SARS-CoV-2

Choosing the Right Control for Your Application

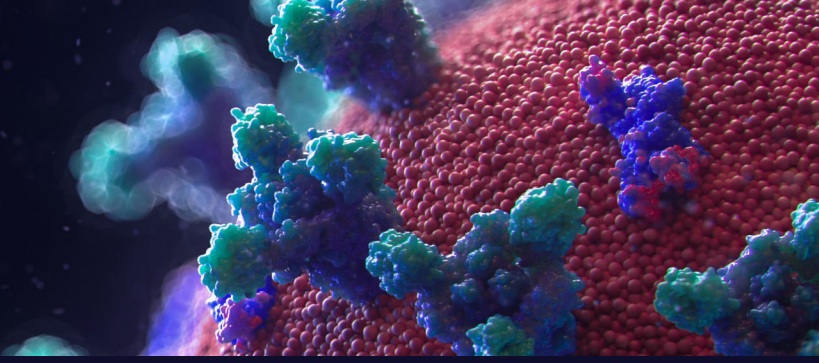

Photo: Fusion Medical Animation Ltd.

Microbiologics IVD SARS-CoV-2 Product Portfolio

COVID-19 has been a disruptive force worldwide. Diagnostic manufacturers and clinical laboratories have responded to the shear enormity of the pandemic with a proliferation of tests that have different sample collection methods and gene targets, among other differences. In the age of Emergency Use Authorization, it's crucial to implement an independent control that challenges your molecular applications. The question remains, **what control do I use and when?**

Microbiologics provides the independent QC you need to streamline your workflow with reliable results.

Table 1. IVD SARS-CoV-2 Product Portfolio

Helix Elite Product Name	SARS-CoV-2 Synthetic RNA (N Gene Targets)	SARS-CoV-2 Synthetic RNA (N/E/RdRp/S Gene Targets)	SARS-CoV-2 Process Control (Pellet)	SARS-CoV-2 Process Control (Swab)	Inactivated SARS-CoV-2 Whole Virus (Pellet)	Inactivated SARS-CoV-2 Whole Virus (Swab)
Helix Elite Catalog Number	**HE0060S**	**HE0061S**	**HE0062S**	**HE0063S**	**HE0065N**	**HE0066NS**
Gene Targets	* N1, N2 & N3	* N/E/RdRp/S	* Orf1ab/RdRP/S/E/ ORF8/M/N	* Orf1ab/RdRP/S/E/ ORF8/M/N	Full genome	Full genome
Format	Dried Synthetic RNA	Dried Synthetic RNA	Synthetic RNA encapsulated in a phage protein envelope and inactivated A549 lung epithelial cells Lyophilized Pellet	Synthetic RNA encapsulated in a phage protein envelope and inactivated A549 lung epithelial cells Lyophilized Swab	Inactivated whole virus and A549 lung epithelial cells Lyophilized Pellet	Inactivated whole virus and A549 lung epithelial cells Lyophilized Swab
Kit Configuration	1 vial of dried synthetic RNA & 1 vial (1.5ml) of molecular standard water	1 vial of dried synthetic RNA & 1 vial (1.5ml) of molecular standard water	5 individually packaged lyophilized pellets & 5 vials (1.5ml each) of molecular standard water	5 individually packaged swabs	5 individually packaged lyophilized pellets & 5 vials (1.5ml each) of molecular standard water	6 individually packaged swabs
Storage	2-25 degrees C	2-25 degrees C	2-25 degrees C	2-25 degrees C	2-25 degrees C	2-25 degrees C
In Use Stability	Aliquots can be stored at -20 degrees C Thawed aliquots are single-use	Aliquots can be stored at -20 degrees C Thawed aliquots are single-use	5 days hydrated at 4 degrees C Multi-use	5 days hydrated at 4 degrees C Single-use	5 days hydrated at 4 degrees C Multi-use	5 days hydrated at 4 degrees C Single-use
Purpose	Quality control for amplification/detection	Quality control for amplification/ detection	Quality control for extraction, amplification and detection	Quality control for extraction, amplification and detection	Quality control for extraction, amplification and detection	Quality control for extraction, amplification and detection
Target Concentration (copies per pellet/swab)	$1x10^6$	$1x10^6$	$1x10^5$	$1x10^5$	$1x10^5$	$1x10^5$

