

# INSTRUCTIONS FOR USE



## HE0063S SARS-CoV-2 Process Control (Swab)

### INTENDED USE

SARS-CoV-2 Process Control (Swab) is intended for use as an external, non-viable control material to evaluate the performance of nucleic acid tests that detect SARS-CoV-2 virus. 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 Process Control (Swab) contains RNA transcripts that include diagnostically relevant SARS-CoV-2 targets listed in Table 1 (including CDC and WHO consensus sequences). The RNA transcripts are encapsulated in phage protein providing close similarity to a patient sample and increased stability over naked RNA. Additionally, each swab contains human A549 cells.

The product allows laboratories to validate the entire process of a molecular assay including extraction, reverse transcription, amplification, and detection. It is nuclease resistant and can be spiked into nuclease-rich patient samples such as nasal secretions or plasma.

Table 1: SARS-CoV-2 Process Control target regions

Genomic Region	Targets
Orf 8	Complete genomic region for gene
RdRP	5 targets including IP2 and IP4
S (Spike)	Orf1b, Pancorona, and other targets
M (Membrane Protein)	Complete genomic region for gene
E (Envelope)	Complete genomic region for gene
N (Nucleocapsid)	Complete genomic region for gene

### COMPOSITION

SARS-CoV-2 Process Control (Swab) is comprised of encapsulated RNA transcripts containing diagnostically relevant SARS-CoV-2 genomic targets and human A549 cells. The SARS-CoV-2 Process Control (Swab) is lyophilized in a PCR compatible patient-relevant matrix. The product consists of five individually packaged lyophilized swabs.

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- Do not open foil pouch until ready to rehydrate and store/use.
- Possible eye and skin irritant.
- Refer to the 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 **320.229.7045** or U.S. Toll Free **1.866.286.6691**.
- The SARS-CoV-2 Process Control (Swab) does not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- The SARS-CoV-2 Process Control (Swab) is not made with natural rubber latex.
- Always wear a lab coat, safety glasses, and disposable gloves when using the SARS-CoV-2 Process Control (Swab).



## **MATERIALS REQUIRED BUT NOT PROVIDED** \_\_\_\_\_

- 1.5-ml microcentrifuge tubes
- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Pipettors capable of delivering 0.5-1000µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex (optional)
- Microcentrifuge (optional)

## **INSTRUCTIONS FOR USE** \_\_\_\_\_

1. Read assay package insert, instructions for use, or applicable lab protocol. 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. Remove swab from pouch and place into a vial of hydrating fluid.
  - a. Minimum hydration volume of 300 µl is required for complete hydration of the swab. Please note, the swab will absorb some of the hydration fluid.
  - b. Note: The swab may be hydrated in liquid or processed directly following diagnostic assay instructions for use.
3. Break the swab by snapping the shaft - lift the swab a few millimeters from the bottom of the vial and push against the rim to break it.
4. Recap the vial and vortex or shake vigorously for 10 seconds or until swab is hydrated.
  - a. Rehydrated material may be stored at 4 °C and used up to 5 days after hydration. Mix before use.
5. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
6. Note: Each swab is intended as a single use test. Dilutions may be performed and used immediately.

## **STORAGE AND EXPIRATION** \_\_\_\_\_

SARS-CoV-2 Process Control (Swab) should be stored at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch rehydrate and use/store immediately.

SARS-CoV-2 Process Control (Swab) should not be used if:

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














## **LIMITATIONS** \_\_\_\_\_

This product may not be suitable for use with all kits and procedures. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s).

## **MICROBIOLOGICAL STATE** \_\_\_\_\_

The SARS-CoV-2 nucleic acids in the synthetic RNA Process Control are not derived from cultured virus. No viable material is present.

## KEY OF SYMBOLS

	Batch Code (Lot)		Manufacturer
	Catalog Number		Temperature Limitation
	Caution, Consult Accompanying Documents		Use By
	Contains sufficient for <n> tests		Refer to Instructions for Use
	In Vitro Medical Device		Telephone Number
	Authorized Representative in the European Community		CE Mark
			Quantity

## PRODUCT WARRANTY

- These products are warranted 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.

## NOTICE TO PURCHASERS

The purchase of this product allows the purchaser to use it for In Vitro Diagnostics Use, 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.

**Purchaser shall not attempt to modify or reverse-engineer (or otherwise determine the chemical structure or sequence of) the product.**

This molecular standard is designed to be used as a positive control in assays using PCR or reverse transcription PCR where primer and/or probe sequences sufficiently hybridize to the standard. Quantitation of the template may vary by assay or instrument platform.

The Microbiologics logo and **Helix Elite™** are registered trademarks of Microbiologics, Inc. The PCR process is covered by patents owned by Roche Molecular Systems, Inc. and F. Hoffmann-La Roche, Ltd. Practice of the patented PCR process requires a license. All other trademarks are the sole property of their respective owners.

## WEBSITE ---

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

## ACKNOWLEDGEMENTS ---



### **Microbiologics, Inc.**

200 Cooper Avenue North  
St. Cloud, MN 56303 USA

### **Customer Service**

Tel. 320-253-1640  
U.S. Toll Free 800-599-BUGS (2847)  
Email [info@microbiologics.com](mailto:info@microbiologics.com)

### **Technical Support**

Tel. 320-229-7045  
U.S. Toll Free 866-286-6691  
Email [techsupport@microbiologics.com](mailto:techsupport@microbiologics.com)  
[www.microbiologics.com](http://www.microbiologics.com)



### **Medimark® Europe**


11, rue Emile Zola B.P. 2332  
38033 Grenoble Cedex 2, France  
Tel. 33 (0)4 76 86 43 22  
Fax. 33 (0)4 76 17 19 82  
E.post. [info@medimark-europe.com](mailto:info@medimark-europe.com)



## ILLUSTRATED INSTRUCTIONS

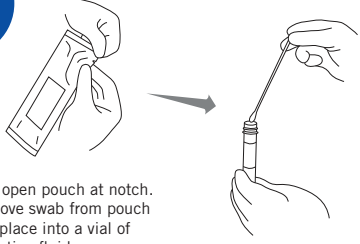
Each kit consists of 5 individually packaged lyophilized swabs.

**1**



Read assay package insert, instructions for use, or applicable lab protocol. 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. Remove swab from pouch and place into a vial of hydrating fluid.

Minimum hydration volume of 300ul is required for complete hydration of the swab. Please note, the swab will absorb some of the hydration fluid.

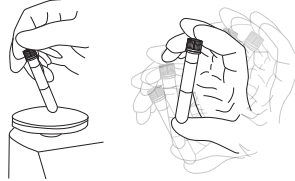
Note: The swab may be hydrated in liquid or processed directly following diagnostic assay instructions for use.

**3**



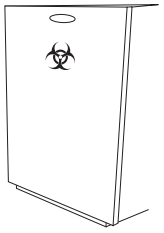
Break the swab by snapping the shaft - lift the swab a few millimeters from the bottom of the vial and pushing against the rim to break it.

**4**

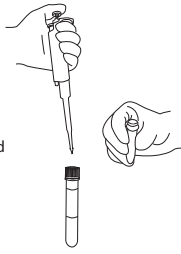


Recap the vial and vortex or shake vigorously for 10 seconds or until swab is hydrated.

Rehydrated material may be stored at 4°C and used up to 5 days after hydration. Mix before use.



**5**



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

**6**

Note: Each swab is intended as a single use test. Dilutions may be performed and used immediately.