CLARITY

COVID-19 Antigen Test Control Kit

INSTRUCTIONS FOR USE

For *in vitro* diagnostic use.
For prescription use only.

Please read instructions carefully before you perform the test.

INTENDED USE

The Clarity COVID-19 Antigen Test Control Kit is intended for in vitro diagnostic use in external quality control testing with the Clarity COVID-19 Antigen Test to ensure that the reagents and materials are functioning properly and that the test procedure is correctly performed.

KIT CONTENTS

- Positive Control Swab(s) with recombinant SARS-CoV-2 antigens and 0.05% ProClin 300 preservative.
- Negative Control Swab(s) with 0.05% ProClin 300 preservative.
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clarity COVID-19 Antigen Test
- Timer or watch

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. The Clarity COVID-19 Antigen Test Control Kit is only for use with the Clarity COVID-19 Antigen Test. They have not been validated for use with other tests.
3. DO NOT use kit contents beyond the expiration date printed on the outside of the box.
4. Do not open the pouch until ready for use.
5. Do not use the control swab if pouch is damaged.
6. Do not re-use any contents in the control kit.
7. The control swabs not for patient use and should not be inserted into the patient's nostrils for sample collection.
8. Follow Good Laboratory Practices, wear protective clothing, use disposable gloves. Do not eat, drink or smoke in the area.
9. All the control swab samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
10. The control swabs and test device should be discarded in a proper biohazardous container after testing.
11. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing. Failure to follow the test procedure, precautions and interpretation of test results may adversely affect test performance and/or produce invalid results.
12. This control kit is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.

KIT STORAGE AND STABILITY

1. Store the Clarity COVID-19 Antigen Test Control Kit at 36-86°F (2-30°C).
2. Kit materials are stable until expiration date printed on the outer box label.
3. Do not freeze.

RUNNING AN EXTERNAL QUALITY CONTROL TEST PROCEDURE

Allow the test materials to reach room temperature 59°F-86°F(15°C-30°C) prior to testing. Do not open pouches until ready to perform the test.

To perform a positive or negative control test, complete the steps in the Test Procedure section of the assay Instructions for Use treating the control swab in the same manner as a patient swab (refer to Clarity COVID-19 Antigen Test Instructions for Use). External quality control requirements should be established as required by site quality control procedure and in accordance with local, state, and federal regulations or accreditation requirements. Minimally, Clarity recommends that positive and negative external controls be run once for each new kit lot, each new shipment received, and each new operator.
If External Quality Control testing fails, repeat the testing of external quality controls with new control swabs on the Clarity COVID-19 Antigen Test.
If the test does not perform as expected, please contact Clarity Diagnostics Group, LLC at 1-877-722-6339 or chat with us on our website www.ClarityDiagnostics.com

INTERPRETATION OF EXTERNAL QUALITY CONTROL RESULTS

When the Positive Control Swab is tested, the appearance of ANY shade of a very light or faint pink to red line at the "T" Test Line, along with a "C" Control Line indicates that the SARS-CoV-2 antigen binding properties of the Test Cassette are functional.
When the Negative Control Swab is tested, there should only be the appearance of the "C" Control Line without lines at the "T" Test Line to indicate that there is no non-specific antigen binding and the Test Cassette is functional.
When the Positive Control Swab/ Negative Control Swab is tested, if a "C" Control Line is not visible, the result is invalid. It is recommended that the control swab be retested using a new test device.
Refer to the Clarity COVID-19 Antigen Test Instructions for Use for a complete description of the assay procedure and interpretation of results.

DISPOSING OF EXTERNAL QUALITY CONTROL MATERIALS

Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

ASSISTANCE

If the test does not perform as expected, please contact Clarity Diagnostics Group, LLC via email at sales@claritydiagnostics.com or chat with us on our website www.ClarityDiagnostics.com

INDEX OF SYMBOLS

Keep away from sunlight	Store between 36°F-86°F (2°C-30°C)	Keep dry
Do not re-use	Catalogue number	Batch code
Use-by date	*In vitro* diagnostic medical device	Consult instructions for use
Positive control	Negative control	Prescription Use Only

Manufactured For:
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Rev. A1
Rel.: 2026/06/17