Content

I. Device Description

1. Product assignment / variations / package sizes / article no. / Summary of performance data

a. General description of test

	SW40006	SW40006_BSX	859256/859257/859258/859261/ 859262/859263
Medical product type:	In vitro diagnostic (IVD) medical device		
Test type:	Rapid visual immunoassay		
Detection of:	Nucleocapsid protein antigen from SARS-CoV-2		
Indication:	Aid in the diagnosis of SARS-CoV-2 infection		This self-testing kit allows to identify if the tested person is infected by the virus which causes COVID-19.
Detection in:	Nasopharyngeal or nasal swab* * Exception in France: only Nasopharyngeal swabs are allowed; Utilization of nasal specimen is not claimed in the French IFU.		Nasal swab
Usage by:	Professionals		Lay user (self-testing)
Determinations per test:	Single use		
Product name and reference :	BIOSYNEX COVID-19 Ag BSS REF.: SW40006	BIOSYNEX COVID - 19 Ag BSX REF.:SW40006_BSX	BIOSYNEX AUTOTEST Antigénique COVID-19 Ag REF.: 859256/ 859257/859258/ 859261/ 859262/ 859263
	Please refer to DoC 1B_ Overview of variants		

b. Short summary of test characteristics (performance data, stability ...)

Analytical sensitivity	1.15 x 10^2 $TCID_{50}$/mL
Analytical specificity	• The interference study showed no interferences between the test and the following substances : Human blood (EDTA anticoagulated), Mucin, Oseltamivir phosphate, Ribavirin, Levofloxacin, Azithromycin,

	Meropenem, Tobramycin, Phenylephrine, Oxymetazoline, 0.9% sodium chloride, A natural soothing ALKALOL (nasal wash), Beclomethasone, Hexadecadrol, Flunisolide, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone propionate • The cross-reaction study showed no cross reaction with the following pathogens : Respiratory syncytial virus Type A, Respiratory syncytial virus Type B, Novel influenza A H1N1 virus (2019), Seasonal influenza A H1N1 virus, Influenza A H3N2 virus, Influenza A H5N1 virus, Influenza B Yamagata, Influenza B Victoria, Rhinovirus, Adenovirus 3, Adenovirus 7, EV-A71, Mycobacterium tuberculosis, Mumps virus, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Haemophilus influenza, Streptococcus pyogenes, Streptococcus pneumoniae, Candida albicans, Bordetella pertussis, Mycoplasma pneumonia, Chlamydia pneumonia, Legionella pneumophila, Pooled human nasal wash
Stability	The shelf life applied to: - the test cassette is 23 months from the date of manufacture - the buffer is 30 months

2. Intended use/user

VARIANTS FOR PROFESSIONAL USERS:

BIOSYNEX COVID-19 Ag BSS / BIOSYNEX® COVID-19 Ag BSX test is a rapid in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen of SARS-CoV-2 in nasopharyngeal or nasal swab specimens*. It is intended as an aid in the rapid diagnosis of SARS-CoV-2 infections.

For professional in vitro diagnostic use only.

REF. SW40006_BSX is for automated readout with the BSX READER (REF. 5060029).

VARIANT FOR LAYMEN USERS:

BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag is intended for the self-diagnosis of lay users. This self-testing kit allows to identify if the tested person is infected by the virus which causes COVID-19.

3. Principle of the assay method

The BIOSYNEX COVID-19 Ag BSS / BIOSYNEX® COVID-19 Ag BSX/ BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag 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 or nasal (NS) 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 specimen has been added and membrane wicking has occurred.

4. Procedure

VARIANTS FOR PROFESSIONAL USERS:

A. SPECIMEN COLLECTION

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.

