INSTRUCTIONS FOR USE

CE IVD

Helix Elite™ Molecular Standards

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 a microorganism (e.g., bacterium, parasite, virus, etc). Development and proper interpretation of a molecular diagnostic test requires the use of a positive control. A positive control confirms the proper performance of a molecular assay and operator. Synthetic **Helix Elite™ Molecular Standards** are nucleic acids created for use as positive control surrogates for various 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 in the organism genome that are typically targeted in molecular diagnostic 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 proprietary stabilizing preservative that is PCR compatible. **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** consists of:

Synthetic DNA or RNA	Stabilized with Biomatrica® RNAstable® or DNAstable® as appropriate	Molecular Standard Water

HELIX | ELITE™
MOLECULAR STANDARDS

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WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- For professional use only.
- Do not open foil pouch until ready to rehydrate and store/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.
- Always wear a lab coat, safety glasses, and disposable gloves when using synthetic **Helix Elite™ Molecular Standards.**
- 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

- 1.5-ml microcentrifuge tubes
- 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

A. Rehydration

The following instructions describe how to handle the molecular standards to achieve approximately 100 positive control reactions. The end material in these instructions is concentrated stock tubes that are stored until diluted for use as positive controls in molecular assays.

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 55 µl **Helix Elite™** molecular standard water to the **Helix Elite™ Molecular Standard** tube.
3. Incubate the **Helix Elite™ Molecular Standard** tube at 2°C-8°C 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. Briefly centrifuge to ensure all liquid is in the bottom of the tube.
6. Aliquot 10 µl of the rehydrated synthetic **Helix Elite™ Molecular Standard** into 5 new, labeled microcentrifuge tubes. Store aliquots at or below -20°C. These tubes are concentrated stock tubes that must be diluted further for use in molecular assays.

B. Dilution and Use

The following instructions describe how to further dilute the molecular standards for use as a positive control in molecular assays.

1. Obtain an aliquot of the rehydrated **Helix Elite™ Molecular Standard**. If needed, thaw the aliquot at 2°C-8°C for 15 minutes and centrifuge briefly.
2. Add 90 µl **Helix Elite™** molecular standard water into the tube containing 10 µl of the rehydrated **Helix Elite™ Molecular Standard**. Gently mix by pipetting up and down several times.
3. Use 5 µl of the diluted **Helix Elite™ Molecular Standard** for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.

4. The remaining 95 µl of diluted **Helix Elite™ Molecular Standard** should be further aliquoted into single-use volumes to avoid freeze-thaw of the material. Store all aliquots of diluted **Helix Elite™ Molecular Standard** tubes at or below -20°C. These tubes are fully diluted and ready to use in molecular assays.

C. Calculations

1. To calculate the final concentration per PCR reaction, use the following equation, assuming 5 µl of the molecular standard being used in a PCR reaction:

$$\text{Copy Number per Reaction} = \frac{\text{Copy Number of Helix Elite™ Molecular Standard}}{\text{55 µl rehydration volume x 10 dilution factor}} \times \text{5µl per Reaction}$$

2. To determine the working concentration of the molecular standard needed to obtain a specific copy number per PCR reaction, use the following equation:

$$\text{Working Concentration (Copy Number/µl)} = \frac{\text{Copy Number per Reaction}}{\text{Volume of Template (µl per Reaction)}}$$

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, aliquot, and use/store immediately.

After rehydration, synthetic **Helix Elite™ Molecular Standards** must be stored at -20°C or below. It is recommended to store the hydrated synthetic **Helix Elite™ Molecular Standard** at high concentrations and at ultra low temperature (< -70°C) for optimal stability.

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.

STABILITY

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.

EXPECTED VALUES

Lot-specific copy number information is provided in a Certificate of Analysis for each synthetic **Helix Elite™ Molecular Standard**. Dilution of the **Helix Elite™ Molecular Standard** according to these instructions will provide sufficient material for 100 PCR reactions. For real-time PCR, the observed Ct value for synthetic **Helix Elite™ Molecular Standard** should range from 25 to 30, depending on the dilution, assay performance, and instrument.

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

Authorized Representative in the European Community

Batch Code (Lot)

Catalog Number


Caution consult accompanying documents Attention, see instructions for use


CE Mark


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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E.post. info@medimark-europe.com

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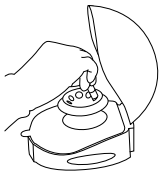
MOLECULAR STANDARDS

ILLUSTRATED INSTRUCTIONS

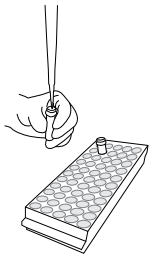
Synthetic **Helix Elite™ Molecular Standards** include: 1 vial of synthetic DNA or RNA, 1 vial of molecular standard water and a Certificate of Authenticity

Rehydration

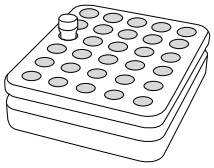
1 Open the foil pouch and then centrifuge the synthetic **Helix Elite™ Molecular Standard** tube before opening the tube to avoid loss of the dried material.



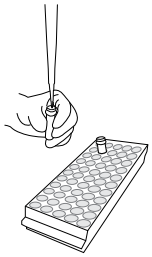
2 Add 55 µl **Helix Elite™** molecular standard water to the **Helix Elite™ Molecular Standard** tube.



3 Incubate the **Helix Elite™ Molecular Standard** tube at 2°C-8°C for 15 minutes to allow for complete rehydration.

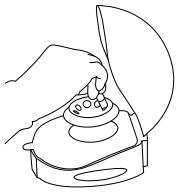


4 Mix the hydrated **Helix Elite™ Molecular Standard** by gently pipetting up and down several times.

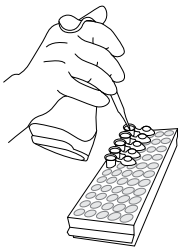


Do not vortex as this may damage the nucleic acids.

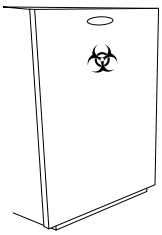
5 Briefly centrifuge to ensure all liquid is in the bottom of the tube.



6 Aliquot 10 µl of the rehydrated synthetic **Helix Elite™ Molecular Standard** into 5 new, labeled microcentrifuge tubes.

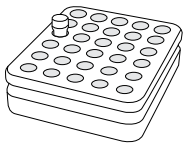


Store aliquots at or below -20°C. These tubes are concentrated stock tubes that must be diluted further for use in molecular assays.

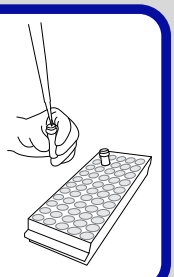


Dilution and Use

1 Obtain an aliquot of the rehydrated **Helix Elite™ Molecular Standard**. If needed, thaw the aliquot at 2°C-8°C for 15 minutes and centrifuge briefly.



2 Add 90 µl **Helix Elite™** molecular standard water into the tube containing 10 µl of the rehydrated **Helix Elite™ Molecular Standard**. Gently mix by pipetting up and down several times.



3 Use 5 µl of the diluted **Helix Elite™ Molecular Standard** for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.

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