



# Assay Training: Xpert<sup>®</sup> GBS

For US-IVD and CE-IVD product only



**CE IVD** In Vitro Diagnostic Medical Device

# Training Agenda

- Xpert® GBS Training
  - Reagents
  - Sample collection
  - Kit storage and handling
  - Preparing the cartridge
  - Quality control
  - Results analysis
- Discussion



# Training Objectives

At the end of the training, users will be able to:

- Store and handle the Xpert® GBS cartridge kit.
- Follow proper laboratory safety precautions.
- Collect appropriate specimen and transport specimens.
- Perform the cartridge set up and run the assay.
- Report the various software-generated results.
- Understand the assay control strategy.

# Xpert<sup>®</sup> GBS



# The Cepheid Solution



- Detection of Group B Streptococcus (GBS) DNA
- On-board internal controls for each sample
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
  - Internal Control (IC)
- Closed cartridge system minimizes risk of contamination
- On-demand testing
  - Early Assay termination
    - Rapid Positive results in just over 30 minutes
- Random access

# Intended Use

The Cepheid Xpert® GBS performed on the GeneXpert® Dx System is a qualitative in vitro diagnostic test designed to **detect Group B Streptococcus (GBS) DNA from vaginal/rectal swab specimens**, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. **Xpert GBS Assay testing is indicated for rapid identification of antepartum and intrapartum GBS colonization.**

The use of the Xpert GBS for intrapartum screening should not preclude the use of other strategies (e.g., antepartum testing). Intrapartum Xpert GBS results are useful to identify candidates for intrapartum antibiotic prophylaxis when administration of intravenous antibiotics is not delayed pending results. The Xpert GBS assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

# System and Reagent Requirements

## GeneXpert® Systems

- 6-color modules

## Test Kits

- GXGBS-100N-10

## Sample Collection

- Cepheid Collection Device (900-0370)

## Materials Required but not Provided

- Disposable, sterile transfer pipette (for retest only)
- Personal Protective Equipment (PPE)
- 1:10 dilution of bleach
- 70% ethanol or denatured ethanol

## Optional

- Uninterruptible Power Supply/ Surge Protector
- Printer

# Good Laboratory Practice

## Personnel Protective Equipment (PPE)

- Wear clean lab coats and gloves
- Change gloves between processing samples

## Lab Bench area

- Clean work surfaces routinely with:
  - ✓ 1:10 dilution of household bleach
  - ✓ 70% Ethanol Solution
- After cleaning, ensure work surfaces are dry

## Specimens, Samples, and Kits Storage

- Store specimens and sample away from kit to prevent contamination

## Equipment(s)

- Use filtered tips when recommended
- Follow the manufacturer's requirements for calibration and maintenance of equipment(s)

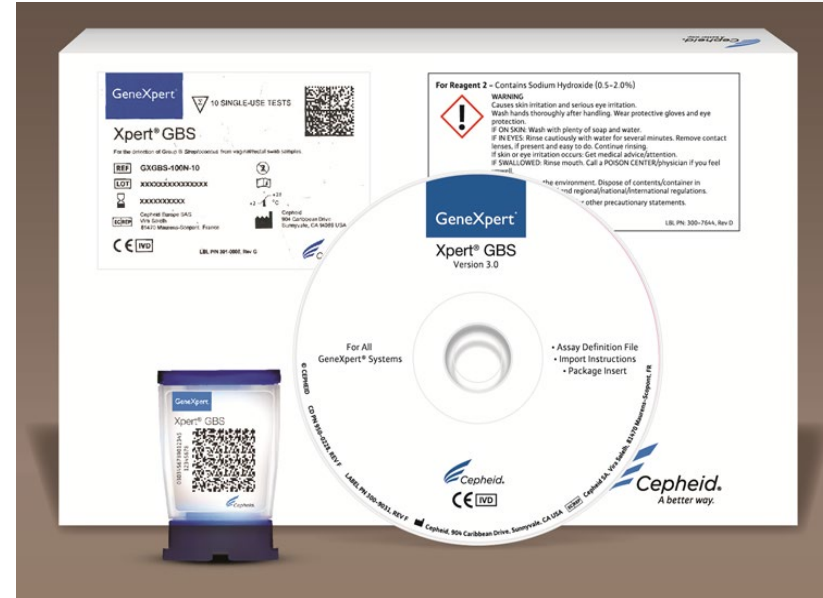


# Kit Handling



# Xpert<sup>®</sup> GBS Kit Components

<b>Catalog Number</b>	<b>GXGBS-100N-10</b>
<b>Tests per kit</b>	10
<b>Cartridge Contents</b>	Reagent beads
	Liquid reagents
<b>Kit CD</b>	Assay Definition Files (ADF)
	Assay Import Instructions
	Package insert
<b>Storage</b>	2-28° C



