

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 sheer 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)	SARS-CoV-2 Whole Virus Antigen Control (Swab)
Helix Elite Catalog Number	HE0060S	HE0061S	HE0062S	HE0063S	**	**	HE0068AG
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	Inactivated whole virus containing full genome and intact SARS-CoV-2 antigens
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	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	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	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 25 degrees C Multi-use	5 days hydrated at 25 degrees C Single-use	8 days hydrated at 25 degrees C Multi-use	8 days hydrated at 25 degrees C Single-use	6 hours after opening foil pouch at 2-25 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	Quality control for extraction, amplification and detection in nucleic acid testing and for the detection of SARS-CoV-2 antigens
Target Concentration (copies per pellet/swab)	1x10 ⁶	1x10 ⁶	1x10 ⁵	1x10 ⁵	1x10 ⁵	1x10 ⁵	1x10 ⁴ - 1x10 ⁷

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

** SARS-CoV-2 whole virus variants now available. Visit [Microbiologics.com](https://www.microbiologics.com) to learn more.

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	Target Location in Genome (All positions in reference to GenBank Acc. NC_045512.2)			
Orf8	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.

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