GeneXpert®
Powered By CEPHEID INNOVATION

Xpert® Xpress GBS

REF **XPRSGBS-CE-10**

Instructions for Use

IVD CE

Cepheid®

In Vitro Diagnostic Medical Device

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Trademark, Patents, and Copyright Statements

See Section 27, Revision History for a description of changes.

Xpert® Xpress GBS

For *In Vitro* Diagnostic Use Only

1 Proprietary Name

Xpert® Xpress GBS

2 Common or Usual Name

Xpert Xpress GBS

3 Intended Purpose

3.1 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.

3.2 Intended User/Environment

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

4 Summary and Explanation

GBS bacterial infection is associated with serious illness in newborns born to females who are colonized with the microorganism. GBS infection is the major cause of death in newborns who develop sepsis, pneumonia, or meningitis (1, 2). About half of females who are colonized with GBS will transmit the bacteria to their newborns. Transmission of GBS usually occurs during labor or after rupture of membranes.

Currently, the standard of care for preventing neonatal GBS disease is either antepartum screening of pregnant females at 36 0/7 and 37 6/7 weeks of gestation or intrapartum screening during labor to determine their GBS colonization status (1, 2). Most antepartum GBS testing is performed by culture or a nucleic acid amplification test (NAAT) performed on an enrichment broth culture after 18–24 hour incubation (3), and typically takes one to three days to finalize results. This timing might be adequate for obtaining antepartum GBS results; however, some females may not have GBS results available at the onset of labor. For females who have had no prenatal care, or who might deliver preterm, or whose GBS test results are unknown at the time of delivery, intrapartum testing performed directly from a non-enriched swab specimen can provide results in time to decide whether to administer antibiotics before delivery.

The potential impact of intrapartum testing is decreased use of unnecessary antibiotics in females not otherwise indicated for prophylaxis and the potential effect on the intestinal microbiota of infants (4), while providing adequate treatment of GBS-colonized females with the resulting decreased risk of neonatal sepsis or meningitis. (5) Effective intrapartum GBS testing

for pregnant females who come to labor and delivery without a known GBS status requires prompt specimen collection and capability of providing results quickly enough to initiate the recommended duration of antibiotic prophylaxis prior to delivery.

5 Principle of the Procedure

The Xpert Xpress GBS test is an automated *in vitro* diagnostic test for qualitative detection of DNA from Group B *Streptococcus* (GBS). The assay is performed on the Cepheid GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample processing, nucleic acid purification and amplification, and detection of the target sequence in clinical samples using real-time PCR Polymerase Chain Reaction (PCR).

The primers and probes in the Xpert Xpress GBS test are designed to amplify and detect unique sequences in two GBS chromosomal targets, one target is within a coding region for a glycosyl transferase family protein and the other target is within a coding region for a *LysR* family transcriptional regulator of *S. agalactiae* DNA. A positive result will be generated if either or both targets are detected.

The GeneXpert systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that contain the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, refer to the appropriate GeneXpert Instrument System operator manual.

The Xpert Xpress GBS test includes reagents for the simultaneous detection of the target GBS DNA, a sample-processing control (SPC) to monitor accurate sample processing conditions and inhibition, and a Sample Adequacy Control (SAC). The SAC detects the presence of a single copy human gene and ensures the sample is properly collected and contains adequate human DNA. The probe check feature verifies reagent rehydration, PCR-tube filling in the cartridge, probe integrity, and dye stability.

After collecting and transporting a swab sample to the GeneXpert testing area, the swab is inserted into the Xpert Xpress GBS cartridge. The GeneXpert Instrument System performs sample preparation by eluting the specimen material from the swab, resuspending the SPC (*Bacillus globigii* in the form of a bead within the cartridge) with Reagent 1, mixing sample, SPC and Reagent 2, capturing cellular material on a filter, lysing the cells, and eluting the DNA. The eluted DNA is then mixed with dry PCR reagents and transferred into the integrated reaction tube for real-time PCR and detection.

The Xpert Xpress GBS has an Early Assay Termination (EAT) function that enables early result reporting. EAT is activated when the pre-determined threshold for a positive test result is reached before the full number of PCR cycles have been completed.

The sample results are interpolated by the GeneXpert System from measured fluorescent signals and embedded calculation algorithms and are shown in the **View Results** window in tabular and graphic formats. Results may be viewed and printed. It also reports if the test is invalid, has encountered an error or produces no result.

6 Materials Provided

The Xpert Xpress GBS kit (XPRSGBS-CE-10) contains sufficient reagents to process 10 patient or quality-control specimens. The kit contains the following:

Xpert Xpress GBS with integrated reaction tubes		**10 per kit**
Component/Reagent	**Ingredient**	**Amount**
Bead 1 (freeze-dried)	Enzyme: Taq DNA polymerase <80U/bead	1 per cartridge
	dNTPs <0.05%, probe <0.005%	
Bead 2	Primer and probes <0.005%	1 per cartridge
Bead 3	Bg spores <1e5spores/bead	1 per cartridge
Reagent 1	Trizma Base <0.3%	3 mL per cartridge
	EDTA <0.04%	
	Trizma HCl <0.4%	
	Tween 20 < 1%	

Xpert Xpress GBS with integrated reaction tubes		10 per kit
Component/Reagent	**Ingredient**	**Amount**
Reagent 2	Sodium Hydroxide <2%	1.5 mL per cartridge

CD-1 per kit

- Assay Definition file (ADF)
- Instructions to import ADF into software
- Instructions for Use (Package Insert)

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling

- Store the Xpert Xpress GBS cartridges at 2° C to 28° C.
- Do not use cartridges that have passed the expiration date on the label.
- Do not use a cartridge that has leaked.
- Do not open the cartridge lid until you are ready to perform testing.

8 Materials Required but Not Provided

- Cepheid Collection Device (part number 900-0370)
- GeneXpert Dx System or GeneXpert Infinity System (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner, and operator manual
  - For *GeneXpert Dx System*: GeneXpert Dx software version 5.3 or higher
  - For *GeneXpert Infinity-80* and *Infinity-48s systems*: Xpertise software version 6.8 or higher

9 Materials Available but not Provided

- Printer: If a printer is required, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.

10 Warnings and Precautions

- For *in vitro* diagnostic use.
- Treat all biological specimens, including used cartridges and reagents, as if capable of transmitting infectious agents. Since it is often impossible to know which specimen might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[6] and the Clinical and Laboratory Standards Institute[7].
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Follow good laboratory practices. Change gloves between handling each patient specimen in order to avoid contamination of specimens or reagents. Regularly clean the work surface/areas.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and reagents. Wash hands thoroughly after handling specimens and test reagents.
- Do not open the Xpert Xpress GBS cartridge lid except when adding sample.
- Do not use a cartridge that has been dropped after removing it from the packaging,
- Do not shake the cartridge. Shaking or dropping the cartridge after opening the lid may yield an erroneous result.
- Do not use a visibly damaged cartridge.
- Do not place the sample ID label on the cartridge lid or on the bar code label.

- Each single-use Xpert Xpress GBS cartridge is used to process one test. Do not reuse cartridges.
- Clean the work surface/areas with 10% bleach before and after processing Xpert Xpress GBS specimens.
- Specimens can contain high levels of organisms. Ensure that specimen containers do not contact one another. Change gloves if they come in direct contact with the specimen and after the processing of each specimen to avoid contaminating other specimens.
- 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.
- Reliable results are dependent on adequate specimen collection, transport, storage, and processing. Incorrect test results may occur from improper specimen collection, handling or storage, technical error, sample mix-up or because the number of organisms in the specimen is below the limit of detection of the test. Careful compliance with the Instructions for Use and the *GeneXpert Dx System Operator Manual* or *GeneXpert Infinity System Operator Manual* are necessary to avoid erroneous results.

