

INSTRUCTIONS FOR USE

■ Helix Elite™ Molecular Standard Genome Extracts

INTENDED USE

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

MATERIALS REQUIRED BUT NOT PROVIDED

- 1.5-ml pyrogen-free 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

1. Open the foil pouch and then briefly centrifuge the **Helix Elite™ Molecular Standard** tube before opening the tube to avoid loss of the dried material.
2. Add **Helix Elite™** molecular standard water to the **Helix Elite™ Molecular Standard** tube to achieve the desired concentration. Ensure that liquid is at the bottom of the tube to allow for complete hydration.
3. Incubate the **Helix Elite™ Molecular Standard** tube at room temperature for 15 minutes.
4. Mix the hydrated **Helix Elite™ Molecular Standard** by gently pipetting up and down several times. Do not vortex. Briefly centrifuge to ensure all liquid is in the bottom of the tube.
5. Perform any additional dilutions if required.
6. Use the diluted **Helix Elite™ Molecular Standard** for each positive control reaction and run according to the protocol appropriate for the molecular assay being used.
7. Aliquot the hydrated **Helix Elite™ Molecular Standard** into multiple new, labeled microcentrifuge tubes. Store aliquots at or below -20°C (less than -70°C recommended).

B. Calculations

1. To calculate the final concentration per reaction, use the following equation, assuming 5 µl of the **Helix Elite™ Molecular Standard** being used in a PCR reaction:

$$\text{Genome Copies per Reaction} = \frac{\text{Genome Copies of Helix Elite™ Molecular Standard}}{\text{rehydration volume} \times \text{dilution factor}} \times 5\mu\text{l per Reaction}$$

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

$$\text{Working Concentration (Genome Copies/}\mu\text{l)} = \frac{\text{Genome Copies per Reaction}}{\text{Volume of Template (}\mu\text{l per Reaction)}}$$



PRECAUTIONS AND LIMITATIONS

- Not intended for use as an IVD. This product is not intended to diagnose, treat, cure or prevent any disease.
- For professional use only.
- Do not open foil pouch until ready to rehydrate and store or 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**.
- **Helix Elite™ Molecular Standards** do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- **Helix Elite™ Molecular Standards** are not made with natural rubber latex.
- Always wear a lab coat, safety glasses, and disposable gloves when using **Helix Elite™ Molecular Standards**.

TECHNICAL NOTES

Stability

Genetic material 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 genome copy number information is provided in a Certificate of Analysis for each

Helix Elite™ Molecular Standard. Performance may vary depending on primers/probes, instrument and amount of nucleic acid used.

Limitations

This product may not be suitable for use with all kits and procedures.

Microbiological State

The nucleic acids in the **Helix Elite™ Molecular Standard** are derived from the specific microorganism. See Certificate of Analysis for information on strain and quantity. This product was prepared using appropriate inactivation methods for various microorganisms.

STORAGE AND EXPIRATION

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 or store immediately.

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








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

FORMULA COMPONENTS

Helix Elite™ Molecular Standard Genome Extracts consist of DNA stabilized with Biomatrixa® DNASTable® preservatives that are compatible with molecular methods (e.g. PCR). **Helix Elite™ Molecular Standard** water is DNase-free water that can be used in rehydration and dilution of **Helix Elite™ Molecular Standard**.

KEY OF SYMBOLS

	Batch Code (Lot)
	Catalog Number
	Caution consult accompanying documents Attention, see instructions for use
	Health Hazard
	Manufacturer
	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 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.

This quantitated molecular standard is designed for use as a positive control in assays using molecular amplification assays 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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Technical Support

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ILLUSTRATED INSTRUCTIONS

Helix Elite™ Molecular Standards include: 1 vial of genomic DNA, 1 vial of molecular standard water and a Certificate of Analysis.


1

Rehydration



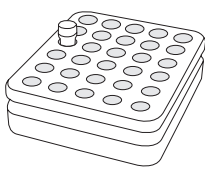
Open the foil pouch and then centrifuge the **Helix Elite™ Molecular Standard** tube.

2



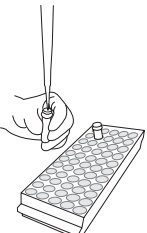
Add **Helix Elite™ Molecular Standard** water to the **Helix Elite™ Molecular Standard** tube to achieve the desired concentration. Ensure that liquid is at the bottom of the tube to allow for complete hydration.

3




Incubate the **Helix Elite™ Molecular Standard** tube at room temperature for 15 minutes.

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

Perform additional dilutions if required.

6

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



Aliquot **Helix Elite™ Molecular Standard** into new, labeled microcentrifuge tubes.

Store aliquots at or below -20°C (less than -70°C recommended).