*Refer to **Table 2** for ***Nucleotide sequences highlighted in the Synthetic RNA and Process Controls***

Microbiologics

Consistent, Accurate Results Start with the Right Controls & the Right Knowledge

Table 2. Illustrates the nucleotide sequences highlighted in the Synthetic RNA and Process Controls (Catalog number HE0060S, HE0061S, HE0062S and HE0063S)

Helix Elite Catalog Number	HE0060S	HE0061S	HE0062S	HE0063S
Genomic Region	**Targets**			
Orf 8	NA	NA	Complete genomic region for gene: 14,250 ..14,450	Complete genomic region for gene: 14,250 ..14,450
Orf1ab/RdRP	NA	IP2, IP4, and one additional WHO consensus sequences: 12,640 ..12,825 13,440 ..16,238	5 targets including IP2 and IP4: 12,690 ..12,797 13,342 ..13,460 14,080 ..14,186 14,250 ..14,450 15,431 ..15,530	5 targets including IP2 and IP4: 12,690 ..12,797 13,342 ..13,460 14,080 ..14,186 14,250 ..14,450 15,431 ..15,530
S (Spike)	NA	Orf1b, Pancorona, and other targets: 21,562 ..25,384	Orf1b, Pancorona, and other targets: 18,778 ..18,909 24,354 ..24,900	Orf1b, Pancorona, and other targets: 18,778 ..18,909 24,354 ..24,900
M (Membrane Protein or Matrix)	NA	NA	Complete genomic region for gene: 26,496 ..27,215	Complete genomic region for gene: 26,496 ..27,215
E (Envelope)	NA	Complete genomic region for gene: 26,245 ..26,472	Complete genomic region for gene: 26,245 ..26,427 26,269 ..26,381	Complete genomic region for gene: 26,245 ..26,427 26,269 ..26,381
N (Nucleocapsid)	Complete genomic region for gene: 28,237..29,280	Complete genomic region for gene: 28,237..29,280	Complete genomic region for gene: 28,237 ..29,280	Complete genomic region for gene: 28,237 ..29,280

To learn more about our complete line of QC, including our negative controls and RUO high-titer SARS-CoV-2 materials, visit our SARS-CoV-2 product page at **www.microbiologics.com**.

Contact us to learn more:
320.253.7400
1.800.599.2847
info@microbiologics.com

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INSTRUCTIONS FOR USE

CE

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 Microbiologics
- website at **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 (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).

HELIX|ELITE™ MOLECULAR STANDARDS

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
EC REP	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.

WEBSITE

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

ACKNOWLEDGEMENTS

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Fax. 33 (0)4 76 17 19 82

E.post. info@medimark-europe.com

HELIX | ELITE™
MOLECULAR STANDARDS

ILLUSTRATED INSTRUCTIONS

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

1

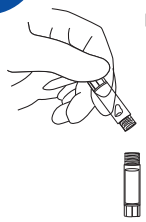
Read assay package insert, instructions for use, or applicable lab protocol. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.

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.

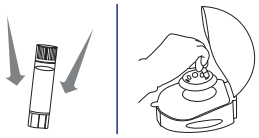


4

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

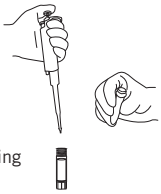
Alternatively, vortex the vial for 10 seconds at full speed to mix.

5



If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial. 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.

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.

INSTRUCTIONS FOR USE

IVD CE

Helix Elite™ Molecular Standards (Inactivated Pellet) Products

- Helix Elite™ Molecular Standards (Inactivated Pellet)
- QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet)

HELIX | ELITE™ MOLECULAR STANDARDS

Microbiologics® QC SETS AND PANELS

INTENDED USE

Helix Elite™ Molecular Standards (Inactivated Pellet) and QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet) are intended for use as external controls for qualitative detection by molecular assays.

SUMMARY AND EXPLANATION

Molecular tests offer rapid and accurate results regarding the presence of an organism. Proper interpretation of a molecular test requires the use of a control. Helix Elite™ Molecular Standards (Inactivated Pellet) Products are easy-to-use process controls that can be used to monitor the extraction, amplification, and detection of molecular assays or instruments. These independent controls may also be used in evaluation of laboratory proficiency and training, or determination of the lot-to-lot consistency of assay consumables as directed by various regulatory requirements and standards.