11 Specimen Collection and Transport

To obtain an adequate specimen, follow the instructions in this section closely.

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

1. Use gauze to wipe away excessive amounts of secretion or discharge from vaginal rectal area.
2. Remove the Collection Device, a double swab, from the pouch.
3. Carefully insert the double swab into the patient's vagina. Sample secretions from the mucosa of the lower one-third part of the vagina. Rotate the swabs three times to ensure uniform sample on both swabs. Do not collect cervical sample.
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.

Important **Keep swabs attached to the red cap throughout the procedure.**

5. Remove and discard the clear cap on the transport tube and place swabs into the transport tube, labeled with Sample ID, pushing the red cap down completely.
6. When possible, store specimens at 2–8°C when not being processed.
   - If the specimens will be processed *within 24 hours*, storage at up to 25°C is acceptable.
   - If the specimens will be tested *after 24 hours*, refrigerate until testing is performed. Specimens may be stored up to six days at 2–8°C.

12 Chemical Hazards[7,8]

Reagent 2 (Sodium Hydroxide)

- **UN GHS Signal Word:** WARNING
- **UN GHS Hazard Pictogram(s):** 
- **UN GHS Hazard Statement(s)**
  - Causes skin irritation
  - Causes serious eye irritation
- **UN GHS Precautionary Statement(s)**
  - **Prevention**
    - Wash thoroughly after handling.
    - Wear protective gloves/protective clothing/eye protection/face protection
  - **Response**

- IF ON SKIN: Wash with plenty of soap and water.
- Take off contaminated clothing and wash before reuse.
- If skin irritation occurs: Get medical advice/attention.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention

- **Storage/Disposal**
  - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13 Procedure

13.1 Preparing the Cartridge

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

Note Only one swab is required. The second swab is extra and can be used for susceptibility or repeat testing. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic females. Do not add 2 swabs to any one cartridge.

To add the specimen to the cartridge:

1. Wear protective disposable gloves.
2. Remove the cartridge from the package.
3. Inspect the test cartridge for damage. If damaged, do not use it.
4. If cartridge have been stored refrigerated ensure equilibration to room temperature prior to use.
5. Label the cartridge with sample identification.

Note Write on the side of the cartridge or affix an ID label. Do not put the label on the lid of the cartridge or over the existing 2D barcode on the cartridge.

6. Open the cartridge lid by lifting the front of the cartridge lid.
7. Open the cap of the specimen transport tube.
8. Remove the swabs from the transport tube.
9. Remove one swab from cap and gently brush the two swabs together using a twirling motion for five seconds (see Figure 1).

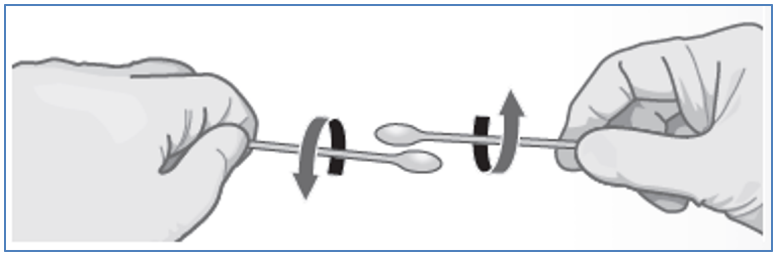

Figure 1. Swab Twirling Motion

10. Return the second swab still attached to the cap back into the transport tube.
11. Using gauze or equivalent, hold the swab to be used for testing above the score mark (see Figure 2).

Figure 2. Xpert Xpress GBS Collection Swab

12. Insert the swab into the Xpert Xpress GBS cartridge sample chamber (see Figure 3).

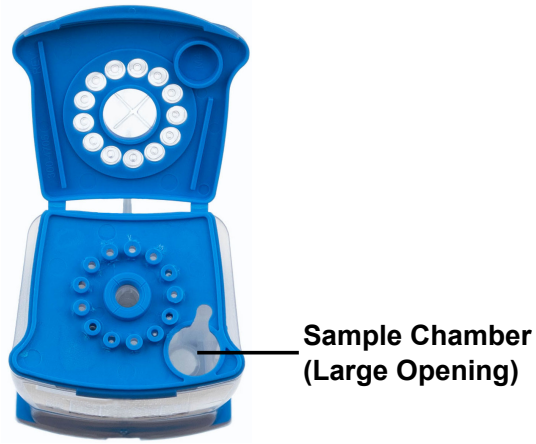

Figure 3. Xpert Xpress GBS Cartridge (Top View)

13. Raise the swab so that the score mark is centered in the notch.
14. Break the swab by snapping the shaft to the right.
15. 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. 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.
16. Close the cartridge lid. Start the test within 30 minutes.

13.2 External Controls

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

14 Running the Test

- For the GeneXpert Dx System, see Section 14.1.
- For the GeneXpert Infinity System, see Section 14.2.

14.1 GeneXpert Dx System

14.1.1 Starting the Test

Important

Before you start the test, make sure that:

- The system is running the correct GeneXpert Dx software version shown in section - Materials Required but Not Provided.
- The correct assay definition file is imported into the software.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Dx System Operator Manual*.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

1. Turn on the GeneXpert Dx System, then turn on the computer and log on. The GeneXpert software will launch automatically. If it does not, double-click the GeneXpert Dx software shortcut icon on the Windows® desktop.
2. Log on using your username and password.
3. In the **GeneXpert System** window, click **Create Test**.
   The **Create Test** window displays. The **Scan Patient ID barcode** dialog box displays.
4. Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly.
   The Patient ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Sample ID barcode** dialog box displays.
5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly.
   The Sample ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Cartridge Barcode** dialog box displays.
6. Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

Note If the barcode on the cartridge does not scan, then repeat the test with a new cartridge. If you have scanned the cartridge barcode in the software and the assay definition file is not available, a screen displays indicating the assay definition file is not loaded on the system. If this screen displays, contact Cepheid Technical Support.

7. Click **Start Test**. In the dialog box that displays, type your password, if required.
8. Open the instrument module door with the blinking green light and load the cartridge.
9. Close the door. The test starts and the green light stops blinking.
   When the test is finished, the light turns off.
10. Wait until the system releases the door lock before opening the module door, then remove the cartridge.
11. Dispose of the used cartridges in the appropriate specimen waste containers according to your institution's standard practices.

14.1.2 Viewing and Printing Results

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual*.

1. Click the **View Results** icon to view results.
2. Upon completion of the test, click the **Report** button of the **View Results** window to view and/or generate a PDF report file.

14.2 GeneXpert Infinity System

14.2.1 Starting the Test

Before you start the test, make sure that:

Important
- The system is running the correct Xpertise software version shown in section - Materials Required but Not Provided.
- The correct assay definition file is imported into the software.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Infinity System Operator Manual*.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

1. Power up the instrument. The Xpertise software will launch automatically. If it does not, double-click the Xpertise software shortcut icon on the Windows® desktop.
2. Log on to the computer, then log on to the GeneXpert Xpertise software using your user name and password.
3. In the **Xpertise Software Home** workspace, click **Orders** and in the **Orders** workspace, click **Order Test**.

The **Order Test - Patient ID** workspace displays.

4. Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly.
   The Patient ID is associated with the test results and displays in the **View Results** window and all the reports.
5. Enter any additional information required by your institution, and click the **CONTINUE** button.
   The **Order Test - Sample ID** workspace displays.
6. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly.
   The Sample ID is associated with the test results and displays in the **View Results** window and all the reports.
7. Click the **CONTINUE** button.
   The **Order Test - Assay** workspace displays.
8. Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

Note If the barcode on the cartridge does not scan, then repeat the test with a new cartridge. If you have scanned the cartridge barcode in the software and the assay definition file is not available, a screen displays indicating the assay definition file is not loaded on the system. If this screen displays, contact Cepheid Technical Support.

