

INSTRUCTIONS FOR USE

IVD

■ HE0059N Inactivated Zika Virus

INTENDED USE

Inactivated Zika Virus is intended for use as an external, non-viable control material to evaluate the performance of nucleic acid tests that detect Zika 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

Inactivated Zika Virus contains the Zika virus. This control can be used to monitor the extraction, amplification and detection of Zika molecular testing assays. Routine use of quality controls monitor test variation, lot to lot test kit performance, operator performance, and aid in identifying random or systemic error.

COMPOSITION

Inactivated Zika Virus is comprised of cultured Zika viral material inactivated by a chemical treatment. The preparation consists of individually packaged control material that contains inactivated pathogens stabilized in a proprietary matrix of excipients. The viral particles are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The solution is lyophilized into a pellet. The product consists of five individually packaged pellets.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only.
- Do not open foil pouch until ready to use.
- This product must be handled in accordance with Biosafety Level 1 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. Although this product has been inactivated; there is no known test or inactivation method that can assure that this product will not transmit infection.
- 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.
- This product does not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- This product is not made with natural rubber latex.

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 (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 material/this product.
2. Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Rehydrate the lyophilized pellet with the appropriate buffer.
 - a. A minimum volume of 100 μ l is recommended.
4. Recap the vial and vortex for 10 seconds at full speed to mix.
5. If 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.
7. 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 Inactivated Zika Virus at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch use the pellet immediately.

This product 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

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



Authorized Representative in the European Community



Contains sufficient for <n> tests



Batch Code (Lot)



In Vitro Diagnostic Medical Device



Consult Instructions for Use



Manufacturer



Catalog Number



Temperature Limitation



Caution, Consult Accompanying Documents



Use By



Do not re-use



Do not use if package is damaged and consult instructions for use.

* Please refer to product labels for applicable symbols.

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.
- If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

NOTICE TO PURCHASERS

The purchase of this product allows the purchaser to use it for 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.

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WEBSITE

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

ACKNOWLEDGEMENTS



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Technical Support

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ILLUSTRATED INSTRUCTIONS

Each kit consists of 5 individually packaged lyophilized pellets.

1



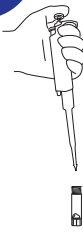
Read assay package insert, instructions for use, or applicable lab protocol. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC material/this product.

2



Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

3




Rehydrate the lyophilized pellet with the appropriate buffer.
A minimum volume of 100 μ l is recommended.

4



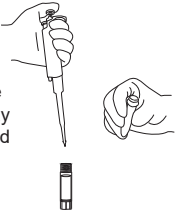
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