PRINCIPLES OF THE TEST

INTENDED USE

The C-Sync™ COVID-19 Antigen Test is a qualitative immunoassay intended for use with nasal swabs for the qualitative detection of SARS-CoV-2 directly from nasal swabs, without the need for nucleic acid amplification. It is a rapid, colloid gold-based test that can provide results in less than 10 minutes. The test is intended for use in healthcare settings where rapid results are needed for infection control decisions, including testing for COVID-19.

MATERIALS AND SUPPLIES PROVIDED

- C-Sync™ Test Cassette
- Sample well containing antigen extraction buffer
- Positive and Negative Quality Controls
- Antigen Test Solutions (VTM and Buffer)
- User Manual

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 not authorized by FDA is prohibited.

In the USA, the emergency use of this product is only authorized for the diagnostic use.

SAYS FOR USE

The presence of one colored line at the C-line indicates that SARS-CoV-2 antigen was detected. The presence of a single line at the C-line means the test was successful.

Test results are interpreted at 10 minutes. A red/purple Test line indicates a positive result. A red/purple Control line (C-line) is used to confirm sufficient flow of the sample along the membrane. The test is not valid if the test cassette does not show the Control line (C-line).

If the Control line (C-line) is red/purple but the Test line is not visible, the test result is invalid. If the Control line (C-line) is not red/purple, the test has failed and must be discarded. If the Control line (C-line) is not red/purple, do not perform a test and contact technical support.

The presence of one colored line at the C-line indicates that SARS-CoV-2 antigen was not detected. The presence of a single line at the C-line means the test was successful.

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SUMMARY AND EXPLANATION OF THE TEST

The C-Sync™ COVID-19 Antigen Test is a qualitative immunochromatographic test that provides results in less than 10 minutes. It is a one-step process that requires no sample processing or amplification. The test is intended for use in healthcare settings where rapid results are needed for infection control decisions, including testing for COVID-19.

The test cassette contains a sample well that contains antigen extraction buffer and four drops are added to the sample well. The test cassette is then allowed to sit for 10 minutes before interpreting results.

RESULTS

POSITIVE RESULT

If the Control line (C-line) is red/purple and the Test line is red/purple, the test result is positive. If the Control line (C-line) is red/purple and the Test line is not visible, the test result is invalid. If the Control line (C-line) is not red/purple, do not perform a test and contact technical support.

NEGATIVE RESULT

If the Control line (C-line) is red/purple and the Test line is not visible, the test result is invalid. If the Control line (C-line) is not red/purple, do not perform a test and contact technical support.

DIAGNOSTIC USE

Viral Transport Media (VTM). Results are available in less than 10 minutes, making it a rapid diagnostic tool. It is intended for use in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform moderate, high or waived complexity tests.

The C-Sync™ COVID-19 Antigen Test is a qualitative immunochromatographic test that provides results in less than 10 minutes. It is a one-step process that requires no sample processing or amplification. The test is intended for use in healthcare settings where rapid results are needed for infection control decisions, including testing for COVID-19.

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NEGATIVE RESULT

If the Control line (C-line) is red/purple and the Test line is not visible, the test result is invalid. If the Control line (C-line) is not red/purple, do not perform a test and contact technical support.

DIAGNOSTIC USE

Viral Transport Media (VTM). Results are available in less than 10 minutes, making it a rapid diagnostic tool. It is intended for use in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform moderate, high or waived complexity tests.
Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as MyDataHelps app. Two-day serial antigen testing is defined as performing two study participants reported symptom status throughout the study using the discordant a third highly sensitive EUA RT-PCR test was performed, and the final test for comparator testing using a home collection kit (using a 15-minute normalization molecular comparator single day testing throughout the course of infection conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to Clinical Performance (Asymptomatic Population)

