INSTRUCTIONS FOR USE

IVD

GS-0001 GI Parasite QC Pellets

INTENDED USE

The GI Parasite QC Pellets are intended for use as non-viable, external, positive control materials to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Table 1. This product has no quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen.

SUMMARY AND PRINCIPLES

The GI Parasite QC Pellets can be used to monitor the extraction, amplification and detection 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 aid in identifying random or systemic error.

COMPOSITION

The GI Parasite QC Pellets consist of 30 individually packaged lyophilized pellets.
The GI Parasite QC Pellets consist of inactivated pathogen(s) and surrogate nucleic acids lyophilized and stabilized in a proprietary matrix of excipients. These analytes have been inactivated using thermal treatment.

The organisms are prepared in a buffered solution with materials of plant origin, preservatives and stabilizers. The solution is lyophilized into a ready-to-use pellet.

Table 1. Contents of the GI Parasite QC Pellet

Analytes*
Blastocystis hominis surrogate
Cryptosporidium parvum surrogate
Cyclospora cayetanensis surrogate
Dientamoeba fragilis surrogate
Encephalitozoon intestinalis surrogate
Entamoeba histolytica surrogate
Enterocytozoon bieneusi surrogate
Giardia lamblia surrogate

*All surrogate analytes listed are *E. coli* carrying a pUC plasmid that has the partial 18S gene of the listed organism along with the GAPDH gene.

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.
- The inactivated lyophilized pellets are single use only. If hydrated, do not freeze for reuse. If reused, the inactivated lyophilized pellets may not perform as expected including, but not limited to, degradation or over-dilution of material resulting in false negative results, or environmental contamination resulting in detection of organisms not in the pellet.
- Do not open foil pouch until ready to use.

HELIX|ELITE™ MOLECULAR STANDARDS

- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. 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 Customer Service at info@microbiologics.com.
- 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.

STORAGE AND EXPIRATION

Store the GI Parasite QC Pellets at 2°C - 8°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 rehydrated pellet at room temperature (25°C) is 1 hour.

The GI Parasite QC Pellets 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

MATERIALS REQUIRED BUT NOT PROVIDED

- Assay for detection including required instrumentation and consumables
- Rehydration fluid/buffer as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µL volumes (if applicable)
- Nuclease-free aerosol barrier pipette tips (if applicable)

INSTRUCTIONS FOR USE

1. Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using GI Parasite QC panels.
2. Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Hydrate the lyophilized pellet into a vial/tube of hydrating fluid/buffer recommended by the assay manufacturer.
    a. If not using a provided hydration fluid/buffer from the assay manufacturer, a hydration buffer such as Phosphate Buffered Saline (PBS) may be used. Minimum hydration volume of 110 µL is recommended.
4. Recap the vial/tube and vortex for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial/tube on a rigid surface to collect material at the bottom of the vial/tube.
    a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial/tube.
6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

LIMITATIONS

- There are no known extrinsic factors or interfering substances specific to this product. Please consult assay instructions for use for any extrinsic factors or interfering substances.
- This product is unassayed control material. It may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. 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.

- Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These organisms

are intact, non-viable, and may be used with any PCR-based test or assay. 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.

- This product is a DNA control only and is not intended to act as a control for reverse transcriptase process.

MICROBIOLOGICAL STATE

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

KEY OF SYMBOLS

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

Please refer to product labels for applicable symbols.

NOTICE TO PURCHASERS

The purchase of this product allows the purchaser to use it for Research Use Only 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.

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WEBSITE

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

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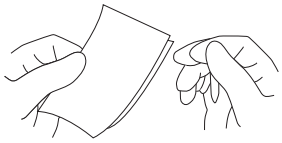
Additional copies of this product insert may be obtained at **www.microbiologics.com** or by emailing info@microbiologics.com

HELIX | ELITE™
MOLECULAR STANDARDS

ILLUSTRATED INSTRUCTIONS

1

Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using GI Parasite QC panels.



2

Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

3

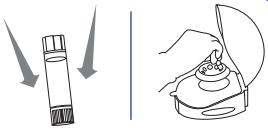
Hydrate the lyophilized pellet into a vial/tube of hydrating fluid/buffer recommended by the assay manufacturer.

If not using a provided hydration fluid/buffer from the assay manufacturer, a hydration buffer such as Phosphate Buffered Saline (PBS) may be used. Minimum hydration volume of 110 µL is recommended.

4

Recap the vial/tube and vortex for 10 seconds at full speed to mix.

5



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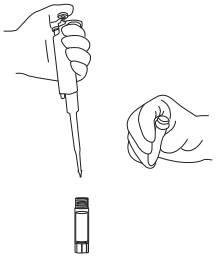
6

Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.



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REVISION HISTORY

Publication History		
Revision	**Date**	**Description of Change**
A	2025-04-14	Initial release
B	2025-04-08	Updated the product name and the stroage temprature