OPTIMIZED
COLLOIDAL GOLD ASSAY

BioSynchronicity™

C-SYNC™

COVID-19 ANTIGEN TEST

FAST | EASY | RELIABLE | RESULTS IN 10 MINUTES

For use under the Emergency Use Authorization (EUA) only.

For *in vitro* diagnostic use.

For prescription use only.

Quick Reference Instructions Read the complete IFU prior to performing a test

IVD Rx REF COV9712AC

INTENDED USE

The C-Sync™ COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and spike protein antigens from SARS-CoV-2 in direct anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptoms onset, when tested at least twice over three days with at least 48 hours between tests, and from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The C-Sync™ COVID-19 Antigen Test does not differentiate between SARS-CoV-1 or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid and spike protein antigens, which are generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to fully determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definitive cause of disease.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The C-Sync™ COVID-19 Antigen Test is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The C-Sync™ COVID-19 Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

MATERIALS AND SUPPLIES PROVIDED

The C-Sync™ COVID-19 Antigen test kits are available with 20 tests per kit including the following components:

- 20 Test cassettes individually packaged in a foil pouch with a desiccant
- 20 Extraction buffer tubes with dropper cap
- 20 Sterile Nasal Swabs for sample collection
- Instructions for Use (IFU)
- Quick Reference Instructions

MATERIALS REQUIRED BUT NOT PROVIDED

- External Positive and Negative Quality Controls sold separately - BioSynchronicity Product Catalog Number: COV9712ACS available at www.biosynchronicity.com
- Personal Protective Equipment per local recommendations
- Timer
- Tube rack for specimens

STORAGE AND STABILITY

- Store the kit between 2°C to 30°C (36°F to 86°F).
- Avoid direct exposure to sunlight.
- Do not freeze the content of the kit.
- The shelf life of the kit is indicated on the outer package.
- Do not use the test kit beyond its expiration date.
- The test device must remain in the sealed pouch until use.

TEST PROCEDURE

A. TEST PREPARATION

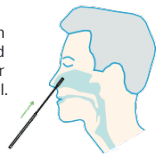
1. Do not use past the expiration on the label.
2. Wear appropriate personal protective equipment and gloves when handling patient samples and running the test.
3. Allow the kit components to reach a temperature between 15°C - 30°C (59°F-86°F) prior to testing.
4. Remove a C-Sync™ test from a pouch. Place the C-Sync™ Test Cassette on a flat and clean surface for the entire duration of the test operation.

B. SPECIMEN COLLECTION PROCEDURE

Remove a nasal swab from the package.

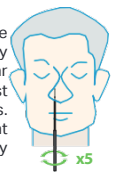
1

Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.



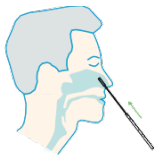
2

Gently, but firmly, collect a sample from the nasal wall by slowly rotating the swab into a circular path against the nasal wall at least 4 times for a total of 15 seconds. Be sure to collect any drainage that may be present on the swab. Slowly remove the swab.



3

Using the same swab, repeat the same sample collection process in the other nostril.

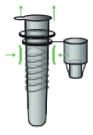


4

If immediate testing is not possible, and to maintain the best performance and avoid possible contamination, it is highly recommended the nasal swab specimen be placed in a clean, unused plastic tube and capped tightly at room temperature (15°C-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. **If greater than 1 hour delay occurs, dispose of the sample. A new sample must be collected for testing.**

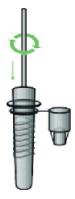
C. SPECIMEN PREPARATION PROCEDURE

Remove the foil seal from the extraction buffer tube.



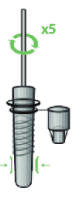
1

Carefully insert the swab inside the tube and plunge it to the bottom. Rotate the swab against the wall of the tube for 10 seconds.



2

Tightly squeeze and release the bottom of the tube against the absorbent part of the swab. This will make the liquid buffer inside the tube rise and fall. Make sure the buffer rises and falls to fully cover and wash the absorbent part of the swab. Twirl the swab while squeezing and washing the swab with the buffer. Repeat this squeezing and twirling technique 5 times.



