Technical Training
Xpert® Xpress GBS

Catalog Number (XPRSGBS-CE-10)
For CE-IVD Only

CE IVD In Vitro Diagnostic Medical Device

303-3300 Rev. A March 2024

Training Agenda

1. Intended Use
2. Kit Handling
3. Specimen Collection, Storage and Transport
4. Preparing the cartridge
5. Quality controls
6. Results analysis
7. Troubleshooting

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Intended Use

- The Xpert® Xpress GBS test, performed on the GeneXpert® Instrument Systems is an automated qualitative *in vitro* diagnostic test for the detection of DNA from Group B *Streptococcus* (GBS) using real-time polymerase chain reaction (PCR). The test is performed using a dual vaginal/rectal swab specimen collected from pregnant females during antepartum or intrapartum.
- The Xpert® Xpress GBS test is intended to aid in the diagnosis of GBS colonization to identify candidates for antibiotic prophylaxis.
- The Xpert® Xpress GBS test does not provide antimicrobial susceptibility test results. Culture is necessary to obtain isolates to perform susceptibility testing as recommended for penicillin-allergic females.

Intended User/Environment

- The Xpert® Xpress GBS is intended to be performed by trained users in both laboratory and near patient testing settings.

Good Laboratory Practice Review

Personnel Protective Equipment (PPE)

- Wear clean lab coats, safety glasses, 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

- Store specimens and sample away from kit to prevent contamination

Specimens, Samples, and Kits Storage

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

Equipment

*Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Kit Handling

Xpert® Xpress GBS Kit Contents

Catalog Number	**Catalog Number**(XPRSGBS-CE-10)
Cartridges* Per Kit	10
Kit CD	Xpert® Xpress GBS Assay Definition File (ADF)
	Xpert® Xpress GBS Import Instructions
	Package Insert (PDF)
Storage	2-28 °C

* *Cartridges contain chemically hazardous substances - please see Package Insert and Safety Data Sheet for more detailed information.*

Specimen Collection, Storage and Transport

Specimen Transport and Storage

- Collect vaginal/rectal swab specimens according to ACOG, European or local recommendations[1, 2, 3] using the Cepheid Collection Device (part number 900-0370).

Specimen Type	Testing	Storage	Transport	Stability
Vaginal/rectal swab	Immediately OR done after 24 hours	2-8ºC (if not being processing/ processed after 24Hrs) OR 25ºC(processed within 24Hrs) OR	2-8ºC	Up to 6 days at 2-8ºC

1. Di Renzo GC, Melin P, Berardi A, et al. Intrapartum GBS screening and antibiotic prophylaxis: a European consensus conference. J Matern Fetal Neonatal Med. 2015 May;28(7):766-82.
2. Prevention of Group B Streptococcal Early-Onset Disease in Newborns: ACOG Committee Opinion, Number 782. Obstet Gynecol. 2019 Jul;134(1):1.doi: 10.1097/AOG.0000000000003334.
3. Filkins, L, Hauser, J, Robinson-Dunn, B et al. Guidelines for the Detection and Identification of Group B *Streptococcus.* American Society for Microbiology, March 2020. https://asm.org/Guideline/Guidelines-for-the-Detection-and- Identification-of accessed Dec 1, 2021.

Cartridge Preparation

Proper Cartridge Handling Techniques

Correct

- Do not touch the reaction tube
- Keep the cartridge upright
- Do not tilt after sample is added

Incorrect

Xpert® Xpress GBS Cartridge Preparation

Xpert® Xpress GBS Cartridge Preparation

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

For a copy of the SDS, visit
www.cepheid.com or
www.cepheidinternational.com

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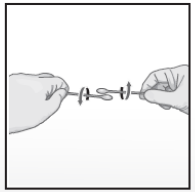
A better way.

1 Obtain one cartridge.

2 Open the cartridge lid.

3 Remove one swab from cap and gently brush the two swabs together using a twirling motion for five seconds. Return the second swab still attached to the cap back into the transport tube.

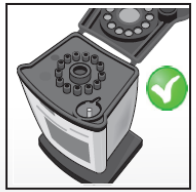


Note: *Do not hold the swab below the score mark*

4 Insert the swab into the cartridge sample chamber. 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 chamber opening.

