

# INSTRUCTIONS FOR USE

IVD

## HE0068AG SARS-CoV-2 Whole Virus Antigen Control (Swab)

### INTENDED USE

SARS-CoV-2 Whole Virus Antigen Control (Swab) is intended for use as non-viable, external, positive control material to evaluate the performance of rapid testing methodologies that detect antigens present on the SARS-CoV-2 virus. The product is also intended to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect SARS-CoV-2 and/or human cells. This product has no qualitative or quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen.

### SUMMARY AND PRINCIPLES

The SARS-CoV-2 Whole Virus Antigen Control (Swab) can be used to monitor the detection of SARS-CoV-2 viral antigens when using an assay suited for the detection of SARS-CoV-2 viral antigens and to monitor the extraction, amplification and detection process of molecular testing assays that include the analytes in Table 1. Routine use of quality controls monitors test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

### COMPOSITION

The SARS-CoV-2 Whole Virus Antigen Control (Swab) consists of 6 individually packaged lyophilized swabs. The analytes in Table 1 have been inactivated using irradiation, chemical, and/or thermal treatments.

The SARS-CoV-2 Whole Virus Antigen Control (Swab) is lyophilized in a PCR compatible patient-relevant matrix. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use swab.

Table 1: Contents of the SARS-CoV-2 Whole Virus Antigen Control (Swab)

Analytes*
SARS-CoV-2, Isolate USA/WA1/2020
Human lung epithelial cells

\*All analytes are added at a concentration of approximately  $10^4$  -  $10^7$  copies per swab.

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- To be used by personnel trained in the use of the assay.
- The inactivated lyophilized pellets or swabs are single-use only. Once hydrated, do not freeze for reuse.
- Do not open foil pouch until ready to use.
- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. This product must be treated as a potential biohazard and be handled using universal laboratory precautions. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills and dispose of all materials in accordance with national and local regulations.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at [www.microbiologics.com](http://www.microbiologics.com) or by contacting Technical Support at 1.320.229.7045 or U.S. Toll Free 1.866.286.6691.

- This product is not made with natural rubber latex.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

## **MATERIALS REQUIRED BUT NOT PROVIDED** ---

### **For Viral Antigen Detection:**

- Viral antigen detection assay
- Instrumentation for detection
- Sample processing reagent as required by the assay to be performed

### **For Nucleic Acid Detection:**

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Rehydration buffer such as nuclease-free water, phosphate-buffered saline (PBS), or sample transport medium as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µl volumes (optional)
- Nuclease-free aerosol barrier pipette tips
- Vortex (optional)
- Microcentrifuge (optional)

## **INSTRUCTIONS FOR USE** ---

### **Preparation**

1. Read package insert, instructions for use or lab protocol for the applicable nucleic acid extraction or antigen detection assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.
2. Tear open pouch at notch.
3. Remove swab from pouch and process further using instructions A through C below. Consult assay product insert for guidance on processing QC samples and patient samples.

### **A. Instructions for Antigen Detection Assay**

4. Read package insert for the antigen detection assay; follow instructions included with the assay, using any supplied reagents accordingly.

### **B. Instructions for Direct Inoculation with Dry or Pre-Wet Swab**

4. Insert the dry or pre-wet swab into the cartridge.
  - a. If directed by the assay instructions, break the swab by snapping the shaft.
5. Process following diagnostic assay instructions for use.

### **C. Instructions for Placing Swab into a Vial or Tube of Hydrating Fluid**

4. Place swab into a vial of hydrating fluid.
  - a. For sample volume and known extrinsic factors and interfering substances, please refer to Table 2 below.
5. Break the swab by lifting the swab a few millimeters from the bottom of the vial and pushing the shaft of the swab against the rim to break it.
6. Recap the vial; mix by inversion, shaking or vortex per assay instructions, or until swab is hydrated.
7. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
8. Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.