3

Stop squeezing the bottom of the tube and rotate the swab against the wall of the tube for 10 seconds.

4

Remove the swab slowly while squeezing tightly the top part of the tube against the absorbent part of the swab to extract as much liquid as possible from the swab with the goal of drying the swab. Firmly place the dropper cap attached to the tube onto the top of the tube. Make sure the dropper cap is securely in place.

5

D. SPECIMEN TESTING

Set the timer at 10 minutes, but do not start yet.
Invert the extraction tube and squeeze the ridge area of the tube to **dispense 4 drops, drop by drop, into the sample well** of the C-Sync™ Test Cassette. Tap the device if the specimen fluid appears viscous when dropping the buffer into the sample well to aid in the wicking processv.

Apply only 4 drops to the sample well. Erroneous results may occur if less/more than 4 drops are applied.

Start the timer for 10 minutes. A visual observation of the red/purple dye entering the evaluation window of the test within 10 to 15 seconds after the test timer has been started shows the test is progressing.
The test must be read within 10 minutes, as indicated below in Reading and Interpretation of Results.

Do not read test results before 10 minutes or after 15 minutes. Erroneous results may occur when reading before 10 minutes or after 15 minutes.

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E. READING AND INTERPRETATION OF RESULTS

After dispensing the drops in the sample well, the results will be available as follows:

Positive:

If the Control line (C-line) is red/purple within 10 minutes and the Test line (T-line) is visible within 10 minutes, the test is positive. The color intensity of the Test line (T-line) will depend on the amount of SARS-CoV-2 nucleocapsid and/or spike protein antigens in the sample. Any very faint colored Test line (T-line) should be considered positive. **Tests should not be interpreted past 15 minutes**

Negative:

If the Control line (C-line) is red/purple at 10 minutes, and the Test line (T-line) is not visible at 10 minutes, the test is negative.

Invalid:

If the Control line (C-line) is not visible at 10 minutes, and regardless if the Test line (T-line) is visible or not visible, the test is invalid. Discard the test. A new test should be repeated.

Do not interpret the results before 10 minutes. Results read after 15 minutes may be invalid.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

POSITIVE RESULT

The presence of both the control line (C) and test line (T) indicates the presence of SARS-CoV-2 antigen. The result suggests current SARS-CoV-2 infection. Samples with low levels of antigen may produce a faint test line. Any visible test line is considered positive.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection

NEGATIVE RESULT

The presence of the red-colored control line (C) and no visible test line (T) indicates that SARS-CoV-2 antigen was not detected. **To increase the chance that the negative result for COVID-19 is accurate, you should:**

- **If the individual has symptoms on the first day of testing, test again at least twice over three days with at least 48 hours between tests.**
- **If the individual does not have symptoms on the first day of testing, and from individuals without, test again at least three times over five days with at least 48 hours between tests.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

INVALID RESULT

If the red-colored control line (C) is not visible, DO NOT interpret the test result. The result is invalid regardless of the appearance of the test line (T). Collect a new anterior nasal swab sample and repeat the assay with a new test.

EXTERNAL QUALITY CONTROLS

External Quality Controls are available from BioSynchronicity Corporation, BioSynchronicity Product Catalog reference: COV9712ACS, available at www.biosynchronicity.com

It is recommended that positive and negative external quality controls be run once with every new lot, every shipment, every new user, or in accordance with Local, State, and Federal regulations, or accreditation requirements.

EMERGENCY USE AUTHORIZATION – WARNING AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only to be used with the C-Sync™ COVID-19 Antigen Test for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

TECHNICAL SUPPORT

For more information, please visit www.biosynchronicity.com
If you have any questions, please contact customer support at:

Phone: +1 (425) 898-3431
Email: support@biosynchronicity.com

- Manufacturer
- CE mark
- Contains sufficient for <n> test
- Store between 2°C and 30°C (36°F and 86°F)
- In Vitro Diagnostic device
- Consult Instructions for Use
- Keep dry
- For prescription use only
- Do not reuse
- Do not use if package is damaged
- Use by date
- REF Catalog Number
- LOT Lot Number
- Keep away from sunlight

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