# Xpert<sup>®</sup> GBS Kit Storage and Handling

- Store the Xpert GBS cartridges and reagents at 2–28°C
- Follow your institution's safety procedures for working with chemicals and handling biological samples
- Open the cartridge lid only when adding the sample, close the lid and proceed with processing

# Warnings and Precautions

- Do not shake the cartridge
- Do not use a cartridge... :
  - if it appears wet, has leaked, or if the lid seal appears to have been broken
  - if it appears damaged
  - that has been dropped after removing it from packaging
  - that has been dropped or shaken after you have added the sample
  - that has a damaged reaction tube
  - that has been used; each cartridge is single-use to process one test
  - is expired
- Do not reuse swabs



**Dispose Xpert® GBS cartridges and reagents according to your institution's and country's guidelines for disposal of hazardous materials.**

# Waste Disposal

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions.
- Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents.
- These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures.
- If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

# Specimen Collection, Storage, and Transport



# Cepheid GBS Sample Collection and Specimen Stability

Specimen	Transport and Storage Temperature (°C)	Storage Time
Vaginal/rectal swab	2-8 °C	6 days
	15-30 °C	24 hours



**Cepheid Part Number 900-0370**

SCORE MARK

# Specimen Collection

## Xpert® GBS Vaginal/Rectal Specimen Collection Protocol

**Important:** Perform the vaginal/rectal specimen collection prior to using a speculum or using a lubricant.

1

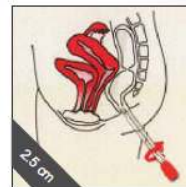
A Copan Venturi Transystem double swab (Cepheid Collection Device #900-0370) must be used to collect the specimen.



4

Using the same double swab, carefully insert the swab approximately 2.5 cm beyond the anal sphincter and gently rotate to sample anal crypts.

**Note:** swabs must stay attached to the red cap throughout the procedure.



2

Use gauze to wipe away excessive secretion or discharge from the vaginal/rectal area.



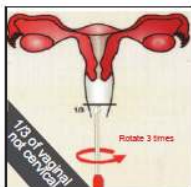
5

Remove and discard the cap on the transport tube and place swabs into the tube, pushing the red cap down completely.



3

Carefully insert the double swab into the lower third of patient's vagina and sample secretions from the mucosa. Rotate swab 3 times to ensure uniform sample on both swabs. Do not collect cervical sample.



6

Specimens that can be tested within 24 hours can be kept at room temperature. Otherwise, specimens stored at 2-8 °C are stable for up to 6 days.





# Xpert<sup>®</sup> GBS Cartridge Preparation

## Xpert GBS Cartridge Preparation

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

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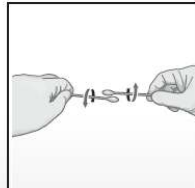
1 Obtain one cartridge.



2 Open the cartridge lid.



3 Remove the swabs from the container. Gently brush the swabs together. Replace one swab in the collection/transport tube.



**Note:** Do not hold the swab below the score mark.

4 Insert the other swab in the cartridge. Break the swab at the score mark.



**Note:** Use gauze or its equivalent to minimize the risk of contamination.

5 Make sure the swab can float freely in the chamber.



Incorrect swab placement. Swab end is caught in the notch of the sample opening.



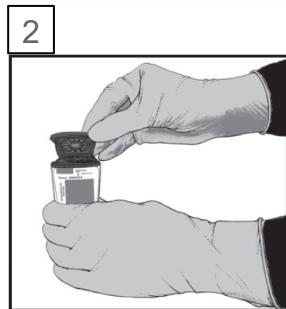
6 Close the cartridge lid. Start the test within the timeframe specified in the package insert.



