INSTRUCTIONS FOR USE

IVD

■ **Quality Control Set for Nanosphere Verigene®**

INTENDED USE

Microbiologics® Quality Control Set for Nanosphere Verigene® contains lyophilized, inactivated combinations of specific microorganisms. It is intended to be used as a positive extraction, hybridization, and analysis control for each of the targets recognized by the applicable Nanosphere Verigene® test.

SUMMARY AND EXPLANATION

Reliable reference stock cultures are an essential part of a microbiology quality assurance program. Microorganisms with known and predictable characteristics may be used to evaluate the analytic performance of a test using patient specimens. Microbiologics® Quality Control Set contains inactivated microorganisms pooled together in a lyophilized pellet for stability and ease of handling. The lyophilized pellets may be dissolved in an appropriate clinical matrix (e.g., blood culture broth or saline) to provide a homogenenous suspension of bacteria ready for extraction. To limit adverse accumulations of moisture, each control is individually packaged.

PRINCIPLE

Microbiologics® Quality Control Set for Nanosphere Verigene® contains specific inactivated bacteria that serve as positive extraction and analysis controls for each of the targets recognized by the applicable Verigene® test. The lyophilized pellets are maintained in a proprietary blend of preservatives that when dissolved, provide a homogenenous suspension of bacteria ready for extraction. Each lyophilized pellet contains a mixture of microorganisms that allow cost-effective quality control of test consumables as well as staff proficiency.

COMPOSITION

A pooled preparation consisting of inactivated microorganisms ($\geq 10^6$ CFU/pellet) that are lyophilized in a proprietary blend of cryopreservatives (skim milk: bovine - USA origin, a carbohydrate, gelatin: porcine - USA or Canada origin, ascorbic acid) to stabilize the cellular and genetic material. The microorganisms that are included in each pool are listed on the vial and outer package labels.

Quality Control Set for Nanosphere Verigene®

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- This product is developed, manufactured, and distributed:
  - In compliance with the mandates of FDA: Quality System Regulation (QSR), 21CFR Part 820
  - In conformance with the elements of ISO 17025; ISO 13485
- Refer to the TIB.244 Microbiologics Lyophilized Microorganism Preparations 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 add 500 µL of sterile saline or blood culture medium. 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.

MATERIALS REQUIRED BUT NOT PROVIDED

- Uninoculated blood culture medium or sterile saline for the hydration of the lyophilized pellet
- Sterile pipettes are required to inoculate the medium/media to be challenged

STORAGE AND EXPIRATION

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

Microbiologics® Quality Control Set for 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. Detection is reported for genus, species and individual genes. Refer to TIB.2024 Microbiologics® QC Set Detection Results for Nanosphere Verigene® for more information.

LIMITATIONS

Microbiologics® Quality Control Set is configured to work with Nanosphere Verigene® tests only. It may not be suitable for other diagnostic platforms.

KEY OF SYMBOLS

Batch Code (Lot)

Catalog Number


Caution consult accompanying documents Attention, see instructions for use

In Vitro Medical Device


Manufacturer


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. The Certificate of Analysis is available by request from Customer Service or Technical Support.

ACKNOWLEDGEMENTS

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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

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U.S. Toll Free 866.286.6691
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www.microbiologics.com

Quality Control Set for Nanosphere Verigene®

ILLUSTRATED INSTRUCTIONS

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3

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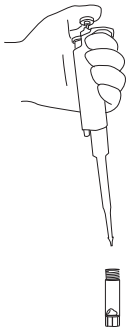
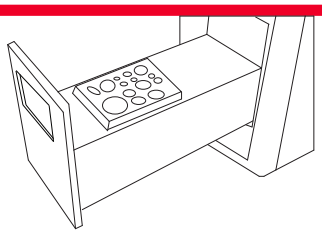


4

Vortex until pellet has completely dissolved and suspension is homogeneous.

5



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

Microbiologics®

A safer, healthier world.