INSTRUCTIONS FOR USE

IVD

Synthetic Helix Elite™ Molecular Standards for use with the BD MAX™ Enteric Parasite Panel

INTENDED USE

Synthetic Helix Elite™ Molecular Standards are intended for use as positive control material in molecular applications.

SUMMARY AND EXPLANATION

Molecular diagnostic tests offer rapid and specific information regarding the presence and quantity of an organism. Development and proper interpretation of a molecular diagnostic test requires the use of a positive control. A positive control monitors the performance of a molecular assay or an operator. Synthetic Helix Elite™ Molecular Standards are nucleic acids that serve as positive control surrogate for microorganisms and viruses where target genomic material may be difficult or unsafe to obtain.

PRINCIPLES

Each synthetic Helix Elite™ Molecular Standard contains either DNA or RNA that corresponds to regions of the genome typically targeted in molecular assays. Only primer and probe sequences that hybridize to the Helix Elite™ Molecular Standard nucleic acid sequences will yield a positive reaction.

Synthetic Helix Elite™ Molecular Standards are dried with a PCR-compatible preservative and stable at 2°C-25°C through expiration date. Helix Elite™ molecular standard water is provided for rehydration and dilutions to ensure the stability and purity of the standard.

COMPOSITION

Synthetic Helix Elite™ Molecular Standards consist of synthetic DNA or RNA stabilized with Biomatrica® RNAstable® or DNAstable® as appropriate.

HELIX | ELITE™
MOLECULAR STANDARDS

Microbiologics®
A safer, healthier world.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- For professional use only.
- Do not open foil pouch until ready to rehydrate and use.
- Possible eye and skin irritant.
- Refer to the 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.
- Synthetic Helix Elite™ Molecular Standards do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Synthetic Helix Elite™ Molecular Standards are not made with natural rubber latex.
- Genetic material, especially RNA, can easily degrade. Always use appropriate lab practices to avoid contamination or loss of genetic material. Use only pyrogen-free tubes and tips.
- Synthetic Helix Elite™ Molecular Standards are appropriate positive controls when primers and probes sufficiently hybridize to the standard. See Certificate of Analysis for information on genetic target.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettors capable of handling 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Microcentrifuge with rotor for 1.5-ml tubes

INSTRUCTIONS FOR USE

1. Open the foil pouch and then centrifuge the synthetic Helix Elite™ Molecular Standard tube briefly before opening the tube.
2. Add 20 µl Helix Elite™ molecular standard water to the Helix Elite™ Molecular Standard tube. Centrifuge briefly to ensure all liquid is at the bottom of the tube.
3. Incubate the Helix Elite™ Molecular Standard tube at room temperature for 15 minutes to allow for complete rehydration.
4. Mix the hydrated Helix Elite™ Molecular Standard by gently pipetting up and down several times. Do not vortex as this may damage the nucleic acids.
5. Add 10 µl of the rehydrated synthetic Helix Elite™ Molecular Standard to the Sample Buffer Tube and follow manufacturer's instructions.
6. Discard the remaining material. Do not freeze and reuse.

STORAGE AND EXPIRATION

Synthetic Helix Elite™ Molecular Standards should be stored at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch rehydrate and use immediately.

Synthetic Helix Elite™ Molecular Standards 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.

MICROBIOLOGICAL STATE

The nucleic acids in the synthetic Helix Elite™ Molecular Standard are not derived from the target microorganism. No viable material is present.

KEY OF SYMBOLS

Batch Code (Lot)

Catalog Number


Caution consult accompanying documents Attention, see instructions for use


Counting


Health Hazard

In Vitro Medical Device


Manufacturer


Refer to Instructions for Use


Telephone Number


Temperature Limitation


Use By

PRODUCT WARRANTY

- These products are warranted 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

NOTICE TO PURCHASERS

The purchase of this product allows the purchaser to use it for In Vitro Diagnostics Use, 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. Purchaser shall not attempt to modify or reverse-engineer (or otherwise determine the chemical structure or sequence of) the product.

This quantitated molecular standard is designed to be used as a positive control in assays using PCR or reverse transcription PCR where primer and/or probe sequences sufficiently hybridize to the standard. Quantitation of the template may vary by assay or instrument platform. Users should recognize that this product is purified nucleic acid when considering its use as an extraction control.

WEBSITE

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

ACKNOWLEDGEMENTS

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Customer Service

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Technical Support

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Email techsupport@microbiologics.com
www.microbiologics.com

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ILLUSTRATED INSTRUCTIONS

Synthetic Helix Elite™ Molecular Standards include: 5 vials of synthetic DNA or RNA, 1 vial of molecular standard water and a Certificate of Authenticity

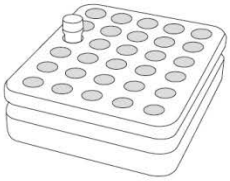
1

Open the foil pouch and then centrifuge the synthetic Helix Elite™ Molecular Standard tube before opening the tube to avoid loss of the dried material.

2

Add 20 µl Helix Elite™ molecular standard water to the Helix Elite™ Molecular Standard tube. Centrifuge briefly.

3



Incubate the Helix Elite™ Molecular Standard tube at room temperature for 15 minutes to allow for complete rehydration.

4

Mix the hydrated Helix Elite™ Molecular Standard by gently pipetting up and down several times. Do not vortex as this may damage the nucleic acids.

5

Add 10 µl of the rehydrated synthetic Helix Elite™ Molecular Standard to the Sample Buffer Tube and follow manufacturer's instructions.

6

Discard remaining material. Do not freeze and reuse.

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