BIBLIOGRAPHY

1. CDC. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. cdc.gov.
2. CDC. Universal Precautions For Prevention Of Transmission Of Human Immunodeficiency Virus, Hepatitis B Virus, And Other Bloodborne Pathogens In Health-Care Settings. MMWR 1988; 37(24):377-388.

EXPLANATION OF SYMBOLS

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number		Manufacturer
	Caution, Consult Accompanying Documents		Temperature Limitation
PN	Part Number		Use By

For Technical or Customer Service within the United States, phone (800) ORASURE (800-672-7873).
For customers outside the United States, phone +(001) 610 882 1820 or go to www.OraSure.com

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Item# 3001-3354 rev. 08/23

InteliSwab®
COVID-19 *RAPID TEST* • Pro

KIT CONTROLS

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.

For *in vitro* Diagnostic Use

These Instructions for Use and the InteliSwab® COVID-19 Rapid Test Pro Instructions for Use must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result. Before proceeding with testing, all operators MUST read and become familiar with Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.[1] These Kit Controls do not contain live virus and are formulated with non-infections materials.

NAME AND INTENDED USE

The InteliSwab® COVID-19 Rapid Test Pro Kit Controls are intended as an external quality control reagents to monitor the performance of the InteliSwab® COVID-19 Rapid Test Pro with direct anterior nasal samples. For use only with the InteliSwab® COVID-19 Rapid Test Pro.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°-30°C (35°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies.

It is the responsibility of each laboratory using the InteliSwab® COVID-19 Rapid Test Pro to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The InteliSwab® COVID-19 Rapid Test Pro Kit Controls are formulated using a nucleocapsid recombinant antigen in a buffered solution. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The COVID-19 Positive Control will produce a reddish-purple line at the Test (T) Zone. The COVID-19 Negative Control will generate a negative test result (no line at the T Zone). Both controls will produce a reddish-purple line in the Control (C) Zone. Refer to *Test Result and Interpretation of Test Result* section of the InteliSwab® COVID-19 Rapid Test Pro Instructions for Use. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the InteliSwab® COVID-19 Rapid Test Pro.

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MATERIALS PROVIDED

InteliSwab® COVID-19 Rapid Test Pro Kit Controls

Each Kit Control box contains an IFU and two vials (one COVID-19 Positive Control and one COVID-19 Negative Control) as described below:

COVID-19 Positive Control

One blue-capped vial containing 0.25 mL of SARS-CoV-2 nucleocapsid recombinant antigen diluted in Phosphate-Buffered Saline with EDTA and Goat Serum. Preservative: 2-methyl-4-isothiazolin-3-one.

COVID-19 Negative Control

One white-capped vial containing 0.25 mL of Phosphate-Buffered Saline with 1% Bovine Serum Albumin. Preservative: 2-methyl-4-isothiazolin-3-one.

Specimen Collection Loops

MATERIALS REQUIRED AND PROVIDED in the InteliSwab® COVID-19 Rapid Test Pro Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial
Test Stands
Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 minutes
Latex, vinyl, or nitrile disposable gloves
Biohazard waste container

WARNINGS

For *in vitro* Diagnostic Use

- **These Instructions for Use must be read completely before using the product.**
- **Follow the instructions carefully when performing the InteliSwab® COVID-19 Rapid Test Pro. Failure to do so may cause an inaccurate test result.**
- **This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; for use by laboratories certified under CLIA 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 for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.**
- **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. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner**
- **Before proceeding with testing, all study personnel MUST read and be familiar with Universal Precautions[2] and Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)[1].**

PRECAUTIONS

Safety Precautions

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the InteliSwab® COVID-19 Rapid Test Pro.

STORAGE INSTRUCTIONS

Store the InteliSwab® COVID-19 Rapid Test Pro Kit Controls at 2°-8°C (35°-46°F). Do not use the Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°C-8°C (35°-46°F) after use. Once opened, Kit Controls should be discarded after eight (8) weeks.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures according to the *General Test Preparation* section of the InteliSwab® COVID-19 Rapid Test Pro IFU.

TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Vial and discard the used loop in a waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Vial containing the specimen. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer Vial.**
5. Leave the Test Device in the Developer Solution Vial and start a timer. Do not remove the Test Device from the vial until you have read the results. Read the results in a fully lighted area after 30 minutes, but no more than 40 minutes. Read the results as described in the *Test Result and Interpretation of Test Result* section of the InteliSwab® COVID-19 Rapid Test Pro Kit IFU.
6. Dispose of the used test materials in a waste container.

EXPECTED RESULTS

COVID-19 Negative Control

The COVID-19 Negative Control will produce a Negative test result. A single line should be present in the Result Window in the Control (C) Zone and NO line should be present in the Test (T) Zone. This indicates a Negative test result.

COVID-19 Positive Control

The COVID-19 Positive Control will produce a Positive test result and has been manufactured to produce a very faint line at the Test (T) Zone. Two lines should be present in the Result Window. A line in the Control (C) Zone and a line in the Test (T) Zone should be present. This indicates a Positive test result. The lines will not necessarily be the same intensity.

NOTE: If the test result for either the COVID-19 Negative Control or the COVID-19 Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. Contact OraSure Technologies' Customer Care if the Kit Control reagents do not produce the expected result.

LIMITATIONS

The InteliSwab® COVID-19 Rapid Test Pro Kit Controls are quality control reagents for use only with the InteliSwab® COVID-19 Rapid Test Pro.