- Of the 5 false negative results observed, 3 specimens were found to be negative for SARS-CoV-2 and their prevalence, which change over time.
- False negative results may occur if specimens are tested beyond 1 hour after the time and location of the clinical evaluation. Performance at the time of testing for Use may adversely affect the performance of the test and invalidate the results for Use may adversely affect the performance of the test and invalidate the results.
- Positive results do not differentiate between SARS-CoV-1 and SARS-CoV-2.
- This is a qualitative test and the test does not provide information on the viral
- False negative results may occur if the concentration of the SARS-CoV-2 antigen in the clinical specimen is below the limit of detection of the test or if the sample
- Of the 1 false positive result observed, subsequent sequencing of this specimen is deemed additionally necessary by laboratory internal quality control procedures, and authorized laboratories using your product must ensure that any records associated with this EUA are reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUAReport DMD/OHT7/OPEQ/CDRH via phone by contacting BioSynchronicity support@biosynchronicity.com or via phone by contacting BioSynchronicity support@biosynchronicity.com).
External Quality Controls
for C-Sync® COVID-19 Antigen Test

For use under the Emergency Use Authorization (EUA) only
For use with the C-Sync® COVID-19 Antigen Test only
For in vitro diagnostic use
For prescription use only

INTENDED USE
C-Sync™ COVID-19 Antigen Test External Quality Controls are to be used as an important step in the QC process to verify that a test is properly and accurately performed.

ELEMENTARY AND DESCRIPTIVE INFORMATION
The External Quality Controls for the C-Sync™ COVID-19 Antigen Test are designed to be used with the C-Sync™ COVID-19 Antigen Test. They are intended to ensure the quality and accuracy of the test results. The QC system is designed to verify that the test is being performed correctly and that the results are reliable.

SUMMARY AND EXPLANATION OF THE TEST
The C-Sync™ COVID-19 Antigen Test External Quality Controls are to be used exclusively with the C-Sync™ COVID-19 Antigen Test to establish an adequate quality assurance program to ensure the performance of the test under its specific locations and conditions of use. The Positive and Negative Controls are intended to ensure that the test is properly performing and that the results are accurate.

It is the responsibility of each laboratory or healthcare setting using the C-Sync™ COVID-19 Antigen Test to establish an adequate quality assurance program to ensure the performance of the test under its specific locations and conditions of use. The Positive and Negative Controls are intended to ensure that the test is properly performing and that the results are accurate. The Quality Controls consist of 1 SARS-CoV-2 nucleocapsid protein positive control and 1 SARS-CoV-2 non-infectious recombinant nucleocapsid protein positive control. The controls are intended to be used to verify that the test is being performed correctly and that the results are reliable.

The controls are intended to be used immediately after being opened. The controls should be run once with every new lot, every new shipment, and every new user, and quality control requirements should be followed in conformance with local, state, and federal regulations.

The controls should be stored in the refrigerator at a temperature between 2°C and 30°C (36°F and 86°F) until use. The controls should not be used beyond the expiration date.

The controls should be opened immediately after being received. The controls should not be used if the package is damaged.

TEST PROCEDURE
A. NEGATIVE CONTROL SWAB PROCEDURE

1. C-Sync™ COVID-19 Antigen Test Non-Infectious Recombinant SARS-CoV-2 Nucleocapsid Protein Negative Control Swab

B. POSITIVE CONTROL SWAB PROCEDURE

1. C-Sync™ COVID-19 Antigen Test Non-Infectious Recombinant SARS-CoV-2 Spike Protein Positive Control Swab

C. QUALITY CONTROL SWAB PROCEDURE

1. C-Sync™ COVID-19 Antigen Test Non-Infectious Recombinant SARS-CoV-2 Spike Protein Positive Control Swab

MATERIALS REQUIRED BUT NOT PROVIDED
- In vitro diagnostic device
- SARS-CoV-2 nucleocapsid protein positive control
- SARS-CoV-2 non-infectious recombinant nucleocapsid protein positive control
- Extraction buffer
- Saline solution
- Absorbent floss
- Sterile dropper cap
- Sterile vial

STORAGE AND STABILITY
- Store the controls between 2°C and 30°C (36°F and 86°F) until use.
- Do not use beyond the expiration date.
- Do not open the External Quality Controls until just before use. Once opened, the External Quality Controls should be used immediately.
- Do not use the Quality Controls beyond the expiration date.

EXERCISE THE NORMAL PRECAUTIONS REQUIRED FOR HANDLING ALL LABORATORY REAGENT MATERIALS.

IN VITRO DIAGNOSTIC DEVICE
Contains sufficient reagents for <n> tests.

CE marking

USE BY DATE

PRODUCT PACKAGE

For prescription use only

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