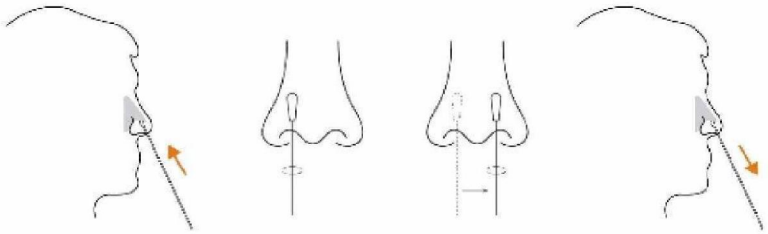
Nasopharyngeal swab specimen collection:

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.



B. 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.

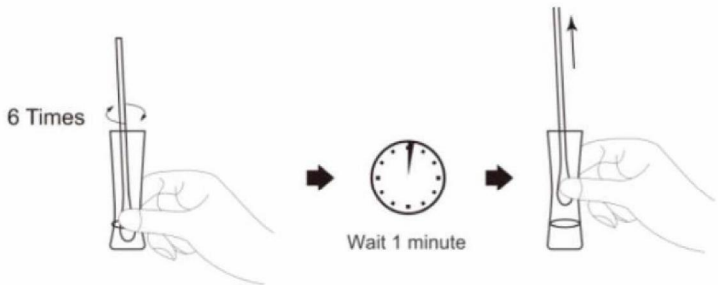
2. Open the aluminum foil of the prefilled extraction tube.

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



C. SPECIMEN 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.

D. TEST PROCEDURE

VARIANTS FOR PROFESSIONAL USERS

FOR REF. SW40006:

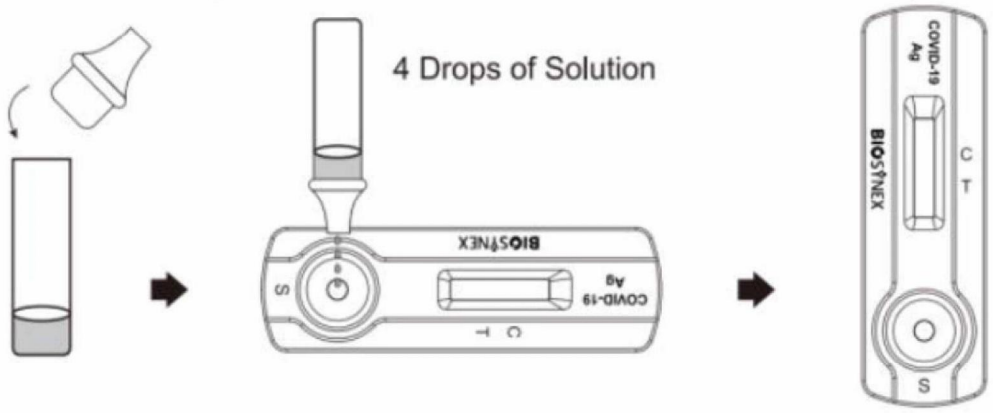
Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

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.



FOR REF. SW40006_BSX:

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

2. Turn on the BSX READER® by pressing and holding the power button. Wait for the instrument to start up. For complete instructions on how to use the BSX READER®, refer to the User Manual of the READER®.

3. Install the method "COVID-19_AG" in the BSX READER® using the Method Card provided. Please, refer to the BSX READER® user manual for complete instructions.

Note: It is recommended to install the supplied Method Card with each new kit to ensure that the latest version of the method is used.

4. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface

Warning: Do not discard the foil pouch, which is necessary to identify the test cassette on the reader.

5. Insert the nozzle into the sample extraction tube.

6. 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.

7. **Reading with manual incubation:**

Allow the cassette to incubate for 15 minutes on the bench at room temperature.
Read the result at 15 minutes using the BSX READER®:

- Select "START NEW TEST" on the home screen.
- Select the "COVID-19_AG" method on the display.
- Scan the QR-CODE printed on the test pouch using the barcode reader
- Select "YES" to skip the cassette incubation step.
- Enter the sample/patient ID, either manually using the GUI (Graphical User Interface) keypad or by scanning the sample/patient barcode.
- Pressing "CONTINUE" will display the final screen before the measurement begins and prompt the user to insert the test cassette into the drawer. Open the drawer and insert the test cassette. Ensure that the test cassette is correctly oriented in the space provided.
- Close the drawer and immediately select "START MEASUREMENT".
- The measurement then starts without an incubation step and the result is read by the Reader.
- After interpretation the test result is displayed on the screen.
- Do not read a result more than 20 minutes after placing the sample in the cassette.