After the cartridge is scanned, the **Order Test - Test Information** workspace displays.

9. Verify that the information is correct, and click **Submit**. In the dialog box that displays, type your password, if required.
10. Place the cartridge on the conveyor belt.
    The cartridge automatically loads, the test runs, and the used cartridge are placed into the waste container.

14.2.2 Viewing and Printing Results

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the *GeneXpert Infinity System Operator Manual*.

1. In the **Xpertise Software Home** workspace, click the **RESULTS** icon. The Results menu displays.
2. In the Results menu, select the **VIEW RESULTS** button. The **View Results** workspace displays showing the test results.
3. Click the **REPORT** button to view and/or generate a PDF report file.

15 Quality Control

Each test includes a Sample Processing Control (SPC), Sample Adequacy Control (SAC) and a Probe check control (PPC).

- **Sample Adequacy Control (SAC)**: Ensures that the sample contains human cells or human DNA. This multiplex assay includes primers and probes for the detection of a single copy human gene. The SAC signal is only to be considered in an analyte negative sample since it serves as a control for adequate sample collection and sample stability to minimize risk of for false negative call out. A negative SAC indicates that no human cells are present in the sample due to incorrect sample collection or insufficient amount of sample on the swab. The SAC should pass —generate a valid cycle threshold (Ct) in a negative sample—and may not amplify in a high-positive sample. The SAC passes if it meets the assigned acceptance criteria and is required for a valid GBS Negative result, if not an invalid result would be reported.
- **Sample processing control (SPC)**: Ensures the sample was correctly processed. The SPC is *B. globigii* in the form of a dry bead and is included in each cartridge. The SPC monitors accurate sample processing conditions, sample inhibition, lysis and elution processing. The SPC should pass —generate a valid cycle threshold (Ct) in a negative sample—and may not amplify in a high-positive sample. The SPC passes if it meets the assigned acceptance criteria, if not an invalid result would be reported.
- **Probe check control (PCC)**: Before the start of the PCR reaction, the GeneXpert Instrument System measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. Probe Check passes if it meets the assigned acceptance criteria. If not, an error result would be reported.

16 Interpretation of Results

The results are determined by the GeneXpert Instrument Systems from measured fluorescent signals and embedded calculation algorithms and will be shown in the **View Results** window. Possible results are shown in Table 1. Examples of Xpert Xpress GBS Assay results are provided in Figure 4, Figure 5, Figure 6, Figure 7, and Figure 8.