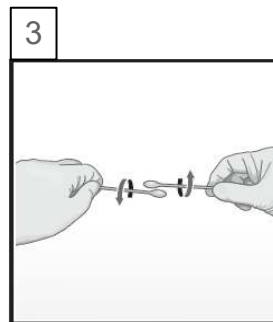
# Xpert<sup>®</sup> GBS Cartridge Preparation



Obtain one cartridge.

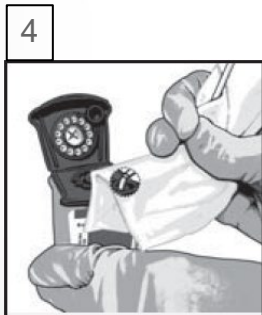


Open the cartridge lid.



Remove the swabs from the container. Gently brush the swabs together. Replace one swab in the collection/transport tube.

**Note:** Do not hold the swab below the score mark.



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**Note:** Use gauze or its equivalent to minimize the risk of contamination.



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Close the cartridge lid. Start the test within the timeframe specified in the package insert.

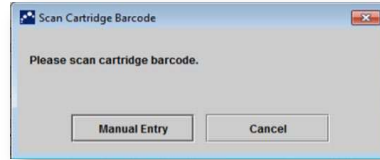
# Run a Test

## 1 Create Test



Start the test within **15 minutes** after adding the sample to the cartridge

## 2 Scan barcodes: Cartridge/ Patient and/or Sample ID



*By default, do not click on  
**Manual Entry** or **Cancel***

## 3 Scan the cartridge



# Create a Test on GeneXpert<sup>®</sup> Dx Software

4 Complete the fields as required

5 The Assay Protocol is selected automatically

6 The module is selected automatically

7 Click on Start Test

8 A green light will flash on the module  
Load the cartridge into module and close the door

The screenshot shows the 'Create Test' software interface. The following fields and buttons are highlighted with orange boxes:

- Patient ID, Sample ID, Patient ID 2, and Last Name input fields.
- Select Assay dropdown menu, currently showing 'Xpert Assay name'.
- Select Module dropdown menu, currently showing 'A3'.
- Reagent Lot ID\* and Expiration Date\* input fields.
- Test Type dropdown menu, currently showing 'Specimen'.
- Sample Type dropdown menu, currently showing 'Other'.
- Start Test button.

Arrows from the numbered instructions point to these elements: instruction 4 points to the ID fields; instruction 5 points to the Select Assay dropdown; instruction 6 points to the Select Module dropdown; instruction 7 points to the Start Test button.



# Automated Xpert® Protocol



# Quality Control

*Refer to the Package Insert for  
complete details*



# Cepheid Assay Control Strategy

- Each Xpert<sup>®</sup> cartridge is a self-contained test device.
- Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes within each cartridge.
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
  - Internal Control (IC)

# Internal Quality Controls

- **Probe Check Controls (PCC)**

- Before the PCR step, fluorescence signal is measured on all probes and compared with default factory settings to monitor
  - bead rehydration
  - reaction tube filling
  - probe integrity
  - dye stability

- **Sample Processing Controls (SPC) and Internal Control (IC)**

- Verifies adequate sample processing
- Verifies lysis, presence of the organism and detects PCR inhibition
- Should be positive in a negative sample
- Can be positive or negative in a positive sample



# Commercially Available External Controls

Company	Description	Catalog Number
<b>Microbiologics</b>	<i>Streptococcus</i> species (Group B) low-level positive control	<b>8164</b>
	<i>Streptococcus</i> species (Group B) moderate-level positive control	
	<i>Streptococcus</i> species (Group B) high-level positive control	
	<i>L. acidophilus</i> as a negative control	
<a href="http://www.microbiologics.com">www.microbiologics.com</a>		

External controls should be used in accordance with local, state, and federal accrediting organizations, as applicable.