Table 2: Sample Volume

Hydration Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and interfering Substances
Antigen detection assay sample extraction/processing reagent	As required by the assay instructions for use	As required by the assay instructions for use	N/A
Water or Phosphate Buffered Saline (for nucleic acid purification)	Required assay volume + minimum hydration volume of 50 µl	As required by the assay instructions for use	N/A
Sample Transport Medium	As required by the assay instructions for use	As required by the assay instructions for use	N/A

## STORAGE AND EXPIRATION

Store the SARS-CoV-2 Whole Virus Antigen Control (Swab) at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately, rehydrating before use if directed by the assay. In-use stability of the rehydrated swab, and of the dry swab after opening the foil pouch, at room temperature (25°C) is 6 hours.

The SARS-CoV-2 Whole Virus Antigen Control (Swab) should not be used if:

- Stored improperly.
- There is evidence of excessive exposure to heat or moisture.
- The expiration date has passed.
- Packaging is damaged.

## PERFORMANCE CHARACTERISTICS

Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These organisms are intact, non-viable, and may be used with any PCR- or antigen-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified, and that surface proteins are detectable by an antigen assay but does not guarantee specific analyte concentrations. Each laboratory should establish its own range of acceptable values on their assay system per their internal quality assurance procedure/program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.




















## LIMITATIONS

This product is unassayed control material. It may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics' provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.

## MICROBIOLOGICAL STATE

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

## KEY OF SYMBOLS

	Authorized Representative in the European Community		Health Hazard
	Batch Code (Lot)		In Vitro Diagnostic Medical Device
	Biological Risks		Manufacturer
	Catalog Number		Negative Control
	Caution		Positive Control
	CE Mark		Quantity
	Consult instructions for use or consult electronic instructions for use		Telephone Number
	Contains sufficient for <n> tests		Temperature Limit
	Do not re-use		Use-By Date
	Do not use if package is damaged and consult instructions for use		

\* Please refer to product labels for applicable symbols.

## PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when:

- The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.
- If the rehydrated material is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

## NOTICE TO PURCHASERS

The purchase of this product allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of this product.

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## WEBSITE

Visit our website, [www.microbiologics.com](http://www.microbiologics.com), for current technical information and product availability.

## ASSISTANCE



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Additional copies of this product insert may be obtained at [www.microbiologics.com](http://www.microbiologics.com) or by emailing [info@microbiologics.com](mailto:info@microbiologics.com)

## ILLUSTRATED INSTRUCTIONS

Each kit consists of 6 individually packaged lyophilized swabs.

**1** Preparation



Read package insert, instructions for use or lab protocol for the applicable nucleic acid extraction or antigen detection assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.

**2**



Tear open pouch at notch.


**3**



Remove swab from pouch and process further using instructions A through C below. Consult assay product insert for guidance on processing QC samples and patient samples.

### A. Instructions for Antigen Detection Assay

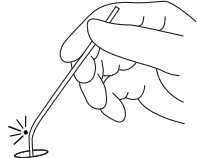
**4**



Read package insert for the antigen detection assay; follow instructions included with the assay, using any supplied reagents accordingly.

### B. Instructions for Direct Inoculation with Dry or Pre-Wet Swab

**4**



Insert the dry or pre-wet swab into the cartridge.

If directed by the assay instructions, break the swab by snapping the shaft.

**5**

Process following diagnostic assay instructions for use.

### C. Instructions for Placing Swab into a Vial or Tube of Hydrating Fluid

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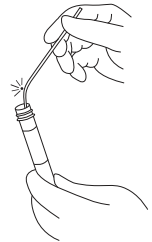
Place swab into a vial of hydrating fluid.

For sample volume and known extrinsic factors and interfering substances, please refer to Table 2.



5

Break the swab by lifting the swab a few millimeters from the bottom of the vial and pushing the shaft of the swab against the rim to break it.

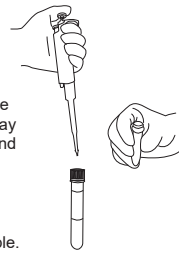


6



Recap the vial; mix by inversion, shaking or vortex per assay instructions, or until swab is hydrated.

7



Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

8

Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.



## REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	12.JUL.2021	Initial Release