Cepheid

Abbreviated Instructions for Use – Xpert® Xpress GBS

This is an abbreviated IFU for near-patient test settings. The full IFU (302-9599) can be found on the accompanying CD or on the Cepheid website.

IMPORTANT: Wear protective disposable gloves, keep the cartridge upright, inspect cartridge for leakage or other damage, do not shake a cartridge, do not use a damaged cartridge, do not touch the reaction tube.

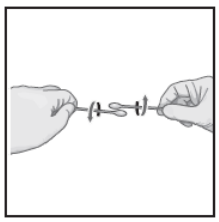
This test can be completed with a dual vaginal/rectal swab. One swab is required for the Xpert Xpress GBS test. Reference 302-9599 for the full instruction on sample collection and storage.

Note: Allow the cartridge to adjust to room temperature (25±3°C) prior to use.

Prepare the Cartridge

1. Open the cartridge lid.

2. Remove one swab from the cap. 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

3. Insert only one swab into the cartridge sample chamber. Break the swab at the score mark.

Do not insert both swabs into the cartridge.

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

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

Note: Do not leave the swab end caught in the cartridge notch

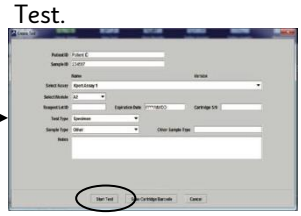
5. Close the Cartridge lid

Start a Test on the GeneXpert Dx System

1. Click on Create Test from the main menu of the GeneXpert Dx.

2. Manually enter or scan the Sample ID and Patient ID. Scan the barcode of the cartridge.

3. Verify that the patient and cartridge information is correct then click on Start Test.



4. Load the cartridge in the module with the blinking green light. Close the module door until the green light stops blinking.

Note: This test can also be performed on the GeneXpert Infinity. Reference 302-9599 for GeneXpert Infinity instructions.

Interpretation of Results

The results are determined by the GeneXpert Instrument Systems from measured fluorescence signals and embedded calculation algorithms and will be shown in the View Results window. Please see 302-9599 for further result interpretation information.

Result	Interpretation
GBS POSITIVE	GBS target DNA is detected – presumed for GBS colonization
GBS NEGATIVE	GBS target DNA is not detected - presumed not colonized for GBS.
INVALID	Presence or absence of the GBS target DNA cannot be determined. SAC and/or SPC failed and does not meet acceptance criteria.
ERROR	Presence or absence of the GBS target DNA cannot be determined. A system component failed, the maximum pressure was reached, or the probe check failed.
NO RESULT	Insufficient data was collected. Presence or absence of GBS target DNA cannot be determined. 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 during the test.

REF XPRSGBS-CE-10
303-0734, Rev B (2025-09)

CE 2797 IVD

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 remaining swab from the collection transport tube.
2. Insert swab into the sample chamber of a new cartridge.

Warnings and Precautions*

- Biological specimens, including used cartridges and transfer devices, should be handled as capable of transmitting infectious agents. Follow your institution's safety procedures. Additional guidelines for specimen handling are available from the Directive 2000/54/EC of the European Parliament and of the Council of 18 Sep 2000 on the protection of workers from risks related to exposure to biological agents at work.
- Do not open the Xpert Xpress GBS cartridge lid except when adding the sample.
- Clean the work surface/areas with 10% bleach before and after processing Xpert Xpress GBS specimens.
- Do not load a cartridge that has been dropped or shaken after you have added the sample.
- Each single-use Xpert Xpress GBS cartridge is used to process one test. Do not reuse spent cartridges.
- Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. Used cartridges may exhibit characteristics of chemical and hazardous waste. Check your national or regional disposal procedures for medical and chemical waste guidelines.

*Refer to full-IFU for a full description

Potentially Interfering Substances*
Potentially interfering substances[(a)] were determined at elevated levels of eight (8) endogenous and twenty-five (25) exogenous substances that may be encountered in vaginal/rectal and vaginal only specimens. No interference with GBS detection was observed for twenty-eight (28) of the tested substances. Five substances had interfering effect on the Xpert Xpress GBS when tested above the levels indicated below. Titration and testing at the highest possible level with no evidence of interference are shown below:

- Aquasonic gel at 20% (v/v)
- Multi-Gyn FloraPlus at 75% (w/v)
- PeptoBismol at 40% (v/v)
- Skin oil at 2/3 coverage of a swab cotton head
- Xyloproct at 8% (v/v)

*Refer to full-IFU for a full description
[(a)] Complete list of exogenous and endogenous substances, see full IFU

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 Vaginal/Rectal swab specimen using the Cepheid Collection kit.
- A negative result does not exclude 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.

Technical Assistance
Collect the following information before contacting Cepheid Technical Support:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version
- Computer service tag number (if applicable)

Contact information for all Cepheid Technical Support offices is available on our website.

Refer to the full length IFU (302-9599) for the following:
Intended Use, Storage & Handling, Quality Control, Materials Provided, Specimen Collection and Transport, Chemical Hazards, and Performance Characteristics.

Revision History

Revision	Effective	Description of Changes
B	**Current**	No change to abbreviated IFU content, update to internal documents only.