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

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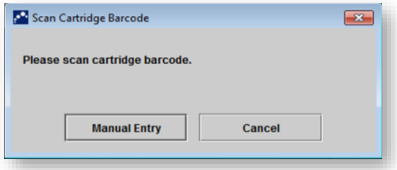
Run a Test on GeneXpert® Dx

1 Create a test.

Start the test within **30 minutes** after adding the sample to the cartridge.

2 Scan barcode for Patient and/or Sample ID.



Do not click on Manual Entry or Cancel.

3 Scan the cartridge.

For complete details on how to run a test, refer to the Package Insert and the GeneXpert Dx Operator Manual.

Quality Controls

Xpert® Xpress GBS Control Strategy

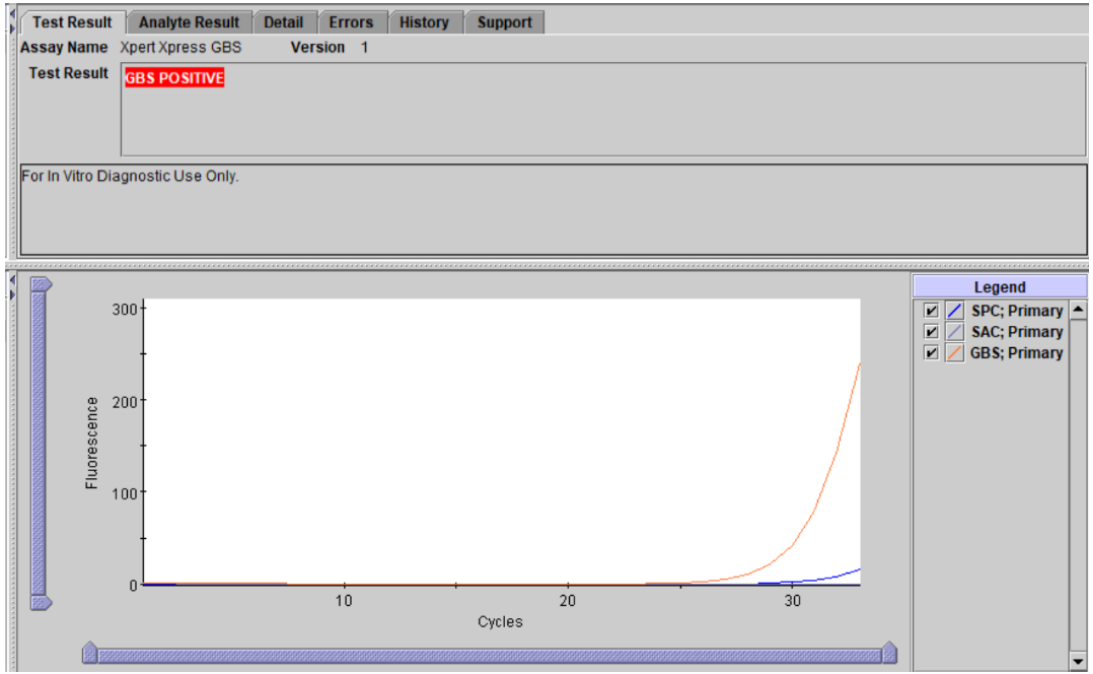
CONTROL

- Xpert® Xpress GBS Quality Controls
  - Each Xpert® 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:
    - Sample Processing Control (SPC)
    - Sample Adequacy Control (SAC)
    - Probe Check Control (PCC)

Refer to 301-4868 GeneXpert® Quality Control Features for all Cepheid Xpert tests.