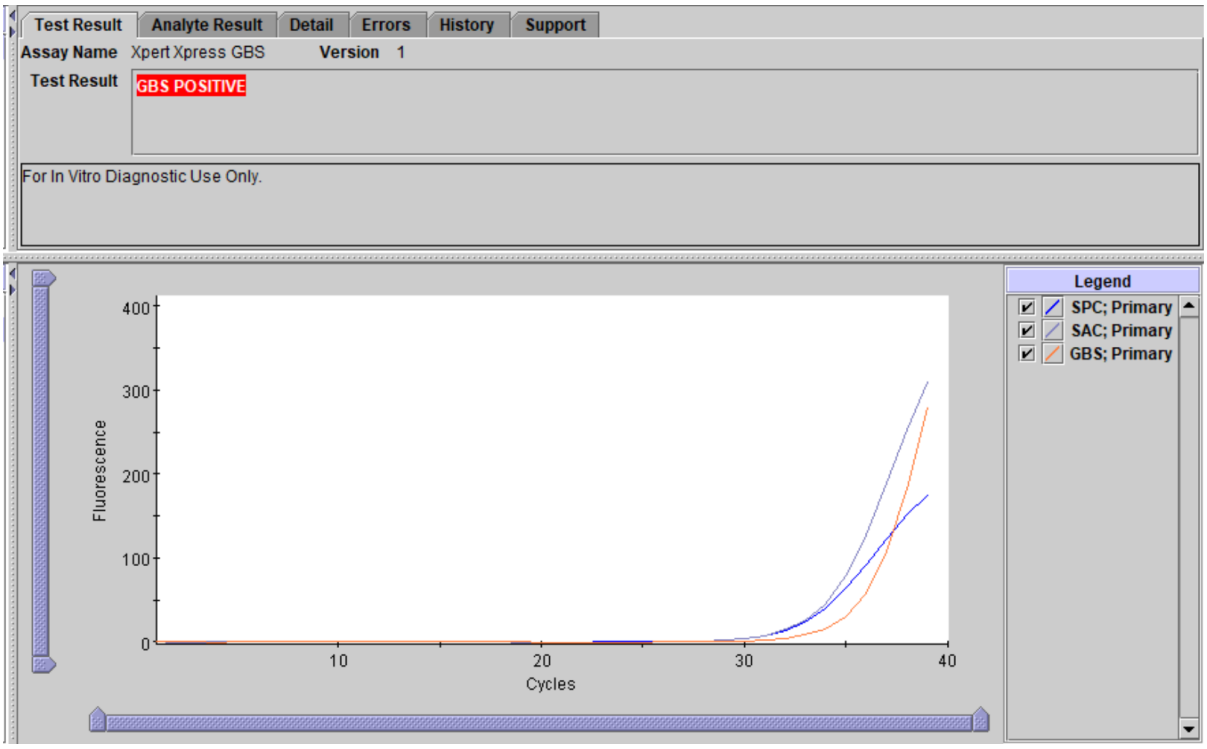

Figure 4. An Example of a GBS POSITIVE Result

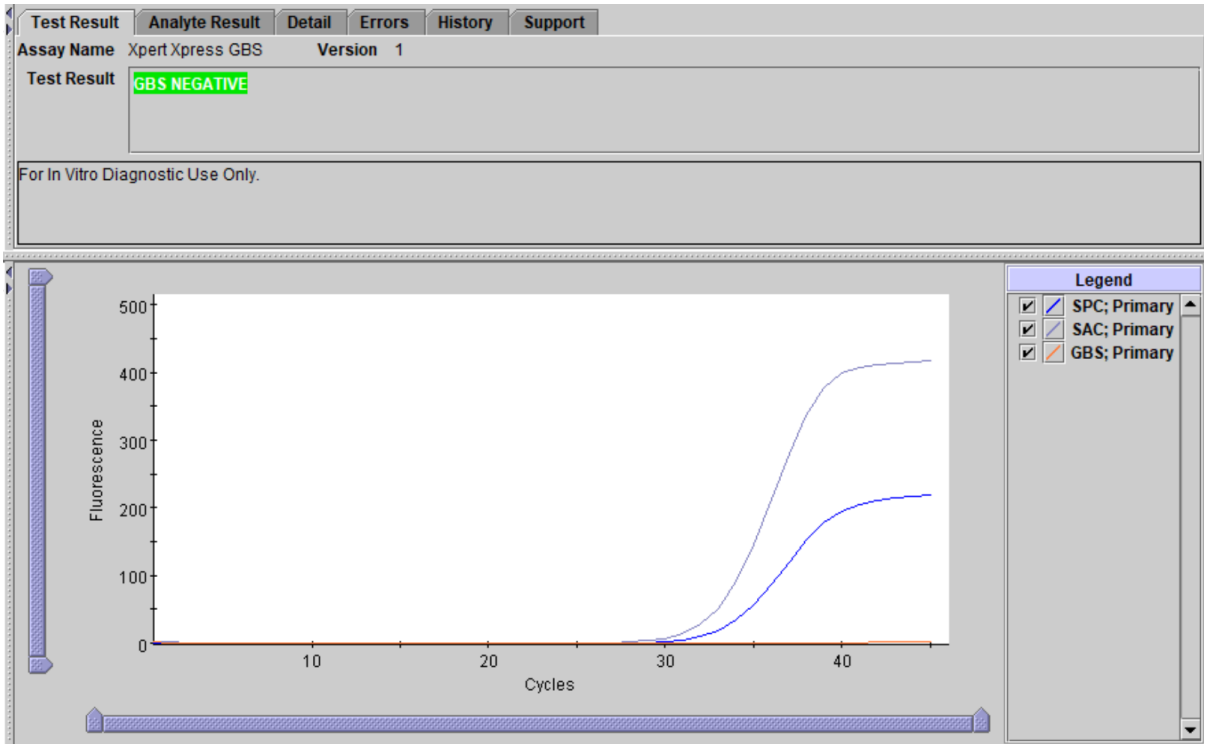

Figure 5. An Example of a GBS NEGATIVE Result

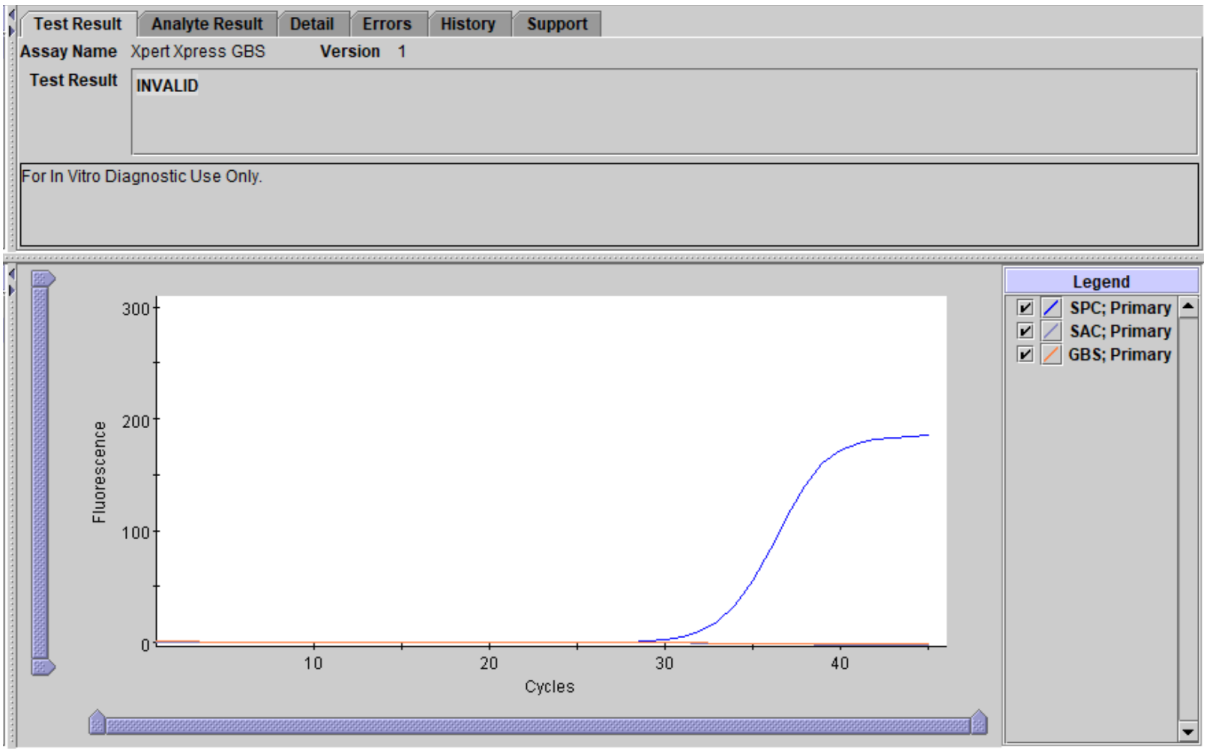

Figure 6. An Example of an Invalid Result

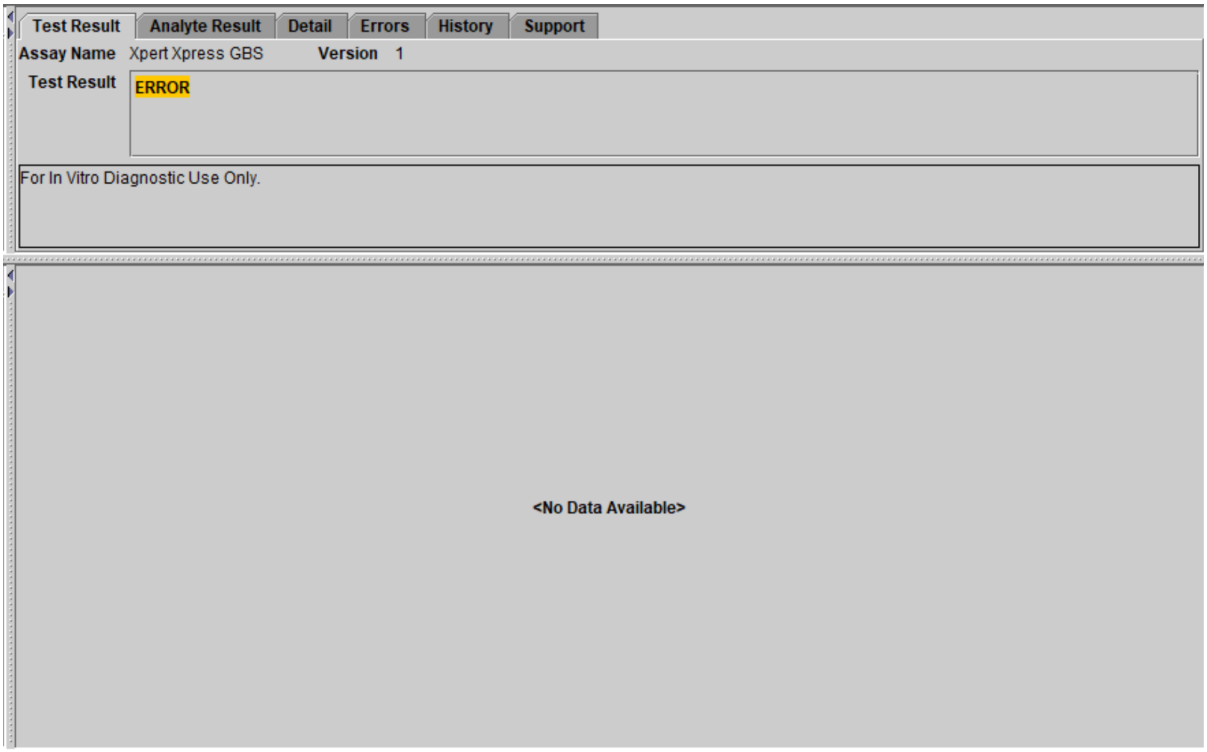

Figure 7. An Example of an ERROR Result

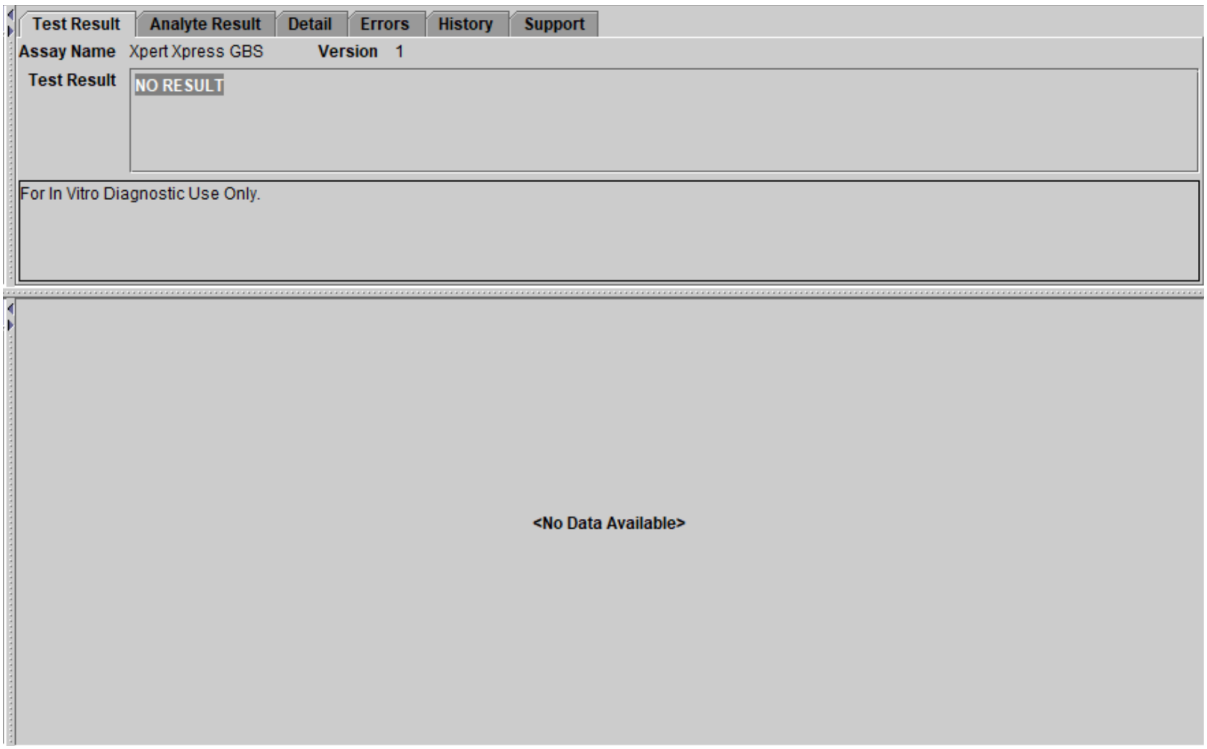

Figure 8. An Example of NO RESULT

Table 1. GBS Results and Interpretation

Result	Interpretation
GBS — POSITIVE[a] See Figure 4.	GBS target DNA is detected – presumed for GBS colonization. • GBS —POSITIVE • SPC – NA (not applicable). The SPC is ignored because GBS target amplification can compete with this control • Probe Check Controls - PASS • SAC — NA (not applicable)
GBS — NEGATIVE See Figure 5.	GBS target DNA is not detected - presumed not colonized for GBS. • GBS — NEGATIVE • SPC — PASS • Probe Check Controls—PASS • SAC - PASS
INVALID[b] See Figure 6.	Presence or absence of the GBS target DNA cannot be determined. SAC and/or SPC does not meet acceptance criteria. • GBS — INVALID • SPC — FAIL[c] • Probe Check Controls—PASS • SAC — FAIL[c]

Result	Interpretation
ERROR[b] See Figure 7.	Presence or absence of GBS target DNA cannot be determined. A system component failed, the maximum pressure was reached, or the probe check failed. • GBS — NO RESULT • SPC — NO RESULT • Probe Check Controls—FAIL[d] • SAC – NO RESULT
NO RESULT[b] See Figure 8.	Insufficient data was collected. Presence or absence of GBS target DNA cannot be determined. The operator stopped a test or a power failure occurred during the test. • GBS — NO RESULT • SPC — NO RESULT • Probe Check Controls—NA (not applicable) • SAC – NO RESULT

[a] Early Assay Termination can reduce the test time for positive results to approximately 30 minutes. With GBS negative samples, the test returns results within 42 minutes.
[b] If an **INVALID**, **ERROR**, or **NO RESULT** occurs, repeat the test according to the instructions in Section 17.2.
[c] The SPC and/or the SAC failed.
[d] If the probe check passed, the error is caused by a system component failure or by exceeding maximum allowable pressure.

17 Retesting

17.1 Reasons to Repeat Testing

If any of the test results mentioned below occur, repeat the test according to the instructions in Section 17.2.

- 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.

17.2 Retest Procedure

For retest of a **NO RESULT**, **INVALID**, or **ERROR** result, use a new cartridge (do not re-use the cartridge). Use the remaining specimen swab for retesting.

1. Remove the cartridge from the package. Open the cartridge by lifting the cartridge lid.
2. Remove the remaining swab from the collection transport tube.
3. Insert swab into the sample chamber of a new Xpert Xpress GBS cartridge.
4. Raise the swab so that the score mark is centered in the notch.
5. Break the swab by snapping the shaft to the right.
6. 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. 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.
7. Close the cartridge lid.
8. Follow the procedure for starting a test.

- For the *GeneXpert Dx System*, see Section 14.1.
- For the *GeneXpert Infinity System*, see Section 14.2.

When performing intrapartum testing, repeat testing may not be feasible and will depend on practices and policies within each facility. Coordination between clinicians and the testing laboratory is important to not delay administration of antibiotics while results are pending.

