INDICAID™ COVID-19 Antigen Quality Controls

For use with the INDICAID™ COVID-19 Rapid Antigen Test

Intended use

The INDICAID™ COVID-19 Antigen Quality Controls are intended for quality control testing performed on the INDICAID™ COVID-19 Rapid Antigen Test. The Quality Controls provide users with assurance that the device is performing within specification.

Summary and explanation of the test

The INDICAID™ COVID-19 Antigen Quality Controls are external liquid quality controls. The controls are specifically formulated and manufactured to ensure that the test's reagents and materials are working and that the test procedure is correctly performed. The Quality Controls consist of positive and negative control samples that should be run once with every new lot, shipment, and each new user, using the test procedure provided.

It is the responsibility of each laboratory or healthcare setting using the INDICAID™ COVID-19 Rapid Antigen Test to establish an adequate quality assurance program to ensure the performance of the test kit under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

Warnings and precautions

- For in vitro diagnostic use only.
- Quality Control Vials are for one-time use only. Do not reuse vials.
- Exercise the normal precautions required for handling all laboratory reagents.
- Do not swallow or inhale.
- Avoid contact with your eyes. If contact occurs, flush with copious amounts of water immediately.

Storage and Stability

- Store controls between 2°C and 8°C (36 – 46°F).
- Unopened controls that are stored between 2°C and 8°C (36 – 46°F) can be used until the expiration date. Do not use Quality Controls beyond the expiration date given on the label.
- Quality Control Vials should remain sealed until ready for use
- Open a Quality Control Vial only when you are planning to perform a quality control test.

Materials Provided in Kit

REF 2110420	$50	• 5 x 250 µL single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) • 5 x 250 µL single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives)

Materials Required But Not Provided

1. INDICAID™ COVID-19 Rapid Antigen Test Device
2. INDICAID™ COVID-19 Rapid Antigen Test Buffer Solution Vial
3. INDICAID™ COVID-19 Rapid Antigen Test Individually Wrapped Swab
4. Timer

Preparing the quality controls

The liquid controls are supplied ready to use. Each Quality Control Vial is single-use only.

Test Procedure

Wear appropriate personal protective equipment and gloves when handling patient samples and running the test.

1. Remove a new Swab and Test Device from their packaging. Place the Test Device on a horizontal (flat) surface for running the test.
2. Hold a new INDICAID™ COVID-19 Antigen Positive Control Vial vertically and open the cap.
3. Dip the new Swab into the Positive Control Vial, making sure that the Swab head is fully wetted by the solution. Remove the Swab from the Vial.
4. Test the Swab immediately performing the same steps as described in section "Test Procedure for Patient Swabs" of the INDICAID™ COVID-19 Rapid Antigen Test Instructions For Use (Package Insert).
5. Repeat all the above steps to test the external negative control in the INDICAID™ COVID-19 Antigen Negative Control Vial.

Expected Results

Consult the INDICAID™ COVID-19 Rapid Antigen Test Instructions for Use or Quick Reference Guide for instructions on how to interpret a test result using the Quality Control.

The Test Devices are working properly and all handling has been done correctly when the following expected test results are obtained:

- The INDICAID™ COVID-19 Antigen Positive Control should provide a positive result.
- The INDICAID™ COVID-19 Antigen Negative Control should provide a negative result.



Positive Result | Negative Result | Invalid Result

If the external controls do not produce the expected results, do not use the test for patient testing or report patient results. Please contact PHASE Scientific Technical Support during normal business hours before using the test with patient specimens.

Manufactured By

PHASE Diagnostics, Inc.
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This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, 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 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.

For more information, questions, or support, please visit www.phasescientificusa.com, or email us at:

Email: ussales@phasesci.com

Symbols



In vitro diagnostic medical device


Do not reuse


Consult Instructions for Use

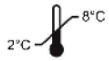


Catalog number


Caution—consult accompanying documents



Batch code



Temperature limitation


Use by


Keep away from sunlight


Manufacturer


Sufficient for use


Keep away from moisture

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