OR

Reading with automatic incubation:

- Select "START NEW TEST" on the home screen.
- Select the "COVID-19_AG" method on the display.
- Scan the QR-CODE printed on the test pouch using the barcode reader.
- Select "NO" on the GUI to submit the cassette to the applicable incubation step.
- Enter the sample/patient ID, either manually using the GUI keypad or by scanning the sample/patient barcode.
- Pressing "CONTINUE" displays the final screen before the measurement begins and prompts the user to insert the test cassette into the drawer.

- Open the drawer and insert the test cassette. Ensure that the test cassette is correctly oriented in the space provided.
- Close the drawer and immediately select "START MEASUREMENT".
- The measurement then starts with an incubation step and the result is read by the reader.
- After interpretation the test result is displayed on the screen.
- Do not read a result more than 20 minutes after placing the sample in the cassette.

8. After reading, remove the test cassette from the drawer and discard according to Good Laboratory Practices and local regulations.
Do not forget to LOG OUT and/or TURN OFF the BSX READER® after use.

VARIANTS FOR LAYMEN USERS

5. Description of kit components

The kits contains the following components:

REF. SW40006:

- 25 Test cassettes
- 25 Sterile swabs
- 25 pre-filled diluent tubes
- 25 Nozzles
- 1 Workstation
- 1 Package insert

REF. SW40006_BSX:

- BIOSYNEX COVID-19 Ag BSS test kit (ref. SW40006) containing:
  - 25 Test cassettes
  - 25 Sterile swabs
  - 25 pre-filled diluent tubes
  - 25 Nozzles
  - 1 Workstation
- 1 Package insert
- 1 Method Card "COVID-19_AG" for use with the BSX READER®

REF. 859256/859257/859258:

- 1 test cassette
- 1 pre-filled diluent tube
- 1 dropper teat
- 1 dropper stopper
- 1 sterile swab
- 1 package insert
-

REF. 859261/859262/859263

- 5 test cassettes
- 5 pre-filled diluent tubes
- 5 dropper teats
- 5 dropper stoppers
- 5 sterile swabs
- 1 package insert

6. Description of various configurations variant of the IVD

Refer to DOC 1B of the Technical File

7. Description of accessories used in combination with the IVD medical Device

REF. SW40006/859256/859257/859258/859261/859262/859263: Not applicable since these IVDs are not used in combination with any accessories.

REF. SW40006_BSX: this IVD is intended to be used in conjunction with the BSX READER, which is a reader device for the analysis of lateral flow immuno-tests by optical read-out.
BSX READER reference: 5060029
Refer to the technical file of the BSX READER for details.

8. For automated assays: description of the appropriate instrumentation characteristics or dedicated instrumentation

This is not applicable since this IVD is a rapid diagnostic test based on visual interpretation (or with the aid of a reader), and not an automated one.

9. Description of any software to be used with the medical device

Not applicable since the test does not incorporate any software.

10. Summary of clinical background

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..

11. Limitations of the procedure

VARIANTS FOR PROFESSIONAL USERS:

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

nonviable 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.

VARIANTS FOR LAYMEN USERS:

• This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2 virus. The Biosynex COVID-19 Ag Antigenic Self-testing Kit can detect both the viable and the non-viable SARS-CoV-2 virus.

• The test must be used to detect the antigen of the SARS-CoV-2 virus, using a nasal swab. Neither the quantitative value nor the rate of increase for the concentration of the SARS-CoV-2 virus can be determined using this qualitative test.

