

INSTRUCTIONS FOR USE

IVD

■ Assayed GBS LB Control Panel

INTENDED USE

The Assayed 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 Assayed GBS LB Control Panel is not intended to replace manufacturer controls provided with the device.

SUMMARY AND EXPLANATION

The Assayed GBS LB Control Panel is an easy-to-use external quality control that can be used to monitor the extraction, amplification and detection of the Cepheid Xpert® GBS LB Assay. 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.

PRINCIPLE

The Assayed GBS LB Control Panel is comprised of cultured organisms which have been inactivated by heat treatments. The positive control contains an isolate of *Streptococcus agalactiae* (Lancefield's Group B) which is detected by the assay. The negative control, *Lactobacillus acidophilus* is an organism that can be expected to be found as part of a microbiome of the sampling location and therefore present in a test specimen. This negative control is not detected by the Cepheid Xpert® GBS LB Assay.

COMPOSITION

Each Assayed GBS LB Control Panel consists of 6 individually packaged positive controls swabs. Each positive control swab contains *S. agalactiae* (Lancefield's Group B). The kit also includes 6 individually packaged negative controls swabs of *L. acidophilus*. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The solution is lyophilized into a ready-to-use swab.

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 +1.320.229.7045 or U.S. Toll Free +1.866.286.6691.
- These products are not made with natural rubber latex.


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MOLECULAR STANDARDS

STORAGE AND EXPIRATION

Store the Assayed GBS LB Control Panel at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately.

The Assayed GBS LB Control Panel 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

MATERIALS REQUIRED BUT NOT PROVIDED

- Cepheid GeneXpert® System.
- Cepheid Xpert® GBS LB Assay and materials required per the assay's instructions.
- LIM Broth 5mL per Cepheid Xpert® GBS LB Assay product insert.
- Package Insert of the Cepheid Xpert® GBS LB Assay.

INSTRUCTIONS FOR USE

1. Read the Cepheid package insert specific to the Xpert® GBS LB assay.
2. Tear open the foil pouch containing the quality control swab at the notch.
3. Remove the swab from the pouch.
4. Insert the dry swab into a vial of LIM Broth to hydrate the swab. Swab should be submerged in LIM Broth no longer than 10 seconds. Do not enrich sample overnight. Vortexing is not required.
5. Open the lid of the Cepheid Xpert® GBS LB cartridge. Remove the rehydrated swab from the LIM Broth and insert the swab immediately into the sample chamber of the Cepheid Xpert® GBS LB cartridge.
6. Break the swab in the Cepheid Xpert® GBS LB Cartridge. Test must be started within 15 minutes of adding the swab to the cartridge.
7. Close the cartridge lid and start the test.

LIMITATIONS

- Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
- Each positive and negative control swab is only intended to be used once.
- Before use of the Assayed GBS LB Control Panel, ensure that the in-use lot of Cepheid Xpert® GBS LB Assay has been validated with the control panel and results are as expected.

EXPECTED VALUES

The following results are expected when running the 8194 controls with the Cepheid Xpert® GBS LB Assay:

8194 Control	Expected Assay Result	Interpretation
6025 – Positive Control	GBS Positive GBS: POS	GBS target nucleic acid is detected.
6026 – Negative Control	GBS Negative GBS: NEG	GBS target nucleic acid is not detected.

A positive control that yields a negative result may be indicative of a specimen handling/preparation problem. Repeat the test using a new swab.

If a negative control yields a positive result, clean the Cepheid GeneXpert® System per the user manual and clean the work area. Repeat the test using a new swab.

The performance of the Assayed GBS LB Control Panel was evaluated in a study that was performed using three different production lots, three sites using three different Cepheid GeneXpert® System and six different users. The results of the study are summarized below.

Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1 ¹	Site 2	Site 3	Overall
<i>S. agalactiae</i>	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
<i>L. acidophilus</i>	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

¹One ERROR occurred; new controls were retested and the expected results were obtained

KEY OF SYMBOLS

	Batch code (Lot)		In vitro diagnostic medical device
	Catalog number		Manufacturer
	Caution		Temperature limit
	Consult instructions for use or consult electronic instructions for use		Use-by-date
	Contains sufficient for <n> tests		Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in the 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.
- Issues regarding performance of the Assayed GBS LB Control Panel should be addressed to Microbiologics, Inc. directly.
- The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc.

WEBSITE ---

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

BIBLIOGRAPHY ---

1. Xpert® GBS LB [product insert]. Cepheid, Sunnyvale, CA 94089 USA

ASSISTANCE ---



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

ILLUSTRATED INSTRUCTIONS

1

Read the Cepheid package insert specific to the Cepheid Xpert® GBS LB assay.

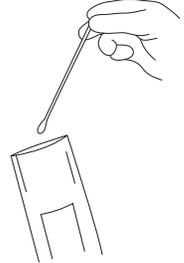
2

Tear open the foil pouch containing the quality control swab at the notch.



3

Remove the swab from the pouch.



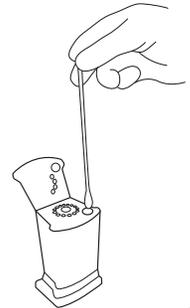
4

Insert the dry swab into a vial of LIM Broth to hydrate the swab. Swab should be submerged in LIM Broth no longer than 10 seconds. Do not enrich sample overnight. Vortexing is not required.



5

Open the lid of the Cepheid Xpert® GBS LB cartridge. Remove the rehydrated swab from the LIM Broth and insert the swab immediately into the sample chamber of the Cepheid Xpert® GBS LB cartridge.



6

Break the swab in the Cepheid Xpert® GBS LB Cartridge. Test must be started within 15 minutes of adding the swab to the cartridge.



7

Close the cartridge lid and start the test.

