

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K182472

B. Purpose for Submission:

To obtain a Substantial Equivalence determination for the Cepheid Xpert GBS LB Control Panel for use with the Cepheid Xpert GBS LB Assay on the GeneXpert Instrument System.

C. Measurand:

Nucleic acid quality control material from inactivated *Streptococcus agalactiae* and *Lactobacillus acidophilus* bacterial cultures for detection of *Streptococcus agalactiae* (Group B *Streptococcus* positive control) and *Lactobacillus acidophilus* (negative control).

D. Type of Test:

The Cepheid Xpert GBS LB Control Panel is an external assayed positive and negative quality control materials to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Streptococcus agalactiae* (GBS) performed with the Cepheid Xpert GBS LB Assay on the GeneXpert Instrument System.

E. Applicant:

Microbiologics, Inc.

F. Proprietary and Established Names:

Cepheid Xpert GBS LB Control 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 assays

4. Panel:

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H. Intended Use:

1. Intended use(s):

The Cepheid Xpert GBS LB Control Panel is intended for use as external assayed positive and negative quality control materials to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of Group B *Streptococcus* (GBS) performed with the Cepheid Xpert GBS LB Assay on the GeneXpert Instrument System. The controls comprise cultured and inactivated *Streptococcus agalactiae* as the positive control and *Lactobacillus acidophilus* as the negative control.

The Cepheid Xpert GBS LB Control Panel is not intended to replace the 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.

This product is not intended to replace the manufacturer controls provided with the Cepheid Xpert GBS LB Assay.

4. Special instrument requirements:

The Cepheid Xpert GBS LB Control Panel is intended for use on the Cepheid GeneXpert Instrument System

I. Device Description:

The Cepheid Xpert GBS LB Control Panel (Assayed Microbiology Control) is used to monitor DNA extraction, amplification and detection by the Cepheid Xpert GBS LB Assay on the GeneXpert Instrument System. Each Panel consists of 6 individually packaged positive control swabs of *Streptococcus agalactiae* (Lancefield's Group B) and 6 individually packaged negative control swabs of *Lactobacillus acidophilus*. The swabs were prepared with cultured, heat-inactivated, lyophilized organisms. When tested on the GeneXpert Instrument System using the Cepheid Xpert GBS LB Assay, *S. agalactiae* gives a Positive result and *L. acidophilus* gives a Negative result.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Amplichek II

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

[DEN150058](#)

3. Comparison with predicate:

Table 1. Comparison of the Cepheid Xpert GBS LB Control Panel with the Predicate Device

Similarities		
Item	Device Cepheid Xpert GBS LB Control Panel K182472	Predicate Bio-Rad Amplichek II DEN150058
Intended Use	External assayed positive and negative quality control materials to monitor the performance of <i>in vitro</i> laboratory nucleic acid testing procedures for the qualitative detection of Group B <i>Streptococcus</i> (GBS) performed with the Cepheid Xpert GBS LB Assay on the GeneXpert Instrument System. The controls comprise cultured and inactivated <i>Streptococcus agalactiae</i> as the positive control and <i>Lactobacillus acidophilus</i> as the negative control. The Cepheid Xpert GBS LB Control Panel is not intended to replace the manufacturer controls provided with the device.	External assayed quality control material to monitor the performance of <i>in vitro</i> laboratory nucleic acid testing procedures for the qualitative detection of Methicillin Resistant <i>Staphylococcus aureus</i> , Methicillin Sensitive <i>Staphylococcus aureus</i> , <i>Clostridium difficile</i> and Vancomycin-resistant Enterococci performed on Cepheid GeneXpert Systems. This product is not intended to replace manufacturer controls provided with the device.
Composition	Cultured and inactivated microorganisms	Same
Test System	Cepheid GeneXpert System	Same
Directions for Use	Process like patient sample	Same
Assay Steps Monitored	Extraction, amplification, and detection	Same

