

INSTRUCTIONS FOR USE

IVD

■ Synthetic Helix Elite™ Molecular Standards

INTENDED USE _____

Synthetic **Helix Elite™ Molecular Standards** are external controls intended for use as external positive controls for qualitative detection by molecular assays.

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 Biomatrix® RNAstable® or DNAstable® as appropriate. **Helix Elite™ Molecular Standard** water is provided for proper rehydration.



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 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 1.320.229.7045 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. Use 10 µl of the rehydrated synthetic Helix Elite™ Molecular Standard for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.
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)		Manufacturer
	Catalog Number		Temperature Limitation
	Caution, Consult Accompanying Documents		Use By
	Contains Sufficient for <n> Tests		Refer to Instructions for Use
	Health Hazard		Telephone Number
	In Vitro Medical Device		

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.

The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc. The PCR process is covered by patents owned by Roche Molecular Systems, Inc. and F. Hoffmann-La Roche, Ltd. Practice of the patented PCR process requires a license. All other trademarks are the sole property of their respective owners.

WEBSITE

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

ACKNOWLEDGEMENTS ---



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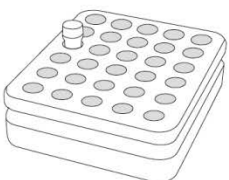
www.microbiologics.com


ILLUSTRATED INSTRUCTIONS


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

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Open the foil pouch and centrifuge the synthetic Helix Elite™ Molecular Standard tube before opening the tube to avoid loss of the dried material.
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Add 20 μ l Helix Elite™ Molecular Standard water to the Helix Elite™ Molecular Standard tube. Centrifuge briefly.
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Incubate the Helix Elite™ Molecular Standard tube at room temperature for 15 minutes to allow for complete rehydration.
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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.
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Add 10 μ l of the rehydrated synthetic Helix Elite™ Molecular Standard for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.
- Discard remaining material. **Do not freeze and reuse.**