

# INSTRUCTIONS FOR USE

## (RUO)

- **R9000 SARS-CoV-2 Process Control (Pellets)**
- **R9001 SARS-CoV-2 Process Control (Swabs)**

### DESCRIPTION ---

The SARS-CoV-2 Process Control (Pellets/Swabs) is manufactured under ISO standard 13485:2016 compliant systems, with RNA transcripts containing diagnostically relevant SARS-CoV-2 targets (CDC and WHO consensus sequences), encapsulated in a phage protein. Additionally, each pellet/swab contains human respiratory epithelial 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: list of the target within each pellet/swab

| Genomic Region   | Included Nucleotides (NC_045512.2)                                       |
|------------------|--|
| Orf1ab/RdRP      | 12,690 ..12,797<br>13,342 ..13,460<br>14,080 ..14,186<br>15,431 ..15,530 |
| S (Spike)        | 18,778 ..18,909<br>24,354 ..24,900                                       |
| E (Envelope)     | 26,245 ..26,427<br>26,269 ..26,381                                       |
| N (Nucleocapsid) | 28,237 ..29,280  |

The SARS-CoV-2 Process Control (Pellets/Swabs) consists of 6 individually packaged pellets or swabs, with at least 10<sup>3</sup> copies of RNA SARS-CoV-2/pellet or swab and at least 10<sup>3</sup> human respiratory epithelial cells, as measured using reverse transcription digital droplet PCR (RT-ddPCR).



**IMPORTANT NOTE:** the product has no assigned Value. The values provided are specific to Microbiologics assay used for the quantification, and are dependent on the analytical procedure, the nucleic acid extraction and molecular assay used, as well as the standards used to calibrate and validate the specified molecular procedure

## STORAGE AND EXPIRATION ---

Store the pellet/swab at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening use the swab or pellet immediately.

## INSTRUCTIONS FOR USE ---

This material must go through extraction, similar to a patient sample

### **Pellet**

- Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water.
- Vortex the rehydrated pellet for 10 seconds or until pellet is dissolved.
- 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.

### **Swab**

- Tear open the foil pouch containing the quality control swab at the notch.
- Remove the swab from the pouch.
- Rehydrate the swab in a method appropriate to the assay and follow laboratory protocols or manufacturer's instructions for processing the sample.

**Note:** Each swab 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.

