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

OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015 USA
(800) ORASURE (1-800-672-7873)
(610) 882-1820
www.OraSure.com

Item# 3001-3357 rev. 05/21B

InteliSwab™ COVID-19 *RAPID TEST* • Pro

VISUAL REFERENCE PANEL

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.
For *in vitro* Diagnostic Use

All new operators must be able to correctly interpret all devices provided within the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel prior to using the InteliSwab™ COVID-19 Rapid Test Pro.

Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the InteliSwab™ COVID-19 Rapid Test Pro and may result in false negative results.

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.

NAME AND INTENDED USE

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is comprised of InteliSwab™ COVID-19 Rapid Test Pro devices that have been designed to represent reading intensities of limit of detection, low positive, and negative test results. The limit of detection test device is indicative of specimens with antigen levels at the limit of detection of the device.

It is the responsibility of each laboratory using the InteliSwab™ COVID-19 Rapid Test Pro to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator's ability to read visual intensities at the Test (T) Zone at all levels including very weak lines representing low antigen levels.

SUMMARY AND EXPLANATION OF THE COVID-19 VISUAL REFERENCE PANEL

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low positive, and negative test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The COVID-19 Limit of Detection Device has a very faint reddish-purple line at the Test (T) Zone. The COVID-19 Low Positive Device has a reddish-purple line at the Test (T) Zone. The COVID-19 Negative Device does not have a line at the Test (T) Zone. All devices have a reddish-purple line at 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 on how to interpret the devices.

This panel is to be used to assist new operators with becoming proficient at reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro results at or near the limit of detection of the device. The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro devices. Any line at the Test (T) Zone is considered a positive result regardless of how faint the line appears.

MATERIALS REQUIRED AND PROVIDED in the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel

- Foil Pouch containing three predetermined InteliSwab™ COVID-19 Rapid Test Pro devices representing limit of detection, low positive and negative test results as described below.

  1. COVID-19 Limit of Detection Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured at a predetermined reactivity level to produce a positive test result consistent with the limit of detection of the device.

  2. COVID-19 Low Positive Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured at a predetermined reactivity level to produce a positive test result.

  3. COVID-19 Negative Device
  One InteliSwab™ COVID-19 Rapid Test Pro device that has been manufactured to produce a negative test result.

- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Latex, vinyl, or nitrile disposable gloves

WARNINGS

For *in vitro* Diagnostic Use

- **These Instructions for Use must be read completely before using the product.**
- **Adequate lighting is required for reading and interpreting the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel and the InteliSwab™ COVID-19 Rapid Test Pro.**
- **Follow the Test Result and Interpretation of Test Result section of the InteliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.**
- **The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel when stored protected from light (either pouched or unpouched) is stable through the expiration date printed on the pouch. If not protected from light or stored above indicated temperature, the unpouched device should be discarded after 15 days.**
- **The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting InteliSwab™ COVID-19 Rapid Test Pro devices. Any line at the Test (T) Zone is considered to be a positive result regardless of how faint the line appears.**
- **All testing MUST be conducted under appropriate biosafety conditions in accordance with CDC guidelines.[1] All study personnel conducting testing MUST read and be familiar with Universal Precautions.[2]**
- **This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA 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.**

PRECAUTIONS

Safety Precautions

- The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel does not contain potentially infectious materials. Hazardous disposal is only required if used in areas containing infectious materials.

- Use of Visual Reference Panels 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 Visual Reference Panel at 15°-30°C (59°-86°F). Do not use the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel pouch only when qualifying new operators in interpreting test results. Reseal and store the devices in their original foil pouch at 15°-30°C (59°-86°F) after use. If not protected from light or stored above the indicated temperatures, the un-pouched device should be discarded after 15 days.

DIRECTIONS FOR USE

Test Procedure

Note: The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the InteliSwab™ COVID-19 Rapid Test Pro occurs.

1. Open the foil pouch containing the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel.
2. Pull out the three devices contained within the foil pouch.
3. Note the date the pouch was opened on the device labels or the pouch label.
4. Follow the Test Result and Interpretation of Test Result section of the InteliSwab™ COVID-19 Rapid Test Pro Instructions for Use for instructions on how to interpret the devices.
5. Store the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel Devices in the original re-sealable foil pouch at 15-30°C (59-86°F).

EXPECTED RESULTS

COVID-19 Limit of Detection Device

The COVID-19 Limit of Detection Device has been manufactured to have a very faint reddish-purple line at the Test (T) Zone. A reddish-purple line should be present in the Result Window in both the Control (C) Zone and the Test (T) Zone. This indicates a weakly positive test result consistent with the limit of detection of the device. The Control (C) Zone and the Test (T) Zone lines will not be the same intensity.

COVID-19 Low Positive Device

The COVID-19 Low Positive Device has been manufactured to have a reddish-purple line at the Test (T) Zone. A reddish-purple line should be present in the Result Window in both the Control (C) Zone and the Test (T) Zone. This indicates a positive test result. The Control (C) Zone and the Test (T) Zone lines will not be the same intensity.

COVID-19 Negative Device

The COVID-19 Negative Device has been manufactured to have a line at the Control (C) Zone. 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.

NOTE: If a new operator is unable to interpret all devices provided as part of the InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel, they are not considered to be proficient at reading and interpreting the InteliSwab™ COVID-19 Rapid Test Pro. Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the InteliSwab™ COVID-19 Rapid Test Pro and may result in false negative results.

LIMITATIONS

The InteliSwab™ COVID-19 Rapid Test Pro Visual Reference Panel is for use only with the InteliSwab™ COVID-19 Rapid Test Pro.