# INSTRUCTIONS FOR USE

IVD CE

## HE0013S Norovirus GI.1 Synthetic RNA

### INTENDED USE

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

### SUMMARY AND PRINCIPLES

The Norovirus GI.1 Synthetic RNA can be used to monitor the amplification and detection process of molecular testing assays that include the analytes in Table 1. Routine use of quality controls monitors test variation, lot-to-lot test kit performance, operator performance, and aids in identifying random or systemic error.

### COMPOSITION

The Norovirus GI.1 Synthetic RNA consists of 1 vial of dried synthetic RNA (up to 100 reactions) and 1 vial of molecular water. The RNA corresponds to the ORF1-ORF2 junction of the Norovirus GI.1 genome.

The Norovirus GI.1 Synthetic RNA is dried in a vial with a proprietary stabilizing preservative that is PCR compatible. The solution is dried into a ready-to-use pellet.

Table 1: Contents of Norovirus GI.1 Synthetic RNA

| Analytes* |
|---|
| Norovirus GI.1 (ORF1-ORF2 junction) |

*All analytes are added at a concentration of 1.1 x $10^8$ copies per pellet.

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the assay.
- Do not open foil pouch until ready use.
- This product must be treated as a potential biohazard and be handled using universal laboratory precautions. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills and dispose of all materials in accordance with national and local regulations.
- 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.
- This product does not contain any hazardous substances listed in 1272/2008/EC.
- This product is not made with natural rubber latex.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Instrumentation for detection
- 1.5-ml microcentrifuge tubes
- Pipettors capable of delivering 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Microcentrifuge

Note: 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.

HELIX|ELITE™ MOLECULAR STANDARDS

## 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 centrifuge the vial before opening the vial to avoid loss of the dried material.
2. Add 55 µl of the provided molecular water to the vial.
3. Incubate the vial at 2°C - 8°C for 15 minutes to allow for complete rehydration.
4. Mix the hydrated material by gently pipetting up and down several times.
    a. Do not vortex as this may damage the nucleic acids.
5. Briefly centrifuge to ensure all liquid is in the bottom of the vial.
6. Aliquot 10 µl of the rehydrated material 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 material for use as a positive control in molecular assays.

1. Obtain an aliquot of the rehydrated material. If needed, thaw the aliquot at 2°C - 8°C for 15 minutes and centrifuge briefly.
2. Add 90 µl of the provided molecular water into the tube containing 10 µl of the rehydrated material. Gently mix by pipetting up and down several times.
3. Use the diluted material as a positive control reaction and run according to the protocol appropriate for the molecular assay being used. Recommended reaction volume is 5 µl of diluted material.
4. The remaining diluted material can be refrigerated at 2°- 8° C and used for up to 8 hours. Do not refreeze.

## STORAGE AND EXPIRATION

Store the Norovirus GI.1 Synthetic RNA at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately. In-use stability of the diluted material is 8 hours at 2°- 8° C.

The Norovirus GI.1 Synthetic RNA should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed
- Packaging is damaged

## PERFORMANCE CHARACTERISTICS

Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. Microbiologics guarantees each nucleic acid is present and can be amplified but does not guarantee specific analyte concentrations. Each laboratory should establish its own range of acceptable values on their assay system per their internal quality assurance procedure/program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.

## LIMITATIONS

These products are unassayed control material. Only primer and probe sequences that hybridize to the Synthetic Helix Elite™ Molecular Standard nucleic acid sequences will yield a positive reaction. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics' provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.

## MICROBIOLOGICAL STATE

This product consists only of synthetic subgenomic transcripts of the Norovirus GI.1 genome. This type of material is not derived from the target microorganism, is non-infectious, and inert.