18 Limitations

- Erroneous test results might occur from improper specimen collection, handling or storage, technical error, or sample mix-up. Careful compliance to the instructions in this insert is important to avoid erroneous results.
- The performance of the Xpert Xpress GBS test was validated using the procedures provided in these Instructions for Use only. Modifications to these procedures may alter the performance of the test.
- The Xpert Xpress GBS test has only been validated with the Vaginal/Rectal swab specimen using the Cepheid Collection kit (listed in Section 8).
- A negative result does not rule out the possibility of GBS colonization. False negative results may occur if the organism is present at levels below the analytical limit of detection.
- The Xpert Xpress GBS test does not provide antibiotic susceptibility results. Culture isolates are needed to perform susceptibility testing as recommended for penicillin-allergic females.
- Test results may be affected by concurrent antibiotic therapy. GBS DNA may continue to be detected following antimicrobial therapy.
- The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.
- A positive result does not necessarily indicate the presence of viable organisms.
- Mutations in primer or probe binding regions may affect detection of new or unknown variants and may result in a false negative result.
- This test was validated on vaginal/rectal swab specimens collected at antepartum or intrapartum from antibiotic naïve pregnant females The use of this test has not been validated in pregnant females having received antibiotics within 14 days prior to sample collection.
- Clinical data includes antibiotic naive study participants of 14 years of age or older. The 14–17 age group for antibiotic naïve participants includes two intrapartum vaginal/rectal specimens and zero antepartum vaginal/rectal specimens.

19 Expected Values

The Xpert Xpress GBS clinical study included vaginal/rectal specimens collected from antibiotic naïve pregnant female participants. The number and percentage of specimens positive for GBS as determined by the Xpert Xpress GBS test are presented in Table 2, per specimen collection type.

Table 2. Positivity Rates by the Xpert Xpress GBS Test in Participants at Antepartum and Intrapartum

Specimen Collection Type	Number of Specimens	Number of Positives	Positivity
Antepartum vaginal/rectal	661	128	19.4%
Intrapartum vaginal/rectal	899	109	12.1%

20 Clinical Performance

Performance characteristics of the Xpert Xpress GBS test were evaluated in a multi-site observational method comparison study using the GeneXpert and GeneXpert Xpress instrument systems. The study was conducted from July 2020 to November 2021 at thirteen (13) sites across the United States (10 enrollment and Xpert testing sites; 1 enrollment only site; 1 reference laboratory site that conducted Xpert testing and comparator method testing; 1 reference laboratory that conducted discrepant testing with an FDA cleared NAAT). The Xpert Xpress GBS test was compared to a comparator method, comprised of enriched bacterial culture with species identification via MALDI-TOF MS. Discordant results between the Xpert Xpress GBS test and the comparator method were investigated using an FDA cleared NAAT. Results from investigations into discrepant test results are presented as footnotes in Table 3, for informational purposes only.

