

INSTRUCTIONS FOR USE

IVD

■ Inactivated SARS-CoV-2 Variant Whole Virus controls (Swab)

INTENDED USE

The Inactivated SARS-CoV-2 Variant Whole Virus controls are intended for use as non-viable, external, positive control material to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Annex 1. These products have no qualitative or quantitative assigned value. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen.

SUMMARY AND PRINCIPLES

The Inactivated SARS-CoV-2 Variant Whole Virus controls can be used to monitor the extraction, amplification and detection process of molecular testing assays that include the analytes in Annex 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 Inactivated SARS-CoV-2 Variant Whole Virus controls consist of 6 individually packaged lyophilized swabs. The analytes in Annex 1 have been inactivated using irradiation, chemical, and/or thermal treatments.

The Inactivated SARS-CoV-2 Variant Whole Virus controls are 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.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the assay.
- The inactivated lyophilized swabs are single-use only. Once hydrated, do not freeze for reuse.
- Do not open foil pouch until ready to use.
- Although these products have been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. These products must be treated as a potential biohazard. 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 or by contacting Technical Support at 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- These products are 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

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


HELIX|ELITE™
MOLECULAR STANDARDS

INSTRUCTIONS FOR USE

Preparation

1. Read package insert, instructions for use or lab protocol for the applicable 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 or B below. Consult assay product insert for guidance on processing QC samples and patient samples.

A. 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's instructions, break the swab by snapping the shaft.
5. Process following diagnostic assay instructions for use.

B. 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 and vortex or shake vigorously for 10 seconds 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.
 - a. Remaining rehydrated material may be stored at 25°C and used up to 8 days after hydration. Mix before use.
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
Nuclease-Free Water	300 µl	Vortex or shake vigorously for 10 seconds	N/A
Phosphate-Buffered Saline (PBS)	300 µl	Vortex or shake vigorously for 10 seconds	N/A
Sample Transport Medium	300 µl	Vortex or shake vigorously for 10 seconds	N/A

STORAGE AND EXPIRATION

Store the Inactivated SARS-CoV-2 Variant Whole Virus controls at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately. In-use stability of the rehydrated swab at room temperature (25°C) is 8 days.

The Inactivated SARS-CoV-2 Variant Whole Virus controls 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-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified 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

These products are unassayed control materials. They 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 these products 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

These products were prepared using suitable inactivation methods. While the products have 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 these products allows the purchaser to use them 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 these products.

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WEBSITE

Visit our website, www.microbiologics.com, for current technical information and product availability.

ASSISTANCE



Microbiologics, Inc.

200 Cooper Avenue North
St. Cloud, MN 56303 USA
www.microbiologics.com

Technical Support

Tel: 320-229-7045
U.S. Toll Free: 866-286-6691
Email: techsupport@microbiologics.com

Customer Service

Tel: 320-253-1640
U.S. Toll Free: 800-599-2847
Email: info@microbiologics.com

Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing 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 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 or B below. Consult assay product insert for guidance on processing QC samples and patient samples.

A. 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's instructions, break the swab by snapping the shaft.

5

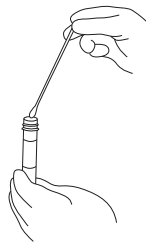
Process following diagnostic assay instructions for use.

B. Instructions for Placing Swab into a Vial of Hydrating Fluid

4

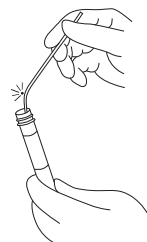
Place swab into a vial of hydrating fluid.

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

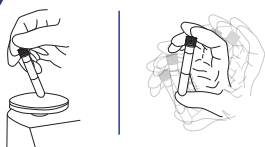


5

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

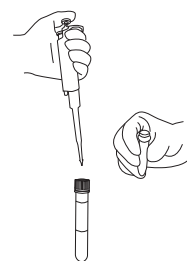


Recap the vial and vortex or shake vigorously for 10 seconds or until swab is hydrated.

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

Remaining rehydrated material may be stored at 25°C and used up to 8 days after hydration. Mix before use.



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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
B	09.AUG.2021	Revised all mentions of product name to encompass all SARS-CoV-2 Variant swab controls. Removed Table 1. Added Annex 1.

ANNEX 1 SUMMARY OF ANALYTES

Item #	Item Name	Analytes	Input Concentration (copies/pellet):
HE0072NS	Inactivated SARS-CoV-2 B.1.1.7 Whole Virus (Swab)	Severe Acute Respiratory Syndrome Coronavirus 2 Isolate USA/CA_CDC_5574/2020 B.1.1.7 Human lung epithelial cells	10 ⁴ - 10 ⁵
HE0074NS	Inactivated SARS-CoV-2 B.1.351 Whole Virus (Swab)	Severe Acute Respiratory Syndrome Coronavirus 2 Isolate South Africa/KRISP-EC-K005321/2020 Lineage B.1.351 Human lung epithelial cells	10 ⁴ - 10 ⁵