# Results Analysis

*Refer to the Package Insert for  
complete details*



# Results Summary

Result displayed	GBS	SPC	IC
Positive	+	+/-	+/-
Negative	-	+	+
INVALID	-	-	+
	-	+	-
	-	-	-

# EAT (Early Assay Termination)

- **What is it?**
  - Real-time monitoring of reaction progress
  - Termination of the reaction when the cycle threshold of a particular reaction is crossed
- **What are the benefits?**
  - Positive results are reported sooner (dependent on sample titer)
  - For time-critical interventions, valuable minutes are saved for patients that need it the most

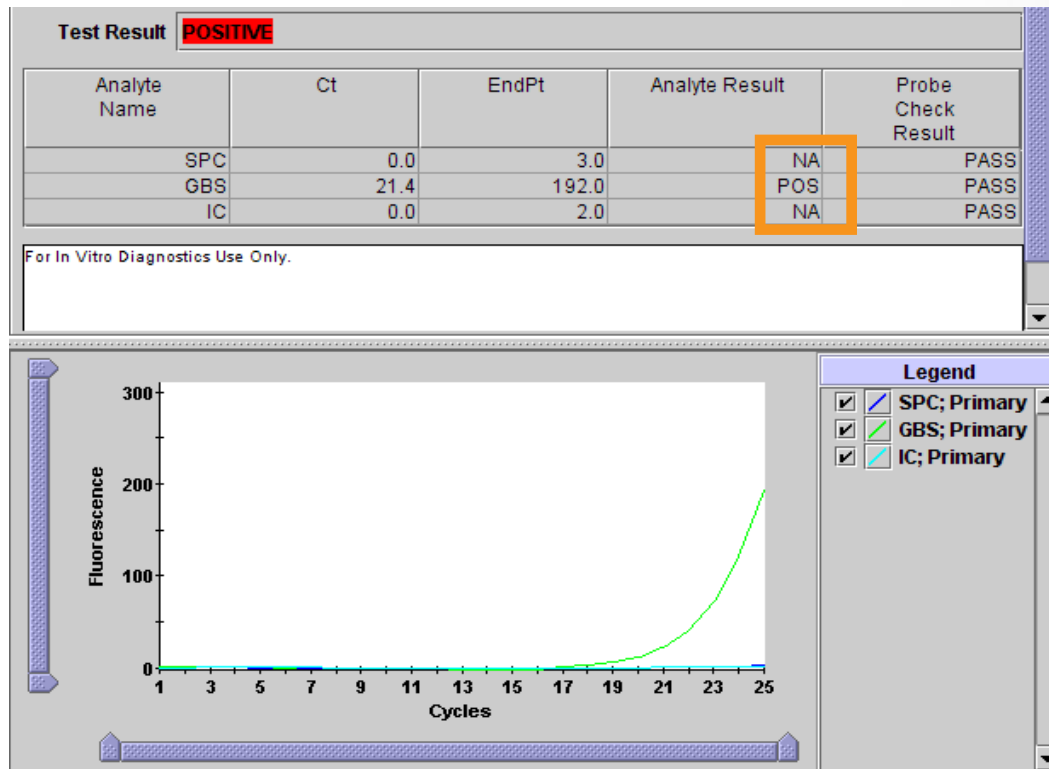
# GBS Positive

## - example of Early Assay Termination

Test Result **POSITIVE**

GBS target nucleic acid is detected.

- SPC and IC: NA (not applicable)  
The SPC and IC are ignored because GBS amplification can compete with these controls.
- Probe Check: PASS  
All probe check results pass.