The study included testing vaginal/rectal swab specimens collected from pregnant female study participants at antepartum and intrapartum who had not received recent treatment with antibiotics. To be enrolled in the study, participants had to provide written consent (or assent), be 14 years of age or older, agree to provide two dual vaginal/rectal swab specimens, and be a suitable candidate for specimen collection as determined by the principal investigator. Vaginal/rectal specimens were collected from each eligible participant using two (2) dual swab sets. The first set of swabs was divided: one swab was used for Xpert Xpress GBS testing; the other was used for culture if the Xpert Xpress GBS test gave a valid result. If the Xpert Xpress GBS test resulted in a non-determinate result, the second set of marked swabs was divided: one swab was used for repeat Xpert Xpress GBS testing; the other was used for culture testing.

Performance of the Xpert Xpress GBS Test vs. Culture

Specimens were collected from a total of 1579 eligible participants: 667 antepartum and 912 intrapartum. Six specimens collected at antepartum were excluded from analyses due to retests not being performed or retests resulting in non-determinate Xpert Xpress GBS results. A total of 661 antepartum vaginal/rectal specimens were included in the analyses. Thirteen specimens collected at intrapartum were excluded from analyses due to non-determinate Xpert Xpress results upon retest or no culture results. A total of 899 intrapartum vaginal/rectal specimens were included in the analyses.

Of the 1579 Xpert Xpress GBS tests performed in the clinical study, 78 resulted in non-determinate (**Error**, **Invalid**, **No Result**, **Instrument Error** or **No Result-Repeat Test**) results on first attempt. Of these 78 specimens, 76 were retested per protocol. Upon retest, 18 specimens remained non-determinate. The initial non-determinate rate was 4.9% (78/1579) overall. Upon retest, the final non-determinate rate was 1.1% (18/1579) overall.

The initial non-determinate rate for antepartum specimens was 3.4% (23/667) and the final non-determinate rate was 0.9% (6/667). The initial non-determinate rate for intrapartum specimens was 6.0% (55/912) and the final non-determinate rate was 1.3% (12/912).

As shown in Table 3, the sensitivity and specificity of the Xpert Xpress GBS test compared to the comparator method were 88.1% and 95.6% in vaginal/rectal swab specimens collected at antepartum and 93.5% and 95.5% in vaginal/rectal swab specimens collected at intrapartum, respectively.

Table 3. Xpert Xpress GBS Results and Estimated Performance by Specimen Collection Type

Specimen Collection Type	Results	Total	Culture Positive	Culture Negative	Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)	PPV (95% Confidence Interval)	NPV (95% Confidence Interval)
Antepartum vaginal/rectal	Xpert Xpress GBS Positive	128	104	24[a]	88.1% (81.1 – 92.8)	95.6% (93.5 – 97.0)	81.3% (73.6 – 87.1)	97.4% (95.6 – 98.4)
	Xpert Xpress GBS Negative	533	14[b]	519				
	Total	661	118	543				
Intrapartum vaginal/rectal	Xpert Xpress GBS Positive	109	72	37[c]	93.5% (85.7 – 97.2)	95.5% (93.9 – 96.7)	66.1% (56.8 – 74.3)	99.4% (98.5 – 99.7)
	Xpert Xpress GBS Negative	790	5[d]	785				
	Total	899	77	822				

[a] Discrepant test results based on an FDA cleared NAAT: 14/24 GBS positive; 7/24 GBS negative; 3/24 no valid result

[b] Discrepant test results based on an FDA cleared NAAT: 11/14 GBS positive; 3/14 no valid result

[c] Discrepant test results based on an FDA cleared NAAT: 13/37 GBS positive; 15/37 GBS negative; 9/37 no valid result

[d] Discrepant test results based on an FDA cleared NAAT: 4/5 GBS positive; 1/5 GBS negative

21 Analytical Performance

21.1 Analytical Sensitivity (Limit of Detection) and Analytical Reactivity (Inclusivity)

The analytical reactivity and limit of detection (LoD) of the Xpert Xpress GBS test were determined for 12 different strains representing 12 known serotypes of GBS, of which 2 were characterized as non-hemolytic (Table 4). Serial dilutions of each serotype were prepared in a simulated sample matrix. Serotypes Ia, III and V were tested with 24 replicates per dilution level for each of two reagent lots across three days. Serotypes Ib, Ic, II, IV and VI-X were tested with one reagent lot for a total of 24 replicates of each dilution level across three days. The LoD was established for each serotype and reagent lot by probit logistic regression analysis.

The LoD for each serotype was verified by testing 20 replicates at the 95% confidence interval upper limit with one reagent lot across three days, in a simulated sample matrix. Serotype Ia, III and V was also verified in clinical matrix. The results for all serotypes except serotype V and VI were ≥95% (≥19/20) percent detected. The result for serotype V and VI was 85% (17/20) percent detected and the claimed LoD is based on the upper level of 95% confidence interval.

Table 4. GBS Limit of Detection (LoD)

Serotype	LoD (CFU/mL) Probit Result	95% CI	Percent Detected	LoD (CFU/mL) Claimed LOD	LoD (CFU/swab) Claimed LOD
Ia	663	492–835	100%	663	50
Ib	40	32–49	95%	40	3
Ic[a]	301	231–370	100%	301	23
II[a]	173	132–213	100%	173	13
III	540	409–670	100%	540	41
IV	429	324–533	95%	429	32
V	618	384–618	85%	618[b]	46
VI	544	353–544	85%	544[b]	41
VII	620	512–728	100%	620	47
VIII	682	509–855	100%	682	51
IX	465	354–575	100%	465	35
X	677	525–829	95%	677	51

[a] Non-hemolytic strain

[b] Claimed LoD corresponds to upper 95% upper CI

21.2 Analytical Reactivity with GBS cfb Mutants

A study was performed to evaluate the analytical reactivity of Xpert Xpress GBS test using GBS strains containing deletions in or adjacent to the region of the chromosome that encodes the CAMP factor hemolysis gene *cfb*. Ten unique, well characterized GBS clinical isolates representing different *cfb* mutations were tested at 833 CFU/mL. All strains with *cfb* mutations were detected with a positivity rate of 100%.

21.3 Analytical Specificity (Exclusivity) and Microbial Interference

The analytical specificity of the Xpert Xpress GBS test was evaluated by testing a panel of 129 strains, representing bacterial, viral, parasite and yeast strains commonly found in vaginal/rectal flora or phylogenetically related to GBS (Table 5). Bacteria were tested at ≥ $1x10^6$ CFU/ml, except as noted, and viruses and parasites were tested at a level of ≥ $1x10^5$ organisms, yeast, IU or copies/ml. All 129 strains were tested in a simulated sample matrix, both in presence of GBS at 3x LoD and in absence of GBS.

No cross-reactivity or interference of GBS detection was observed, both *in silico* and *in vitro*, with any of the tested clinically relevant pathogens.