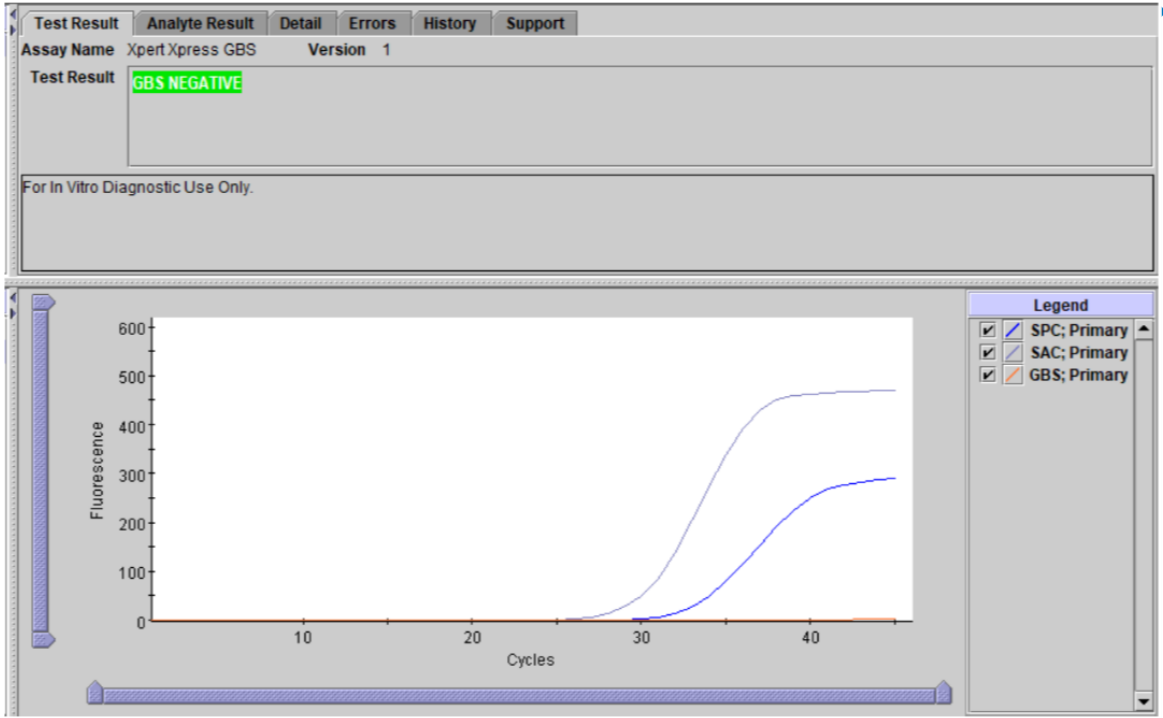
Result Interpretation

GBS POSITIVE



- GBS target DNA is detected – presumed for GBS colonization.
  - GBS – POSITIVE
  - SPC – NA (The SPC is ignored because GBS target amplification can compete with this control
  - PCC – PASS
  - SAC – NA (not applicable)

GBS NEGATIVE



- GBS target DNA not detected
  - GBS – NEGATIVE
  - SPC – PASS
  - PCC – PASS
  - SAC – PASS

Troubleshooting

Factors That Negatively Affect Results

- Improper specimen collection.
  - The performance of this assay with other specimen types or samples has not been evaluated.
- Inadequate numbers of organisms are present in the specimen.
- Improper transport or storage of collected specimen.
  - Storage and transport conditions are specimen specific.
  - Refer to the Instructions For Use for the appropriate handling instructions.
- Improper testing procedure.
  - Modification to the testing procedures may alter the performance of the test.
  - Careful compliance with the Instructions For Use is necessary to avoid erroneous results.

Retesting

- If any of the test results mentioned below occur, repeat the test

- An **INVALID** result indicates GBS is not detected and the control SPC and/or SAC failed in one or more of the following causes:
  - The specimen was not properly collected or processed.
  - The specimen was not added to the cartridge.
  - PCR was inhibited.
- An **ERROR** result indicates that the assay was aborted. Possible causes include:
  - the reaction tube was filled improperly;
  - a reagent probe integrity problem was detected; system component failure or the maximum pressure limit was exceeded.
- A **NO RESULT** indicates that insufficient data were collected.
  - For example, the operator stopped a test that was in progress, or a power failure occurred.

Retest Procedure

Xpert Retest Procedure

• Xpert® Xpress GBS

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

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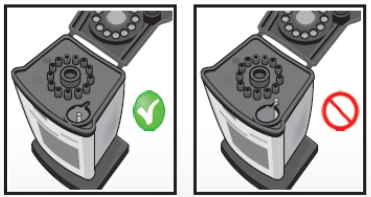
A better way.

1 Discard used cartridge. Obtain a new Xpert® Xpress GBS cartridge. Remove the remaining swab from the collection transport tube.

2 Insert swab into the sample chamber of the new cartridge. Raise the swab so that the score mark is centered in the notch. Break the swab by snapping to the right.

3 Ensure the swab is properly positioned in the cartridge and the swab end is not in the notch of the sample chamber opening and does not prevent lid closure.



4 If the swab is stuck in the notch, use a lint free wipe/gauze or the remaining end of the swab to release it from the notch to minimize the risk of contamination.

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

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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

- Log your complaint online using the following link ***http://www.cepheid.com/en/support:*** *Create a Support Case*

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Thank You

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