## KEY OF SYMBOLS

| | | | |
|---|---|---|---|
| EC REP | Authorized Representative in the European Community / European Union | | Health hazard |
| LOT | Batch code (Lot) | IVD | In vitro diagnostic medical device |
| | Biological risks | | Manufacturer |
| REF | Catalog number | CONTROL - | Negative control |
| | Caution | CONTROL + | Positive control |
| CE | CE mark | QTY | Quantity |
| | Consult instructions for use or consult electronic instructions for use | | Telephone number |
| Σ | Contains sufficient for <n> tests | | Temperature limit |
| 2 | Do not re-use | | Use-by-date |
| | Do not use if package is damaged and consult instructions for use | EU REP | EU Authorized Representative |

*Please refer to product labels for applicable symbols.*

## 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 Synthetic Helix Elite™ Molecular Standard is designed for use as a positive control in assays using nucleic acid amplification 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.

## WEBSITE

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

## BIBLIOGRAPHY


- Vinjé J. Advances in laboratory methods for detection and typing of norovirus. J Clin Microbiol. 2015;53(2):373-381. doi:10.1128/JCM.01535-14

## ASSISTANCE

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Additional copies of this product insert may be obtained at **www.microbiologics.com** or by emailing info@microbiologics.com

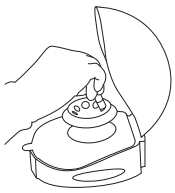
HELIX | ELITE™
MOLECULAR STANDARDS

## ILLUSTRATED INSTRUCTIONS

Each Norovirus GI.1 Synthetic RNA kit consists of 1 vial of dried synthetic RNA (up to 100 reactions) and 1 vial of molecular water.

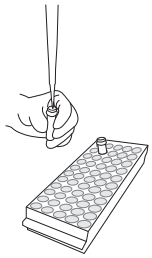
### 1 Rehydration

Open the foil pouch and centrifuge the vial before opening the vial to avoid loss of the dried material.

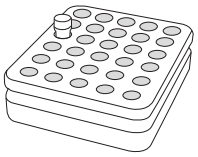


### 2

Add 55 µl of the provided molecular water to the vial.



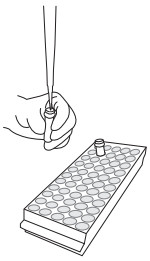
### 3



Incubate the vial at 2°C - 8°C for 15 minutes to allow for complete rehydration.

### 4

Mix the hydrated material by gently pipetting up and down several times.

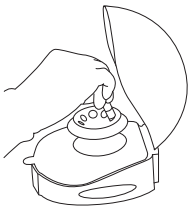


Do not vortex as this may damage the nucleic acids.



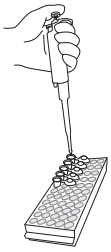
### 5

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



### 6

Aliquot 10 µl of the rehydrated material into 5 new, labeled microcentrifuge tubes.

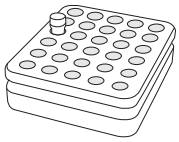


Store aliquots at or below -20°C. These tubes are concentrated stock tubes that must be diluted further for use in molecular assays.



## Dilution and Use

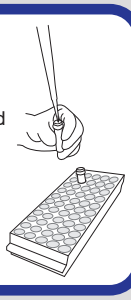
### 1



Obtain an aliquot of the rehydrated material. If needed, thaw the aliquot at 2°C - 8°C for 15 minutes and centrifuge briefly.

### 2

Add 90 µl of the provided molecular water into the tube containing 10 µl of the rehydrated material. Gently mix by pipetting up and down several times.



### 3

Use the diluted material as a positive control reaction and run according to the protocol appropriate for the molecular assay being used. Recommended reaction volume is 5 µl of diluted material.



### 4

The remaining diluted material can be refrigerated at 2°- 8° C and used for up to 8 hours. Do not refreeze.



## REVISION HISTORY

| Publication History | | |
|---|---|---|
| **Revision** | **Date** | **Description of Change** |
| A | 2022-09-02 | Initial Release |
| B | 2025-09 | Added Bibliography section, updated MediMark® Address, replaced EC rep Symbol with EU Rep and removed Warranty information. |