Table 5. Analytical Specificity of Xpert Xpress GBS

Organism		
Arcanobacterium (Trueperella) pyogenes	*Haemophilus influenzae*	*Serratia marcescens*
Atopobium (Fannyhessea) vaginae	*Hafnia alvei*	*Shigella flexneri*
Abiotrophia defectiva	Hepatitis B virus	*Shigella sonnei*
Acinetobacter baumannii	Hepatitis C virus	*Staphylococcus aureus*[a]
Acinetobacter lwoffii	Human immunodeficiency virus	*Staphylococcus epidermidis*
Actinobacillus pleuropneumoniae	Human Papillomavirus 18[b]	*Staphylococcus haemolyticus*
Aeromonas hydrophila	*Klebsiella (Enterobacter) aerogenes*	*Staphylococcus intermedius*
Alcaligenes faecalis	*Klebsiella oxytoca*	*Staphylococcus lugdunensis*
Anaerococcus lactolyticus	*Klebsiella pneumoniae*	*Staphylococcus saprophyticus*
Anaerococcus prevotii[b]	*Lactobacillus acidophilus*	*Staphylococcus simulans*
Anaerococcus tetradius	*Lactobacillus casei*	*Stenotrophomonas maltophilia*
Bacillus cereus	*Lactobacillus delbrueckii lactis*	*Streptococcus acidominimus*
Bacillus coagulans	*Lactobacillus gasseri*	*Streptococcus anginosus*
Bacteroides fragilis	*Lactobacillus plantarum*	*Streptococcus bovis*
Bifidobacterium adolescentis Reuter	*Lactobacillus reuteri*	*Streptococcus canis*
Bifidobacterium brevis	*Listeria monocytogenes*	*Streptococcus constellatus*
BK virus	*Micrococcus luteus*	*Streptococcus criceti*
Blastocystis hominis[b]	*Mobiluncus curtisii subsp. Curtisii*[b]	*Streptococcus cristatus*
Bordetella pertussis	*Moraxella atlantae*	*Streptococcus downei*
Burkholderia cepacia	*Moraxella catarrhalis*	*Streptococcus dysgalactiae subsp. dysgalactiae*
Campylobacter jejuni	*Morganella morganii*	*Streptococcus dysgalactiae subsp. equisimilis*
Candida albicans	*Mycoplasma genitalium*[b]	*Streptococcus equi subsp. equi*
Candida glabrata	*Neisseria gonorrhoeae*	*Streptococcus gordonii*
Candida tropicalis	Norovirus	*Streptococcus intermedius*
Chlamydia trachomatis	*Pantoea agglomerans*	*Streptococcus mitis*

Organism		
Citrobacter freundii	*Pasteurella aerogenes*	*Streptococcus mutans*
Clostridium difficile	*Peptoniphilus asaccharolyticus*	*Streptococcus oralis*
Cytomegalovirus	*Peptostreptococcus anaerobius*	*Streptococcus parasanguinis*
Corynebacterium accolens	*Porphyromonas asaccharolytica*	*Streptococcus pneumoniae*
Corynebacterium sp. (genitalium)	*Prevotella bivia*	*Streptococcus pseudoporcinus*
Corynebacterium urealyticum	*Prevotella melaninogenica*	*Streptococcus pyogenes*[b]
Cryptococcus neoformans	*Prevotella oralis*	*Streptococcus ratti*
Enterobacter cloacae	*Propionibacterium acnes*	*Streptococcus salivarius*
Enterococcus durans	*Proteus mirabilis*	*Streptococcus sanguinis*
Enterococcus faecalis	*Proteus vulgaris*	*Streptococcus sobrinus*
Enterococcus faecium	*Providencia stuartii*[b]	*Streptococcus suis*
Enterococcus gallinarum	*Pseudomonas aeruginosa*	*Streptococcus uberis*
Epstein-Barr virus	*Pseudomonas fluorescens*	*Streptococcus vestibularis*
Escherichia coli	*Rhodococcus equi*	*Toxoplasma gondii*
Finegoldia magna	Rubella virus	*Trichomonas vaginalis*
Fusobacterium nucleatum	*Salmonella enterica subsp. enterica ser. Dublin (group D)*	*Vibrio cholerae*
Gardnerella vaginalis	*Salmonella enterica subp. typhimurium*	*Yersinia enterocolitica*
Giardia lamblia[b]	*Serratia liquefaciens*	*Providencia sp*

[a] Tested < $1x10^6$ ($2x10^5$ CFU/ml)

[b] Evaluated with DNA

21.4 Potentially Interfering Substances Study

Substances that may be present in vaginal/rectal specimens with the potential to interfere with the Xpert Xpress GBS test were evaluated. Potentially interfering endogenous and exogenous substances include human amniotic fluid, meconium, urine, fecal material, human blood, lubricating gel, vaginal anti-itch medications, vaginal antifungal medications, anti-diarrheal medications, laxatives, stool softeners, topical hemorrhoid ointments, body oil, body powder, deodorant sprays, enema solutions, and spermicidal foam.

These substances are listed in Table 6. All liquid substances were tested by adding 100% of the substance to the swab, solid substances by covering swab head to 75% and tablets were dissolved to their highest soluble concentration in simulate sample matrix and added to the swab. Five exogenous substances (Aquasonic® gel, Floraplus, Pepto Bismol®, Skin oil and Xyloproct) were tested at lower concentration to determine the highest tolerated amount on swab (Table 6). The interferents were tested on each swab in the presence and absence of GBS at 3x LoD. There was no interference in the presence of the substances at the concentrations tested in this study. All positive and negative samples were correctly identified using the Xpert Xpress GBS test.

Table 6. Potentially Interfering Substances Tested

Substance	Substance Form	Concentration on Swab
Human Amniotic Fluid	Liquid	60% (v/v)
Human Urine	Liquid	60% (v/v)
Human Whole Blood - EDTA	Liquid	80% (v/v)
Human Whole Blood - Na Citrate	Liquid	80% (v/v)
Leukocytes, Buffy coat, $2x10^7$ WBCs/ml	Liquid	80% (v/v)
Meconium	Solid	100%
Mucus	Solid	30% (w/v)
Human Feces - Pool of 10 donors	Solid	100%
Anti-Diarrheal Medication – Pepto Bismol	Liquid[a]	40 % (v/v)
Anti-Diarrheal Medication – Dimor Comp [Dimeticone]	Tablet	0.03% loperamid + 1.7% dimetikon (w/v)
Lubricant – RFSU Klick Ultra Glide	Solid	100%
Lubricant – Sense Me Aqua Glide	Solid	100%
Lubricant – KY-Jelly	Solid	100%
Body Oil – ACO Repairing Skin Oil	Solid[b]	100%
Dialon Baby – Dialon Baby powder	Solid	100%
Deodorant Powder – Vagisil® Deodorant Powder	Solid	100%
Deodorant Spray – LN Intimate Deo	Liquid	60% (v/v)
Deodorant Suppositories – Norforms Feminine Deodorant Suppositories	Tablet	46.4% (w/w)
Enema solution – Microlax mikrolavemang	Solid	100%
Oral Laxative – Mylan	Solid	25% (w/v)
Oral Laxative – Phillips Milk of Magensia	Liquid	60% (v/v)
Oral Laxative – Pursennid Ex-Lax	Tablet	0.64% (w/v)
Spermicidal Foam – Caya preventivgel	Solid	100%
Stool Softener – Laktulos - Meda	Liquid	60% (v/v)
Stool Softener – Movicol	Tablet	9% (w/v)
Topical Hemorrhoid Ointment – Xyloproct Rectal Ointment	Liquid[c]	8% (v/v)
Topical Hemorrhoid Ointment – Scheriproct rektalsalva / Prednisolone Ointment	Solid	100%
Ultrasound Transmission Gel – Aquasonic Gel	Liquid	20% (v/v)
Vaginal Antifungal Gel – Multi-Gyn Actigel	Solid[c]	100%
Vaginal Antifungal Gel – Multi-Gyn Floraplus	Solid	75% (w/v)
Vaginal Anti-itch Cream – Ellen Probiotisk Utvärtes Intim Creme	Solid	100%
Vaginal Antifungal Cream – Canesten	Solid	100%

Substance	Substance Form	Concentration on Swab
Vaginal Antifungal Cream – Daktar	Solid	100%

[a] Pepto Bismol diluted to 40% in simulated background matrix and no interference observed.

