510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K181683

B. Purpose for Submission:

To obtain a substantial equivalence determination for the BD MAX CT/GC/TV 20-Day QC Panel.

C. Measurand:

Nucleic acids from inactivated *Chlamydia trachomatis*, *Neisseria gonorrhoeae,* and *Trichomonas vaginalis*

D. Type of Test:

The BD MAX CT/GC/TV 20-Day QC Panel is an external assayed positive quality control material designed to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae,* and *Trichomonas vaginalis* in genitourinary specimens.

E. Applicant:

Microbiologics, Inc.

F. Proprietary and Established Names:

Trade Name: BD MAX CT/GC/TV 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

4. Panel:

   (83) Microbiology

H. Intended Use:

1. Intended use:

   The BD MAX CT/GC/TV 20-Day QC Panel is intended for use as an external assayed positive quality control material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* performed with the BD MAX CT/GC/TV Assay on the BD MAX System. This product is not intended to replace manufacturer controls provided with the device. The controls comprise cultured and inactivated *C. trachomatis, N. gonorrhoeae* and *T. vaginalis* organisms. The BD MAX CT/GC/TV 20-Day QC Panel is 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 only

   For prescription use only

3. Special instrument requirements:

   The BD MAX CT/GC/TV 20-Day QC Panel is intended for use on the BD MAX Instrument.

I. Device Description:

The BD MAX CT/GC/TV 20-Day QC Panel is a quality control material provided to the customer as 20 individually packaged positive control pellets. Each pellet consists of inactivated *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* microorganisms. The organisms are purified and suspended in a buffered aqueous matrix (Base Matrix), followed by inactivation by gamma radiation. The organisms are then quantified by a by quantitative PCR assay and spiked into the Base Matrix at predefined target concentrations. Aliquots of the suspension are lyophilized and packaged. Each production lot is tested for purity and is assayed for performance on the BD MAX instrument.

The pellets are contained in a vial and enclosed in a vacuum sealed foil pouch. The user opens the pouch, uncaps the tube and transfers the pellet into the BD MAX UVE Sample

Buffer Tube. The mixture is vortexed and processed like a patient sample according to the test instructions for the BD MAX CT/GC/TV assay. Negative controls are not included in the 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:

Characteristic	**BD MAX™ CT/GC/TV 20-Day QC Panel**	**Predicate Device – Bio-Rad Amplichek II (DEN 150058)**
Intended Use	The BD MAX CT/GC/TV 20-Day QC Panel is intended for use as an external assayed positive quality control material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* with the BD MAX CT/GC/TV Assay on the BD MAX System. The controls comprise cultured and inactivated *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*. The BD MAX CT/GC/TV 20-Day QC Panel is not intended to replace manufacturer controls provided with the device.	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 listed in the Representative Results Chart in this labeling.
Physical Format	Lyophilized pellet	Ready-to-use liquid
Composition	Inactivated microorganisms	Inactivated microorganisms
Analytes	*Chlamydia trachomatis* *Neisseria gonorrhoeae* *Trichomonas vaginalis*	Methicillin Resistant *Staphylococcus aureus* Methicillin Sensitive *Staphylococcus aureus* *Clostridium difficile* Vancomycin-resistant Enterococci

Test System	BD MAX System	Cepheid GeneXpert System
Directions for Use	Process like patient sample	Process like patient sample
Assay Steps Monitored	Extraction, amplification, and detection	Extraction, amplification, detection
Number of Targets monitored in one assay	Multiple	Multiple

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.

L. Test Principle:

Not applicable; this is control material to monitor performance of a test.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Reproducibility:

The reproducibility of results obtained with the BD MAX 20-Day QC Panel was evaluated in a study performed at three sites over five days, with two operators per site. Three lots of the control material were evaluated by testing with the BD MAX CT/GC/TV Assay on three BD MAX instruments. Each operator tested three lyophilized control pellets on each day of the study (3 sites x 5 days x 2 operators x 3 replicates (lots) = 90 measurements 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 was also tested at least once a day on each instrument to monitor for contamination. The results of the study are summarized below. All Negative Controls produced the expected results.