PRINCIPLES

Helix Elite™ Molecular Standards (Inactivated Pellet) Products are comprised of cultured organisms inactivated by chemical, radiological, or heat treatments. Each pellet is packaged in a single-use foil pouch. Users should follow assay manufacturer or laboratory procedures for processing controls.

COMPOSITION

Helix Elite™ Molecular Standards (Inactivated Pellet) Products consist of individually packaged control material that contain inactivated pathogen(s) stabilized in a proprietary matrix of excipients.

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.
- See *QC Sets and Panels: Technical Information* document at www.microbiologics.com for known extrinsic factors and interfering substances for each catalog number.
- 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.
- 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 or by contacting Technical Support at 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- These products do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- These products are not made with natural rubber latex.
- Not all instruments and assays are compatible with multi-target controls. 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
- Rehydration buffer such as nuclease-free water, phosphate-buffered saline (PBS), sample preparation reagent, or transport medium as required by assay to be performed
- Pipettors capable of delivering 0.5-1000µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex
- Microcentrifuge

INSTRUCTIONS FOR USE

Preparation

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.
3. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

A. Helix Elite™ Molecular Standards (Inactivated Pellet)

4. Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 µl is recommended.
5. Vortex the vial for 10 seconds at full speed to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.
6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

B. QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet)

4. Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water. For minimum hydration volume:
   - Refer to the catalog number's product page at www.microbiologics.com or to the *QC Sets and Panels: Technical Information* document at www.microbiologics.com, or
   - Contact Technical Support at 320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com.
5. Vortex the rehydrated pellet for 10 seconds or until pellet is dissolved.

6. Use the appropriate volume of the rehydrated pellet for the assay being performed and follow laboratory protocols or manufacturer instructions for processing the sample. **Note:** Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

STORAGE AND EXPIRATION

Store the Helix Elite™ Molecular Standards (Inactivated Pellet) Products at 2°C - 25°C in the original packaging up to the indicated expiration date*. After opening the foil pouch use the pellet immediately.

Helix Elite™ Molecular Standards (Inactivated Pellet) Products should not be used if:

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

*Note: catalog numbers 8180, 8181, 8184 and 8198 are to be stored at 2°C - 8°C in the original packaging up to the indicated expiration date.

LIMITATIONS

This product may not be suitable for use with all kits and procedures. Only primers and probes that hybridize to sequences of the extracted nucleic acids of the organism should be expected to yield a positive reaction.

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

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

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

WEBSITE

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

ACKNOWLEDGEMENTS

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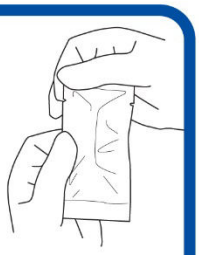
ILLUSTRATED INSTRUCTIONS

Preparation

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

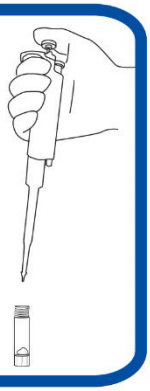


Tear open pouch at notch.

3 Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

A. Helix Elite™ Molecular Standards (Inactivated Pellet)

4 Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 µl is recommended.



5 Vortex the vial for 10 seconds at full speed to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.

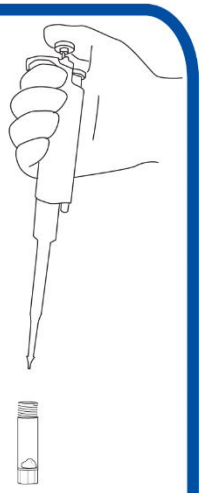
6 Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

B. QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet)

4

Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water.



For minimum hydration volume:

- Refer to the catalog number's product page at www.microbiologics.com or to the *QC Sets and Panels: Technical Information* document at www.microbiologics.com, or
- Contact Technical Support at 320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com.

5

Vortex the vial for 10 seconds at full speed to mix.

6

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

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

Microbiologics®
A safer, healthier world.