[b] Skin oil tolerated when 2/3 of swab head covered (tested as solid substance).

[c] Substances were diluted into a simulated background matrix prior to testing: Xyloproct Rectal Ointment was tested at 8%, Aquasonic Gel was tested at 20% and MultiGyn Floraplus was tested at 75%. No interference was detection after dilution.

21.5 Carry-over Contamination Study

A study was conducted to demonstrate that no carry-over contamination occurs when testing these single-use, self-contained GeneXpert cartridges in the same GeneXpert module. The study consisted of a negative sample processed in the same GeneXpert module immediately following a high GBS positive sample. Twenty-one runs alternating high titer GBS positive and GBS negative samples were performed consecutively on two GeneXpert modules, thus a total of 42 runs were executed for the study. All 20 positive samples were correctly reported as GBS positive. All 22 negative samples were correctly reported as GBS negative.

22 Reproducibility and Precision

Two panels totaling ten samples with varying concentrations of four different GBS strains were tested in triplicate by two operators on six different days at three sites (10 samples × 2 operators × 3 times/day × 6 days × 3 sites). Three lots of Xpert Xpress GBS test were used at each of the three testing sites. The panels were composed of three strains of GBS representing hemolytic phenotypes (serotype Ia, III, IV) and one strain (Serotype Ic) representing a non-hemolytic phenotype .Panel members spanned the relevant limit of detection (LoD) spectrum (negative, at ~1x or ~1.5x and ~3x LoD) for the intended target types.

Xpert Xpress GBS testing was performed on the GeneXpert Instrument Systems according to the Xpert Xpress GBS test procedure. The percent agreement of the qualitative results for GBS detection for each sample analyzed by each of the six operators and by each site is shown in Table 7. In addition, the overall percent agreement for each sample (total agreement) and the 95% two-sided Wilson Score confidence interval are shown in the last column.

Table 7. Summary of Reproducibility and Precision Results – Percent Agreement

Panel Member	Sample	Level	Site 1			Site 2			Site 3			Total Agreement (95% CI)
			Op 1	Op 2	Site	Op 1	Op 2	Site	Op 1	Op 2	Site	
1	Negative	Negative	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	94.1% (16/17)	100.0% (18/18)	97.1% (34/35)	99.1% (106/107) (94.9% - 100.0%)
2	GBS serotype Ia Low Pos	~1xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (108/108) (96.6% - 100.00%)
3	GBS serotype III Low Pos	~1xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	83.3% (15/18)	100.0% (17/17)	91.4% (32/35)	97.2% (104/107) (92.1% - 99.0%)
4	GBS serotype IV Low Pos	~1xLoD	94.4% (17/18)	88.9% (16/18)	91.7% (33/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	88.9% (16/18)	94.4% (34/36)	95.4% (103/108) (89.6% - 98.0%)

Panel Member	Sample	Level	Site 1			Site 2			Site 3			Total Agreement (95% CI)
			Op 1	Op 2	Site	Op 1	Op 2	Site	Op 1	Op 2	Site	
5	GBS serotype Ia Mod Pos	~3xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (108/108) (96.6% - 100.0%)
6	GBS serotype III Mod Pos	~3xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100% (108/108) (96.6% - 100.0%)
7	GBS serotype IV Mod Pos	~3xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100% (108/108) (96.6% - 100.0%)
8	Negative 2	Negative	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (108/108) (96.6% - 100.0%)
9	GBS Serotype Ic Low Pos	~1.5xLoD	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (108/108) (96.6% - 100.0%)
10	GBS Serotype Ic Mod Pos	~3xLoD	94.4% (17/18)	100.0% (18/18)	97.2% (35/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	100.0% (18/18)	100.0% (18/18)	100.0% (36/36)	99.1% (107/108) (94.9% - 100.0%)

Evaluation of repeatability and the within-laboratory precision of the underlying Ct values obtained in the Xpress GBS test was analyzed. The mean, standard deviation (SD), and coefficient of variation (CV) between-sites, between-lots, between-days, and between-runs for each panel member are shown in Table 8.

Table 8. Summary of Reproducibility Data

Panel Member	N[a]	Mean	Site		Op		Lot		Day		Within Assay		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Negative[b]	107[c]	32.4	0.1	0.5	0.0	0.0	0.5	27.0	0.2	5.9	0.8	66.6	1.0	2.9
Low Pos GBS serotype Ia ~1xLoD	108	34.7	0.0	0.0	0.0	0.0	0.3	7.0	0.2	2.1	1.2	90.9	1.2	3.5
Low Pos GBS serotype III ~1xLoD	104[d]	34.8	0.0	0.0	0.0	0.0	0.4	7.9	0.0	0.0	1.3	92.1	1.4	3.9
Low Pos GBS serotype IV ~1xLoD	103[e]	35.2	0.2	2.1	0.0	0.0	0.5	20.4	0.0	0.0	1.0	77.6	1.1	3.1
Mod Pos GBS serotype Ia ~3xLoD	108	33	0.3	10.2	0.0	0.0	0.0	0.0	0.0	0.0	1.0	89.8	1.1	3.3

Panel Member	N[a]	Mean	Site		Op		Lot		Day		Within Assay		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Mod Pos GBS serotype III ~3xLoD	108	33.1	0.0	0.0	0.0	0.0	0.3	11	0.3	11.6	0.8	77.4	1.0	2.9
Mod Pos GBS serotype IV ~3xLoD	108	33.7	0.0	0.0	0.3	13.7	0.3	10.3	0.1	1.3	0.8	74.7	0.9	2.7
Negative 2[b]	108	32.5	0.2	3.6	0.0	0.0	0.5	31	0.2	6.4	0.6	58.9	0.8	2.6
Low Pos GBS serotype Ic ~1.5xLoD	108	34.7	0.1	0.6	0.0	0.0	0.2	3.3	0.5	13.6	1.1	82.5	1.2	3.5
Mod Pos GBS serotype Ic ~3xLoD	107[f]	33.8	0.0	0.0	0.2	4.7	0.1	1.7	0.4	25.5	0.7	68.1	0.8	2.4

[a] Results with non-zero Ct values out of 108

[b] SPC Ct values were used to perform ANOVA analysis for Negative samples.

[c] One sample gave a non-determinate result.

[d] Three samples with GBS Ct value = 0 and one non-determinate sample were excluded from ANOVA analysis.

[e] Five samples with GBS Ct value = 0 were excluded from ANOVA analysis.

[f] One sample with a GBS Ct value = 0 was excluded from ANOVA analysis.

23 References

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- Error messages (if any)
- Software version and, if applicable, Computer Service Tag Number

United States

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26 Table of Symbols

Symbol	Meaning
	Catalog number
	*In vitro* diagnostic medical device
	CE marking – European Conformity
	Do not reuse
	Batch code
	Consult instructions for use
	Manufacturer
	Country of manufacture
	Contains sufficient for *n* tests
	Expiration date
	Temperature limitation
	Biological risks
	Caution
	Warning

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27 Revision History

Description of Changes: 302-7665 Rev. B to Rev. C

Purpose: Revised table.

Section	Description of Change
21.3	Includes additional strain.
21.4	Revised table.