

# INSTRUCTIONS FOR USE



## ■ HE0065N Inactivated SARS-CoV-2 Whole Virus (Pellet)

### INTENDED USE

Inactivated SARS-CoV-2 Whole Virus (Pellet) 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

Inactivated SARS-CoV-2 Whole Virus (Pellet) contains Severe Acute Respiratory Syndrome Coronavirus 2 isolate USA/WA1/2020. This control can be used to monitor the extraction, amplification and detection of SARS-CoV-2 molecular testing assays. Routine use of quality controls monitor test variation, lot to lot test kit performance, operator performance, and aid in identifying random or systemic error.

### COMPOSITION

Inactivated SARS-CoV-2 Whole Virus (Pellet) is comprised of cultured and inactivated Severe Acute Respiratory Syndrome Coronavirus 2 isolate USA/WA1/2020, and human A549 cells. The SARS-CoV-2 virus has been inactivated using chemical and heat treatments, and the A549 cells have been inactivated using thermal treatment. The viral particles are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The solution is lyophilized into a pellet. The product consists of five individually packaged pellets and five vials of molecular standard water.

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines. Although this product has been inactivated; there is no known test or inactivation method that can assure that this product will not transmit infection.
- Wear proper personal protective equipment.
- 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 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- This product does not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- This product is not made with natural rubber latex.
- Customer is responsible for ensuring compatibility of the control with the assay or protocol in use.



## **MATERIALS REQUIRED BUT NOT PROVIDED**

- 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 vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Tip the lyophilized pellet into the provided 1.5ml vial of hydrating fluid.
4. Recap the vial and shake vigorously until pellet is completely dissolved.
  - a. Alternatively, vortex the vial for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial.
  - a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the tube.
6. 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 4°C and used up to 5 days after hydration. Mix before use.
7. Once hydrated, each vial may be used for a maximum of 5 uses/vial. Number of uses is dependent upon appropriate volume for the assay being performed.

## **STORAGE AND EXPIRATION**

Store the Inactivated SARS-CoV-2 Whole Virus (Pellet) at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch use the pellet immediately.

Inactivated SARS-CoV-2 Whole Virus (Pellet) 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**

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

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

## ACKNOWLEDGEMENTS



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## ILLUSTRATED INSTRUCTIONS


Each kit consists of 5 individually packaged lyophilized pellets and 5 vials of molecular standard water for rehydration.

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



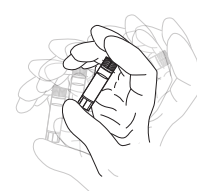
Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

3




Tip the lyophilized pellet into the provided 1.5ml vial of hydrating fluid.

4




Recap the vial and shake vigorously until pellet is completely dissolved.

Alternatively, vortex the vial for 10 seconds at full speed to mix.

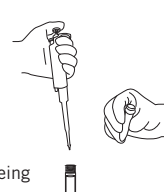


5



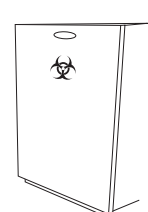
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6



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 4°C and used up to 5 days after hydration. Mix before use.



7

Once hydrated, each vial may be used for a maximum of 5 uses/vial. Number of uses is dependent upon appropriate volume for the assay being performed.