CLARITY

COVID-19/Influenza A&B Antigen Test Control Kit

INSTRUCTIONS FOR USE

For *in vitro* diagnostic use.
For professional use.

Please read instructions carefully before you perform the test.

INTENDED USE

The Clarity COVID-19 / Influenza A&B Antigen Test Control Kit is intended for in vitro diagnostic use in quality control testing with the Clarity COVID-19 / Influenza A&B Antigen Test.

SUMMARY

The Clarity COVID-19 / Influenza A&B Antigen Test Control Kit includes Flu A/Flu B/SARS--CoV-2 Positive Control Swab and Flu A/Flu B/SARS-CoV-2 Negative Control Swab for external quality control testing. Use the Clarity COVID-19 / Influenza A&B Antigen Test Control Kit to help ensure that the Clarity COVID-19 / Influenza A&B Antigen Test is functioning properly and to demonstrate proper performance by the test operator. External controls are intended to monitor substantial device failure.

If External Quality Control testing fails, repeat the testing of the failed control or contact Clarity Diagnostics Group, LLC at 1-877-722-6339 or chat with us on our website www.ClarityDiagnostics.com before running patient samples.

External quality control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, Clarity Diagnostic Group recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

KIT CONTENTS

- Positive Control Swab(s), packaged in individual pouch with a desiccant, coated with recombinant influenza A antigens, recombinant influenza B antigens and SARS-CoV-2 antigens and 0.05% ProClin 300.
- Negative Control Swab(s), packaged in individual pouch with a desiccant, coated with inactivated Streptococcus Group A antigen and 0.05% ProClin 300.
- One (1) Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clarity COVID-19 / Influenza A&B Antigen Test
- Timer or watch

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. DO NOT use kit contents beyond the expiration date printed on the outside of the box.
3. The control swabs not for patient use and should not be inserted into the patient's nostrils for sample collection.
4. Follow Good Laboratory Practices, wear protective clothing, use disposable gloves, do not eat, drink or smoke in the area.
5. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. The control swabs and test device should be discarded in a proper biohazardous container after testing.
7. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
8. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
9. This product 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

Store the Clarity COVID-19 / Influenza A&B Antigen Test Control Kit at 36-86°F (2-30°C). Kit materials are stable until expiration date printed on the outer box label.

RUNNING AN EXTERNAL QUALITY CONTROL TEST PROCEDURE

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 / Influenza A&B Antigen Test Instructions for Use).

INTERPRETATION OF EXTERNAL QUALITY CONTROL RESULTS

When the Flu A/Flu B/SARS-CoV-2 Positive Control Swab is tested, the appearance of ANY shade of a very light or faint pink to red line at the "F-A" Test Line, "F-B" Test Line, and "CoV" Test Line, along with a "C" Control Line indicates that the influenza and SARS-CoV-2 antigen binding properties of the test cassette are functional.
When the Flu A/Flu B/SARS-CoV-2 Negative Control Swab is tested, there should only be the appearance of the "C" Control Line without lines at the "F-A" Test Line, "F-B" Test Line, or the "CoV" Test Line to indicate that there is no non-specific antigen binding and the test cassette is functional.

Refer to the Clarity COVID-19 / Influenza A&B 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.

REORDER

Clarity COVID-19 / Influenza A&B Antigen Test Kit
Clarity COVID-19 / Influenza A&B Antigen Test Control Kit

ASSISTANCE

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

INDEX OF SYMBOLS

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

Manufactured For:
Clarity Diagnostics Group, LLC
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