Analyte	**Agreement (%) by Test Site/BD MAX System**			
	Site 1 [1]	**Site 2** [1]	**Site 3**[2]	**Overall**
C. trachomatis	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
N. gonorrhoeae	30/30 (100%)	30/30 (100%)	29/30 (96.7%)	89/90 (98.9%)
T. vaginalis	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)

[1]Three Unresolved results were obtained; in all cases a new control was retested and the expected results were obtained

[2]One unresolved result was obtained, no retest was performed.

The calculated average Ct score value, the associated standard deviation, and % coefficient of variation were calculated for each organism in the panel (based on results from two testing sites, the third site did not have software allowing access to the signal generated by the instrument):

	C. trachomatis	***N. gonorrhoeae***	***T. vaginalis***	**IPC**
N	60	60	60	60
Mean	30.2	33.6	30.8	30.5
SD	0.472	1.086	0.475	0.365
%CV	1.56	3.23	1.55	1.09

b. Linearity/assay reportable range:

Not applicable

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

Traceability:

Not applicable

Stability:

1. Shelf life stability was initially determined through an accelerated study with three lots of the controls. The product was placed into chambers at elevated temperatures: 43˚C, 53˚C and 63˚C. Each lot was tested in 4 replicates at each time point: Day 0, Day 14 and Day 42. The stability of the product was evaluated by calculating the mean Ct value at each time point for CT and for NG and comparing that to the mean Ct value obtained at Day 0. The data showed that there was no product degradation under the conditions tested. The change in Ct score, across the three lots ranged from -0.2 to 1.3 for *C. trachomatis,* from -0.6 to 1.6 for *N. gonorrhoeae*, and from -0.5 to 0.6 for *T. vaginalis*. The data is summarized below.

C. trachomatis		Lot 1			Lot 2			Lot 3		
		43°C	53°C	63°C	43°C	53°C	63°C	43°C	53°C	63°C
	Day	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score
Mean	0	30.1	30.1	30.1	30.1	30.1	30.1	29.8	29.8	29.8
Mean Change in Ct score	14	-0.1	0.8	0.5	0.3	0.4	1.0	0.6	1.3	1.0
	28	1.1	-0.2	1.0	0.2	0.0	0.8	0.8	0.5	1.1
	42	0.6	0.1	0.2	0.9	0.3	0.6	0.6	0.4	0.5

N. gonorrhoeae		Lot 1			Lot 2			Lot 3		
		43°C	53°C	63°C	43°C	53°C	63°C	43°C	53°C	63°C
	Day	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score
Mean	0	34.0	34.0	34.0	34.0	34.0	34.0	33.8	33.8	33.8
Mean Change in Ct score	14	0.0	0.0	-0.2	0.6	0.4	0.2	1.3	0.7	0.4
	28	0.7	0.3	-0.4	0.2	0.7	0.8	0.1	0.2	-0.4
	42	0.6	-0.3	-0.3	1.6	0.5	0.9	0.4	0.8	-0.6

T. vaginalis		Lot 1			Lot 2			Lot 3		
		43°C	53°C	63°C	43°C	53°C	63°C	43°C	53°C	63°C
	Day	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score	Ct score
Mean	0	31.3	31.3	31.3	31.0	31.0	31.0	30.7	30.7	30.7
Mean Change in Ct score	14	-0.3	0.3	-0.1	0.5	0.2	0.4	0.5	0.6	0.1
	28	0.4	0.3	0.3	0.2	0.3	0.4	0.2	0.6	0.3
	42	0.0	-0.2	0.0	0.4	0.1	-0.5	0.6	0.6	-0.2

A real-time shelf life stability study is in process with a goal of 24 months stability claim.

2. An in-use stability of the dissolved pellets was evaluated by keeping the hydrated pellets at room temperature (23˚C) for six hours. The testing was conducted with 4 replicates at 3 and at 6 hours. The calculated % CV (based on Ct values) across all three analytes ranged from 0.16% to 1.95%, demonstrating no degradation of the product once hydrated for up to 5 hours at ambient laboratory temperature.

Expected Values:

The BD MAX CT/GC/TV 20-Day QC Panel is a qualitative positive control expected to produce positive results for *C. trachomatis, N. gonorrhoeae,* and *T. vaginalis.*

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.

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.