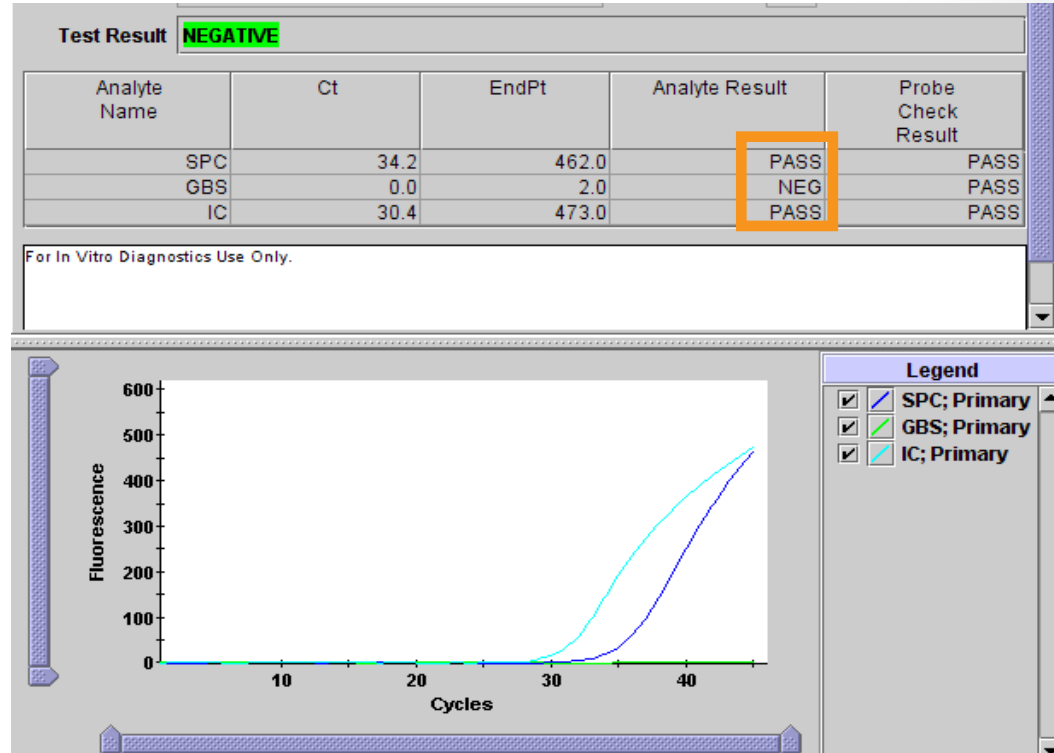


# GBS Negative

Test Result **NEGATIVE**

GBS target nucleic acid is not detected.

- GBS: NEG
- SPC and IC: PASS  
The SPC and IC have valid Cts.
- Probe Check: PASS  
All probe check results pass.



# Troubleshooting



# Factors That Negatively Affect Results

- **Improper specimen collection**
  - Performance with other collection devices and specimen types has not been assessed.
- **Improper transport or storage of collected specimen**
  - Storage and transport conditions are specimen specific.
  - Refer to the Package Insert for the appropriate handling instructions.
- **Improper testing procedure**
  - Modification to the testing procedures may alter the performance of the test.
  - Technical error or sample mix-up can impact test results.
  - Careful compliance with the Package Insert is necessary to avoid erroneous results.
- **Interfering substance**
  - False negative test results or invalid results may be observed in the presence of interfering substances.
- **The number of organisms in the specimen is below the detection limit of the test**
- **Mutations in primer or probe binding regions may affect detection of new or unknown GBS variants resulting in a false negative result.**

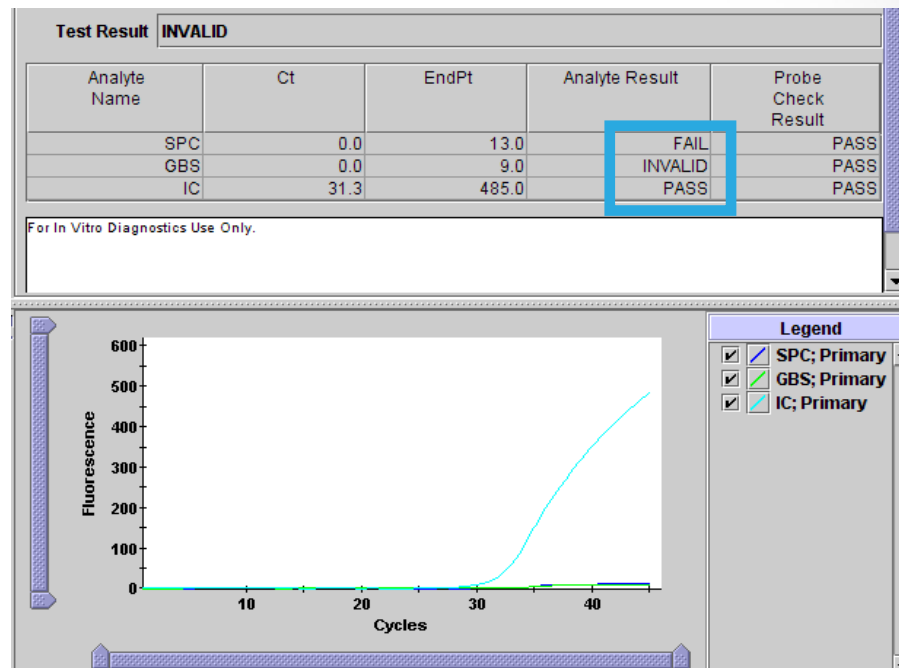


# INVALID

Test Result **INVALID**

Presence or absence of GBS target nucleic acid cannot be determined. IC and/or SPC does not meet acceptance criteria, or air bubbles formed in the reaction tube.

