

Applications:

- Sensitivity
- Specificity
- Validation and Verification
- Assay Optimization
- Training
- Proficiency Testing
- Lot-to-Lot Testing

Package Details:

- 1 vial of dried, stabilized RNA or DNA (approximately 100 reactions)
- 1 vial of molecular standard water for rehydration
- Instructions for Use
- Certificate of Analysis


Highlights:

- Non-hazardous positive controls for molecular diagnostic assays
- Contains consensus sequences of diagnostic regions from the target's genome, representing the known genetic diversity of the microorganism
- Compatible with a variety of instruments, kits and applications
- Independent external controls provide accurate, reliable results
- Convenient test ready format saves you time and money
- Room temperature storage is easy and economical
- FDA listed and CE Marked as an In-Vitro Diagnostic (IVD) Medical Device
- Technical Support experts available for guidance

Synthetic Helix Elite™ Strains:

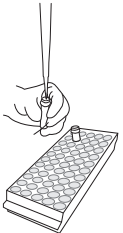
- HE0001S *Cryptosporidium hominis* Synthetic DNA
- HE0002S *Cryptosporidium parvum* Synthetic DNA
- HE0025S *Cyclospora cayetanensis* Synthetic DNA
- HE0015S *Dientamoeba fragilis* Synthetic DNA
- HE0016S Eastern Equine Encephalitis Virus Synthetic RNA
- HE0004S *Encephalitozoon intestinalis* Synthetic DNA
- HE0007S *Entamoeba dispar* Synthetic DNA
- HE0006S *Entamoeba histolytica* Synthetic DNA
- HE0003S *Enterocytozoon bieneusi* Synthetic DNA
- HE0005S *Giardia lamblia* Synthetic DNA
- HE0046S Human papillomavirus 16 Synthetic DNA
- HE0048S Human papillomavirus 18 Synthetic DNA
- HE0013S Norovirus GI.1 Synthetic RNA
- HE0012S Norovirus GII.4 Synthetic RNA
- HE0008S *Plasmodium falciparum* Synthetic DNA
- HE0011S *Plasmodium malariae* Synthetic DNA
- HE0010S *Plasmodium ovale* Synthetic DNA
- HE0009S *Plasmodium vivax* Synthetic DNA
- HE0047S *Treponema pallidum* Synthetic DNA
- HE0014S West Nile Virus Synthetic RNA

1 Rehydration



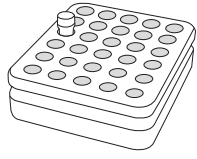
Open the foil pouch and then centrifuge the Synthetic Helix Elite™ Molecular Standard tube before opening the tube to avoid loss of the dried material.

2



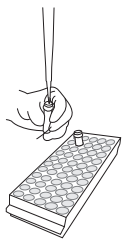
Add 55 µl Helix Elite™ Molecular Standard water to the Helix Elite™ Molecular Standard tube.

3




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

4

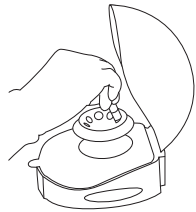


Mix the hydrated Helix Elite™ Molecular Standard by gently pipetting up and down several times.

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

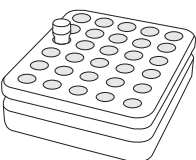


Aliquot 10 µl of the rehydrated Synthetic Helix Elite™ Molecular Standard into 5 new, labeled microcentrifuge tubes.



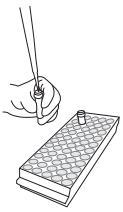
Store aliquots at or below -20°C. These tubes are concentrated stock tubes that must be diluted further for use in molecular assays.

1 Dilution and Use




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.