Differences		
Item	Device Cepheid Xpert GBS LB Control Panel K182472	Predicate Bio-Rad Amplichek II – DEN150058
Physical Format	Lyophilized swab	Ready-to-use- liquid
Analytes	<ul style="list-style-type: none"> • Positive Control: <i>Streptococcus agalactiae</i> • Negative Control: <i>Lactobacillus acidophilus</i> 	<ul style="list-style-type: none"> • Methicillin Resistant <i>Staphylococcus aureus</i> • Methicillin Sensitive <i>Staphylococcus aureus</i> • <i>Clostridium difficile</i> • Vancomycin-resistant Enterococci
Assay Compatibility	Cepheid Xpert GBS LB Assay (K121539)	<ul style="list-style-type: none"> • 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 <i>C. difficile</i> (K091109) • Cepheid Xpert <i>C. difficile/Epi</i> (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 Cepheid Xpert GBS LB Control Panel is intended for use as external assayed quality control materials for use in monitoring the DNA extraction, amplification and detection processes associated with the Cepheid Xpert GBS LB Assay ([K121539](#)) on the GeneXpert Instrument System.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Studies to determine precision and reproducibility of the Cepheid Xpert GBS LB Control Panel were performed on the GeneXpert Instrument using the Cepheid Xpert GBS LB assay. Testing was done at three different locations over five days. At each location, two operators each tested three different lots of control material for a total of 90 test results each for the Positive and Negative Control swabs (3 sites x 5 days x 2 operators x 3 replicates = 90 replicates in total). A summary of the qualitative results for both the Positive and Negative Controls are provided in **Table 2**. All Positive Controls produced the expected Positive result, although one control was re-tested due to an instrument ERROR which indicated that the assay was aborted. When re-tested, the Positive Control produced the expected result. All Negative Controls produced the expected Negative result.

Table 2. Summary of results from the Reproducibility Study (qualitative)

Positive Control (PC)					
Test location	Total Tests Performed	Invalid Tests	Correct PC Result	Incorrect PC Result	Percent Correct ²
1 ¹	31	1	30	0	100%
2	30	0	30	0	100%
3	30	0	30	0	100%
All sites	91	1	90	0	100%
Negative Control (NC)					
Test location	Total Tests Performed	Invalid Tests	Correct NC Result	Incorrect NC Result	Percent Correct ²
1 ¹	31	0	31	0	100%
2	30	0	30	0	100%
3	30	0	30	0	100%
All sites	91	0	91	0	100%

¹ One ERROR result was observed for the positive control. Both the positive control and negative control were re-tested, as indicated in the test protocol.

² Data from the test run with the ERROR result was not included in the Percent Correct analysis.

The reproducibility of the Cepheid Xpert GBS LB Control Panel within and between test locations, GeneXpert Instruments, operators, and lots was determined to be acceptable.

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 established through an Accelerated Stability Study that was performed with three lots of the Positive Control from the Cepheid Xpert GBS LB Control Panel. The Positive Control was placed at elevated temperatures (43°C, 53°C and 63°C) and tested in four replicates at four time points (Day 0, Day 14, Day 28 and Day 42). When the stability of the product was evaluated qualitatively, all analytes tested positive on the GeneXpert Instrument System using the Cepheid Xpert GBS LB assay. Thus, the data provided no evidence of product degradation under the conditions tested and may support shelf-life claims of 24 months.

2. A Real-Time, Shelf-Life Stability Study is in process with a goal of a 24 months stability claim. Positive Control samples incubated at two temperatures (2-8°C and 25°C) will be qualitatively tested four times throughout a 25 months study (four samples/sampling). Testing is expected to be completed by 08/27/2020.

3. An In-Use Stability Study was done to determine if the Positive and Negative Control products would remain stable for five hours after hydration to demonstrate stability of the product within the recommended time frame of use (i.e., ≤15 minutes). Two replicates from a single lot were hydrated and set aside (in a centrifuge tube) at room temperature (21°C). Samples were tested on the GeneCpert System after zero, four, and six hours and gave expected values indicating that the product may be hydrated and used within a six hour period without concern of performance.

Expected Values:

The Cepheid Xpert GBS LB Control Panel is a qualitative control expected to produce positive results with the Positive Control (*Streptococcus agalactiae*) and negative results with the Negative Control (*Lactobacillus acidophilus*) when tested with the Cepheid Xpert GBS LB assay using the GeneXpert Instrument 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 Cepheid Xpert GBS LB Control Panel is a qualitative quality control panel with no assigned values. Performance was evaluated as described in Section M.

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.