative	0	0	2	583	585
Total Results		22	45	12	583	662

Sensitivity 0≤Ct≤20: 100% (95%CI*: 84.6-100%) *Confidence Intervals
Sensitivity 21≤Ct≤29: 100% (95%CI*: 92.1-100%)
Sensitivity 30≤Ct≤35: 83.3% (95%CI*: 51.6-97.9%)

Nasal swab NS

The BIOSYNEX COVID-19 Ag+ BSS test has been evaluated with specimens obtained from patients. RT-PCR was used as the reference method. The study included 547 samples.

		PCR		
		Positive	Negative	Total Results
BIOSYNEX COVID-19 Ag+ BSS (NS)	Positive	124	1	125
	Negative	6	416	422
Total Results		130	417	547

Sensitivity: 95,4% (95%CI*: 90,2-98,3%) *Confidence Intervals
Specificity: 99,8% (95%CI*: 98,7-100%)
Accuracy: 98,7% (95%CI*: 97,4-99,5%)

Cross Reactivity

The BIOSYNEX COVID-19 Ag+ BSS has been tested for Influenza A & B viruses, Adenovirus, Coxsackie virus, Parainfluenza Virus (Types 1-4a), Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, *Bordetella pertussis*, *Haemophilus parainfluenzae*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Neisseria meningitides*, *Streptococcus* sp. (groups A, B, 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, OC43, NL63), MERS-CoV 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 x 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
	Manufacturer	LOT	Lot number		Expiry
DIL	Buffer				

IFU_SW40010_EN_V06202103R01
Date of revision: 03/2021

***The procedure with nasal (NS) swab specimen is not allowed in France. There is no reimbursement for collecting nasal samples or testing nasal samples.**

BIOSYNEX SWISS SA
Rue de Romont 29-31
CH-1700 FRIBOURG – Suisse
Tel CH : 026 552 51 52
Fax : +33 3 88 78 76 78
Tel FR : +33 3 88 78 78 87
client.pro@biosynex.com
Tel clients Export : +33 3 88 77 57 52
export@biosynex.com
www.biosynex.com