INSTRUCTIONS FOR USE

IVD

BD MAX™ Enteric Parasite Control Panel and BD MAX™ Enteric Parasite 20-Day QC Panel

INTENDED USE

The BD MAX™ Enteric Parasite Control Panel and the BD MAX™ Enteric Parasite 20-Day QC Panel are intended for use as external assayed positive quality control materials to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Cryptosporidium parvum*, *Giardia lamblia*, and *Entamoeba histolytica* performed with the BD MAX™ Enteric Parasite Panel on the BD MAX™ System. The controls comprise cultured and inactivated *C. parvum*, *G. lamblia* and recombinant *Escherichia coli*. The *E. coli* carries a plasmid which is a surrogate control material for detection of *E. histolytica*.

The BD MAX™ Enteric Parasite Control Panel and BD MAX™ Enteric Parasite 20-Day QC Panel are not intended to replace manufacturer controls provided with the device.

SUMMARY AND EXPLANATION

The BD MAX™ Enteric Parasite Control Panel and BD MAX™ Enteric Parasite 20-Day QC Panel are easy-to-use process controls that can be used to monitor DNA extraction, amplification and detection by the BD MAX™ Enteric Parasite Panel. Routine use of quality controls helps in identifying problems with the test system due to instrument or reagent failure. At a minimum, controls should be run at the frequency recommended by the assay system manufacturer.

PRINCIPLES

Inactivated Helix Elite Molecular Standards are comprised of cultured organisms inactivated by heat treatments. For *Entamoeba histolytica* the control comprises a recombinant *Escherichia coli* with a plasmid bearing an *E. histolytica* gene fragment as a surrogate for *E. histolytica* organisms.

COMPOSITION

Each 8202, BD MAX™ Enteric Parasite 20-Day QC Panel consists of 20 individually packaged positive control pellets. Each 8204, BD MAX™ Enteric Parasite Control Panel consists of 6 individually packaged positive control pellets. Both panels contain individually packaged pellets consisting of inactivated, *Cryptosporidium parvum*, *Giardia lamblia*, and a recombinant *Escherichia coli* at target levels designed to provide reproducible performance above the limit of detection of the assay. The organisms are prepared in a buffered suspension with materials of animal origin, preservatives and stabilizers. The suspension is lyophilized into a ready-to-use pellet.

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WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.
- Wear proper personal protective equipment.
- 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 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- These products are not made with natural rubber latex.

STORAGE AND EXPIRATION

Store the Inactivated Helix Elite™ Molecular Standards at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the pellet within 5 hours of addition to the sample buffer.

Inactivated Helix Elite Molecular Standards should not be used if:

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

INSTRUCTIONS FOR USE

Note: Follow the Specimen Preparation section of the instructions for use in the BD MAX™ Enteric Parasite Panel package insert. Do not follow the Quality Control instructions for sample preparation. The Microbiologics controls are ready to use controls and must be processed as a patient sample after transfer to the Sample Buffer Tube.

1. Read the instructions for use specific to the BD MAX™ Enteric Parasite Panel.
2. Tear open the foil pouch at notch. Remove the tube from the pouch and ensure that the pellet is at the bottom of the vial before opening the tube.
3. Uncap the tube and carefully transfer the pellet to the sample buffer tube provided with BD MAX™ Enteric Parasite Panel.
4. Vortex for 5 seconds on high to mix.
5. Invert the sample buffer Tube 5 times.
6. Vortex again for 5 seconds on high to mix.
7. Pre-warm and process following instructions listed in the BD MAX™ Enteric Parasite Panel instructions for use. Note: The sample buffer tube should only be tested once.
8. Mixture must be used within 5 hours of mixing.

MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System
- BD MAX™ Enteric Parasite Panel
- BD Pre-warm Heater
- BD MAX™ PCR Cartridges
- Package insert of the BD MAX™ Enteric Parasite Panel
- Vortex mixer

LIMITATIONS

- Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
- Once inoculated with the control, the Sample Buffer Tube should only be processed once on the BD MAX™ System. Studies have not been performed to support performance of the control if the remaining suspension in the Sample Buffer Tube is stored and processed a second time.

EXPECTED VALUES

The following results are expected when running the 8202 and 8204 controls with the BD MAX™ Enteric Parasite Panel:

Expected Assay Result	Interpretation
Glamb POS	*Giardia lamblia* DNA Detected.
Crypto POS	*Cryptosporidium parvum* or *hominis* DNA Detected.
Ehist POS	*Entamoeba histolytica* DNA Detected.

All three results are expected with a single run of the positive control. A positive control that yields a negative result may be indicative of a specimen handling/preparation problem. Repeat the test using a new pellet and a new sample buffer tube. Repeat testing from a previously rehydrated control has not been evaluated.

The performance of the BD MAX™ Enteric Parasite Control and 20-Day QC Panels was evaluated in a study that was performed using three different production lots of controls at three sites with three different BD MAX™ Systems and six different operators. The results of the study are summarized below.

Analyte	Agreement (%) by Test Site/BD MAX System			
	Site 1 [1]	Site 2 [2]	Site 3	Overall
G. lamblia	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
E. histolytica	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
C. parvum	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

[1] Two Incomplete Run errors occurred; in both cases a new control was retested and the expected results were obtained
[2] An Unresolved result was obtained with one control; a new control was retested and the expected results were obtained

KEY OF SYMBOLS

LOT	Batch Code (Lot)		Manufacturer
REF	Catalog Number		Temperature Limitation
	Caution, Consult Accompanying Documents		Use By
Σ	Contains sufficient for <n> tests		Refer to Instructions for Use
IVD	In Vitro Medical Device		Telephone Number

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.

WEBSITE

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

BIBLIOGRAPHY

1. BD MAX™ Enteric Parasite Panel [product insert]. Becton, Dickinson and Company, Sparks, MD 21152 USA.

ACKNOWLEDGEMENTS

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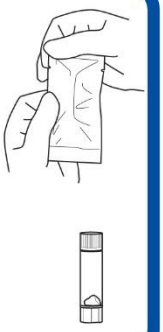
ILLUSTRATED INSTRUCTIONS

1

Read the instructions for use specific to the BD MAX™ Enteric Parasite Panel.

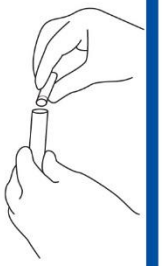
2

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



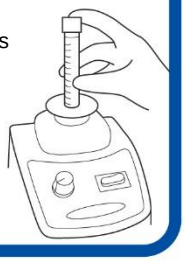
3

Uncap the tube and carefully transfer the pellet to the sample buffer tube provided with BD MAX™ Enteric Parasite Panel.



4

Vortex for 5 seconds on high to mix.



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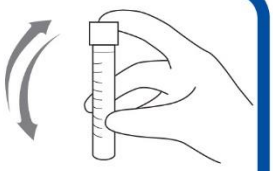
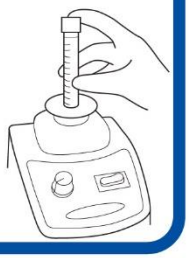


Invert the sample buffer tube 5 times.

6

Vortex again for 5 seconds on high to mix.



7

Pre-warm and process following instructions listed in the BD MAX™ Enteric Parasite instructions for use.

Note: The sample buffer tube should only be tested once.

8

Mixture must be used within 5 hours of mixing.

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