- GBS: INVALID
- SPC and/or IC: FAIL  
The SPC and/or target results are negative, and the SPC and/or IC do not have a valid Ct.
- Probe Check: PASS  
All probe check results pass.



# ERROR

Test Result **ERROR**

Presence or absence of GBS target nucleic acid cannot be determined. A system component failed, the maximum pressure was reached, or the probe check failed.

- GBS: NO RESULT
- SPC: NO RESULT
- IC: NO RESULT
- Probe Check: FAIL\*

\* If the probe check passed, the error is caused by a system component failure.

Test Result <b>ERROR</b>				
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	0.0	0.0	NO RESULT	NA
GBS	0.0	0.0	NO RESULT	NA
IC	0.0	0.0	NO RESULT	NA

For In Vitro Diagnostics Use Only.

Test and Analyte Result				Detail	Errors	History
Troubleshoot						
#	Description	Detail			Time	
1	Operation terminated	Error 2008 - Syringe pressure reading of 120.0 PSI exceeds the protocol limit of 120.0 PSI			6/27/2009 13:09:49	

# NO RESULT

Test Result **NO RESULT**

Presence or absence of GBS target nucleic acid cannot be determined.

- GBS: NO RESULT
- SPC: NO RESULT
- IC: NO RESULT
- Probe Check: NA (not applicable)

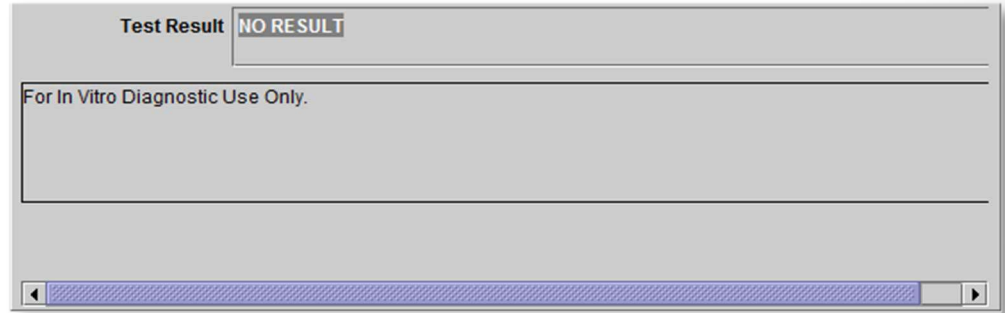
## Possible Causes

A NO RESULT indicates that insufficient data were collected.

- Test was stopped with stop test button
- Electrical failure

## Solution

- Secure the power
- Repeat the test with a new cartridge



# Xpert GBS Retest Procedure

## Xpert Retest Procedure

- Xpert GBS

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

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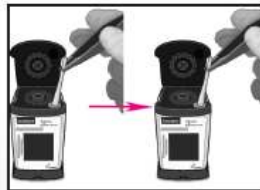
- 1 Retain the used cartridge.  
Obtain a new Xpert cartridge.



- 2a If there is fluid in the cartridge sample chamber, use a sterile transfer pipette to transfer all the fluid to the sample chamber of a new cartridge.



- 2b If there is no fluid, use sterile tweezers to transfer the swab to a new cartridge.



- 2c Or prepare a new cartridge using the second swab as shown on the reverse side.



- 3 Close the cartridge lid. Start the test within the specified timeframe.



# Limitations

- Refer to the Package Insert for a complete list of limitations.

# Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Error messages (if any)
  - Software version and, if applicable, Computer Service Tag number
- Log your complaint online using the following link <http://www.cepheid.com/us/support> : *Create a Support Case*

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	<a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a>
Australia and New Zealand	+ 1800 107 884 (AU) + 0800 001 028 (NZ)	<a href="mailto:techsupportANZ@cepheid.com">techsupportANZ@cepheid.com</a>
Brazil and Latin America	+ 55 11 3524 8373	<a href="mailto:latamsupport@cepheid.com">latamsupport@cepheid.com</a>
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Thank You.

[www.Cepheid.com](http://www.Cepheid.com)

