510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K181711

B. Purpose for Submission:

To obtain a substantial equivalence determination for the BD MAX Enteric Parasite Control Panel and BD MAX Enteric Parasite 20-Day QC Panel.

C. Measurand:

Multi-analyte quality control panel

D. Type of Test:

External assayed quality control material used to monitor the performance of the BD MAX Enteric Parasite Assay (K143648) for the qualitative detection of *Cryptosporidium parvum*, *Giardia lamblia* and *Entamoeba histolytica* in formalin-fixed stool specimens.

E. Applicant:

Microbiologics, Inc.

F. Proprietary and Established Names:

BD MAX Enteric Parasite Control Panel

BD MAX Enteric Parasite 20-Day QC Panel

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.3920: Assayed quality control material for clinical microbiology assays

2. Classification:

   Class II (Special Controls)

3. Product code:

   PMN: Assayed external control material for microbiology nucleic acid amplification (NAT) assays

4. Panel:

   83-Microbiology

H. Intended Use:

1. Intended use(s):

   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.

2. Indication(s) for use:

   Same as Intended Use.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use.

   For prescription use only.

   This product is not intended to replace manufacturer controls provided with the BD MAX Enteric Parasite Panel.

4. Special instrument requirements:

   BD MAX System with the BD MAX Enteric Parasite Panel

I. Device Description:

The BD MAX Enteric Parasite Control Panel and BD MAX Enteric Parasite 20-Day QC Panel comprise invidually packaged lyophilized pellets that each contain inactivated *Cryptosporidium parvum*, *Giardia lamblia* and a recombinant strain of *Escherichia coli* that

carries a plasmid containing an *Entamoeba histolytica* gene fragment, as well as preservatives/stabilizers. The pellets are formulated to contain the target analytes at specific concentrations as determined by quantitative PCR. The two panels differ only in terms of the number of individually packaged controls contained within each control set (6 vs 20). Negative controls are not included in either panel.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Amplichek II

2. Predicate 510(k) number(s):

   DEN150058

3. Comparison with predicate:

Similarities		
Item	**Device** **BD MAX Enteric Parasite Control Panel** **BD MAX Enteric Parasite 20-Day QC Panel (K181711)**	**Predicate** **Amplichek II (DEN150058)**
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.*	Amplichek II is intended for use as an external assayed quality control material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of Methicillin Resistant *Staphylococcus aureus*, Methicillin Sensitive *Staphylococcus aureus*, *Clostridium difficile* and Vancomycin-resistant *Enterococci* performed on Cepheid GeneXpert Systems. This product is not intended to replace manufacturer controls provided with the device. This product is only for use with assays and instruments

Similarities		
Item	**Device** **BD MAX Enteric Parasite Control Panel** **BD MAX Enteric Parasite 20-Day QC Panel (K181711)**	**Predicate** **Amplichek II (DEN150058)**
	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.	listed in the Representative Results Chart in this labeling.
Control Format	Cultured and inactivated organisms	Same

Differences		
Item	**Device** **BD MAX Enteric Parasite Control Panel** **BD MAX Enteric Parasite 20-Day QC Panel (K181711)**	**Predicate** **Amplichek II (DEN150058)**
Target Analytes	• *Cryptosporidium parvum* • *Giardia lamblia* • *Entamoeba histolytica*	• Methicillin Resistant *Staphylococcus aureus* • Methicillin Sensitive *Staphylococcus aureus* • *Clostridium difficile* Vancomycin-resistant *Enterococci*
Control Format	Cultured and inactivated parasites and recombinant *Escherichia coli* (surrogate for *E. histolytica*)	Cultured and inactivated bacteria
Instrument System	BD MAX System	Cepheid GeneXpert

Differences		
Item	**Device**	**Predicate**
	BD MAX Enteric Parasite Control Panel **BD MAX Enteric Parasite 20-Day QC Panel (K181711)**	**Amplichek II (DEN150058)**
		Systems
Assay Compatibility	• BD MAX Enteric Parasite Panel (K143648)	• Cepheid Xpert MRSA/SA Blood Culture Assay (K130894) • Cepheid Xpert MRSA (K070462) • Cepheid Xpert SA Nasal Complete (K100822) • Cepheid Xpert MRSA/SA SSTI (K080837) • Cepheid Xpert *C. difficile* (K091109) • Cepheid Xpert *C. difficile/Epi* (K110203) • Cepheid Xpert vanA (K092953)

K. Standard/Guidance Document Referenced (if applicable):

CLSI. *Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.* CLSI Document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

CLSI. *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline – Third Edition.* CLSI Document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

L. Test Principle:

The BD MAX Enteric Parasite Control Panel and BD MAX Enteric Parasite 20-Day QC Panel are intended for use as external assayed quality control materials for use in monitoring the DNA extraction, amplification and detection processes associated with the BD MAX Enteric Parasite Panel (K143648) performed on the BD MAX System.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The reproducibility of results obtained with the BD MAX Enteric Parasite control panels was evaluated in a study performed at three sites over five days, with two operators per site. Each operator tested three lyophilized control pellets on each day of the study according to the instructions for use (3 sites x 5 days x 2 operators x 3 replicates = 90 replicates in total). Controls associated with incomplete instrument runs (2) or that produced unresolved results (1) were retested using a new control pellet according to the Instructions For Use. A Negative Control consisting of molecular grade water (not provided in the BD MAX Enteric Parasite Control and 20-Day QC Panels) was also tested at least once a day on each instrument to monitor for contamination. The results of the study are summarized in **Table 1**. All Negative Controls and produced the expected results.

Table 1. Summary of results from the Reproducibility Study

Analyte	Agreement (%) by Control Lot			
	Lot 1	**Lot 2** [1]	**Lot 3** [2]	**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)
Analyte	**Agreement (%) by Test Site/BD MAX System**			
	Site 1 [3]	**Site 2** [4]	**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] An Incomplete Run error occurred with one control; a new control was retested and the expected results were obtained

[2] An Incomplete Run error occurred with one control and another produced and Unresolved result; in both cases, a new control was retested and produced the expected results

[3] Two Incomplete Run errors occurred; in both cases a new control was retested and the expected results were obtained

[4] An Unresolved result was obtained with one control; a new control was retested and the expected results were obtained

The reproducibility of the BD MAX Enteric Parasite Control and 20-Day QC Panels within and between sites/BD MAX Systems and operators and within and between lots was determined to be acceptable.

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Stability
Reagent shelf-life was established in an Accelerated Stability Study that was performed with three lots of BD MAX Enteric Parasite Panel controls that were placed at 43, 53 or 63°C for up to 42 days. All results were as expected and there was no evidence of product degradation under the conditions tested. The results of this study were used to support a claimed shelf-life of 18 months at 2-25°C, which will be verified through a Real-time Stability Study.

Expected Values
The BD MAX Enteric Parasite Control and 20-Day QC Panels are expected to produce positive results for *G. lamblia*, *C. parvum* and *E. histolytica* when tested with the BD MAX Enteric Parasite Panel on the BD MAX System.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The BD MAX Enteric Parasite Control Panel and BD MAX Enteric Parasite 20-Day QC Panel do not have assigned values. Performance was evaluated through testing at three sites using three different BD MAX Systems and three lots of controls (refer to **Section M(1)(a)**).

N. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.