

INSTRUCTIONS FOR USE



HE0062S SARS-CoV-2 Process Control (Pellet)

INTENDED USE

SARS-CoV-2 Process Control (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

The SARS-CoV-2 Process Control (Pellet) 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 pellet 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 (Pellet) is comprised of encapsulated RNA transcripts containing diagnostically relevant SARS-CoV-2 genomic targets and human A549 cells. The SARS-CoV-2 Process Control (Pellet) is lyophilized in a PCR compatible patient-relevant matrix. Each kit also contains molecular standard water for rehydration to ensure the stability and purity of the standard.

The product consists of five individually packaged pellets and five vials of molecular standard water.

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 Microbiology website at www.microbiology.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 (Pellet) does not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- The SARS-CoV-2 Process Control (Pellet) 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 (Pellet).



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 vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Tip the lyophilized pellet into provided 1.5 ml 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

SARS-CoV-2 Process Control (Pellet) 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 (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

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, 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



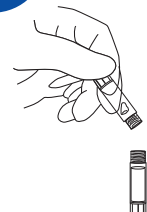
Read assay package insert, instructions for use, or applicable lab protocol. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.

2



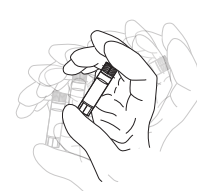
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3




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

4

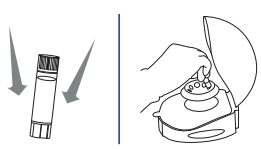


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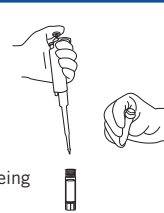


5



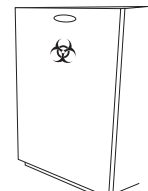
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