• The accuracy of the test depends on the quality of the swab sample. False negative results may be given following poor sampling, or following poor sample storage.

• Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.

• If the result of the test is negative, yet clinical symptoms persist, it is advised that you carry out additional tests using other clinical methods. A negative result at no time rules out the presence of antigens of the SARS-CoV-2 virus in the sample, as they may be present but at a level inferior to the minimum detection level of the test, or if the sample has been collected incorrectly.

• A negative result does not rule out infection by the SARS-CoV-2 virus, particularly in people who have come into contact with the virus.
Follow-up tests with molecular diagnostics should be scheduled to rule out infection in these people.

• This test is not a substitute for a medical consultation, or for the result of a biological analysis carried out in a medical analysis laboratory.

• Positive test results do not exclude the possibility of co-infections of other pathogens.

• Positive test results do not allow for differentiating between the SARS-CoV virus and the SARS-CoV-2 virus.

• The antigen detected by the test is the N protein. The different variants of the virus reported, at the time of publishing, in certain countries (United Kingdom, South Africa, Brazil, etc.) concern mutations of the Spike protein and therefore have no impact on the functionality of the test.

• Erroneous errors may be obtained:

- If the test is not used in line with the instructions provided,
- If the aluminium sachet is damaged, or if the test has not been carried out immediately after opening the aluminium sachet,
- If the storage conditions are not respected, or if the test is carried out after the expiry date provided on the aluminium sachet.

• A positive result must be confirmed by a laboratory analysis. Consult your doctor, and do not make any medical decisions without first seeking advice from your GP.

II. Manufacturer identification

BIOSYNEX SWISS SA
Rue de Romont 29-31
CH-1700 Fribourg – Switzerland

Tel.: 026 552 51 52
Fax: 026 552 51 54

III. Reference to the Manufacturer's Previous Device Generation(s) and/or Similar Devices or Device History

1. For an IVD medical device not yet available on any market

Not applicable – no previous generation of the device.

2. For an IVD medical device already available on the market in any jurisdiction

Not applicable – the device is newly commercialized by Biosynex Swiss SA.

IV. History (changes)

Revision	Date	Part	Reason/Changes
01	2020-09-07	NA	Creation of the document
02	2020-09-14	I.3 I.4 I.11	Reformulation according to the wording of the IFU
03	2020-10-14	I. 2. I. 10. I. 6.	Reformulation according to content of the IFU (V05) Addition of languages DE and DK
04	2020-11-02	All I.5.	Addition of the new variant : BIOSYNEX® COVID-19 Ag BSX REF. SW40006_BSX Addition of "nozzles" in the kit composition (nozzles were already supplied within the kit but were previously not mentioned in DOC1)
05	2021-02-15	I.	General revision of §I. following new claim of utilisation of the test on nasal specimen. §I.4: - Additional information on specimen collection (let the patient blow his/ her nose if necessary; Only the sample collection can be performed outdoors. The test procedure should be performed indoors at 15-30°C.) - Additional information on specimen storage (up to 30 min at 15-30°C for the extracted solution ; 3 hours at 2-8°C for the direct swabs) §I.11.: - Addition of limits n° 7 and n°8
06	2021-02-26	NA I.5	Addition of new variants for the self-testing version, Biosynex COVID-19 Ag Antigenic Self-testing Kit, Ref.: 859256/859257/859258 Change of format of diluent buffer from 2 vials to 25 pre-filled diluent tubes in the composition of the professional versions.
07	2021-03-03	I.1.	Correction of the shelf life information

		I.4.B.	Update of the procedure for the professional version to adapt to the new format of extraction buffer in prefilled single-use tubes.
08	2021-03-08	All	Addition of new references (self test variants in presentation 5 tests/kit): REF. 859261, 859262, 859263)

* Exception in France: only Nasopharyngeal swabs are allowed; Utilization of nasal specimen is not claimed in the French IFU.