

INSTRUCTIONS FOR USE



■ QC Panels for Nanosphere Verigene®

INTENDED USE

Microbiologics® QC Panels for the Nanosphere Verigene® contain lyophilized, inactivated combinations of specific microorganisms. They are intended to be used as an extraction, analysis control for each of the targets recognized by the applicable Nanosphere Verigene® test.

SUMMARY AND EXPLANATION

Microorganisms with known and predictable characteristics are used in verification, validation, and quality control of molecular instruments.

PRINCIPLE

Each pellet contains inactivated microorganism(s) in a lyophilized pellet. The lyophilized pellet is dissolved and then processed by the Nanosphere Verigene as a patient sample. Nucleic acid from the inactivated microorganism(s) are extracted and target sequences detected using specific primers and probes.

COMPOSITION

A pooled preparation consisting of inactivated microorganisms that are lyophilized in a proprietary blend of cryopreservatives and bulking agents to stabilize the cellular and genetic material. This product also contains skim milk and gelatin.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- 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 **866.286.6691**.
- The material in this device has been inactivated. However, universal precautions for handling infectious materials should be followed.
- Proper techniques must be employed to avoid exposure and contact with material in the device.
- The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of this material.
- Only trained laboratory personnel should use these devices.
- Microbiologics products and packaging do not contain natural rubber latex.



INSTRUCTIONS FOR USE

1. Prepare Verigene® cartridge and reagents per manufacturer's instructions.
2. Tear open the foil pouch and remove the vial containing 1 lyophilized pellet.
3. Remove the cap from the pellet vial and rehydrate with the appropriate volume (see specifications below). Immediately recap vial.

QC Set or Panel	Rehydration	Volume
Cat #8180 Nanosphere Verigene® Gram-Positive Blood Culture Control Panel	Sterile Saline or Blood Culture Medium	500 µl
Cat #8181 Nanosphere Verigene® Gram-Negative Blood Culture Control Panel	Sterile Saline or Blood Culture Medium	1,000 µl
Cat #8184 Nanosphere Verigene® Enteric Pathogen Control Panel	Stool Prep Buffer	300 µl
Cat #8198 Nanosphere Verigene® Respiratory Pathogens <i>Flex</i> Control Panel	Sterile Saline or Viral Transport Medium	250 µl

4. Vortex until pellet has completely dissolved and suspension is homogeneous.
5. Follow manufacturer's instructions and transfer the recommended volume to the Extraction Tray Sample Loading Well.
6. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

MATERIALS REQUIRED BUT NOT PROVIDED

- Uninoculated blood culture medium, sterile saline, stool prep buffer or phosphate buffer for the hydration of the lyophilized pellet (see rehydration/volume specifications in the "Instructions for Use" section for more information)
- Sterile pipettes

STORAGE AND EXPIRATION

Store Microbiologics® QC Panels for the Nanosphere Verigene® at 2°C-8°C in the original, sealed pouch containing the desiccant. Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.

Microbiologics® QC Panels for the Nanosphere Verigene® should not be used if:

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

QUALITY CONTROL

Consult laboratory SOP or manufacturer instructions for quality control needs.

RESULTS

Each control provides inactivated material for presence/absence detection of select targets by specific Nanosphere Verigene® tests. Refer to TIB.2024 Microbiologics® QC Panels: Detection Results for the Nanosphere Verigene® for more information.

LIMITATIONS

Microbiologics® QC Panels are configured to work with Nanosphere Verigene® tests only. They may not be suitable for other diagnostic platforms.

KEY OF SYMBOLS

	Batch Code (Lot)
	Catalog Number
	Caution, Consult Accompanying Documents
	Contains Sufficient for < n > Tests
	<i>In Vitro</i> Diagnostic Medical Device
	Manufacturer
	Consult Instructions for Use
	Temperature Limitation
	Use By

PRODUCT WARRANTY

- These products are covered under warranty 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, product availability and biohazard cleanup.

ACKNOWLEDGEMENTS



Microbiologics, Inc.
200 Cooper Avenue North
St. Cloud, MN 56303 USA

Customer Service

Tel. 320.253.1640
U.S. Toll Free 800-599-BUGS (2847)
Email info@microbiologics.com

Technical Support

Tel. 320.229.7045
U.S. Toll Free 866.286.6691
Email techsupport@microbiologics.com
www.microbiologics.com

QC Panels for the Nanosphere Verigene®

ILLUSTRATED INSTRUCTIONS

1

Prepare Verigene® cartridge and reagents per manufacturer's instructions.

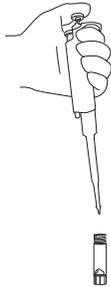
2



Tear open the foil pouch and remove the vial containing 1 lyophilized pellet.

3

Remove the cap from the pellet vial and rehydrate with the appropriate volume (see specifications below). Immediately recap vial.



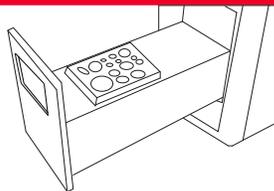
4

Vortex until pellet has completely dissolved and suspension is homogeneous.



5

Follow manufacturer's instructions and transfer the recommended volume to the Extraction Tray Sample Loading Well.



6

Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

REHYDRATION/VOLUME SPECIFICATIONS

QC Set or Panel	Rehydration	Volume
Cat #8180 Nanosphere Verigene® Gram-Positive Blood Culture Control Panel	Sterile Saline or Blood Culture Medium	500 µl
Cat #8181 Nanosphere Verigene® Gram-Negative Blood Culture Control Panel	Sterile Saline or Blood Culture Medium	1,000 µl
Cat #8184 Nanosphere Verigene® Enteric Pathogen Control Panel	Stool Prep Buffer	300 µl
Cat #8198 Nanosphere Verigene® Respiratory Pathogens <i>Flex</i> Control Panel	Sterile Saline or Viral Transport Medium	250 µl