PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

BD MAX™ GBS Assay Procedure

Department of Microbiology

Number:

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1.0 Principle

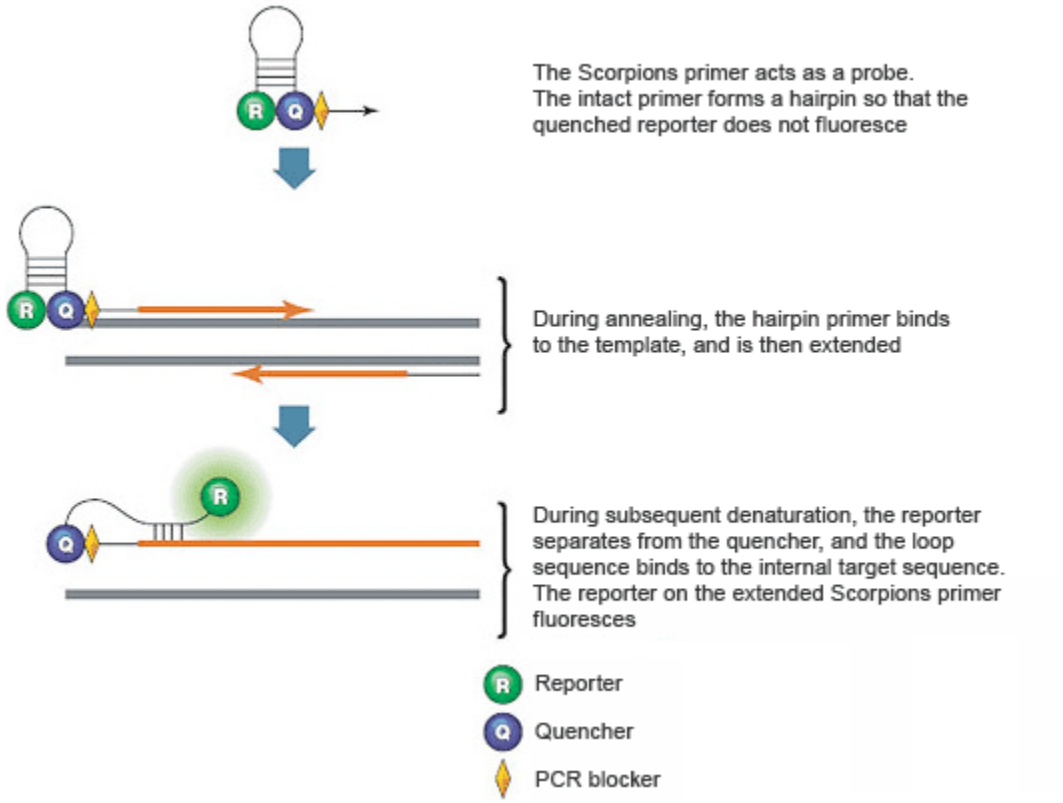
The BD MAX™ GBS Assay is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA in Lim Broth cultures of vaginal/rectal specimens collected from antepartum pregnant women. Results from the BD MAX™ GBS Assay can be used as an aid in determining colonization status in antepartum women. A vaginal and rectal swab is collected and transported to the laboratory using standard bacterial swab transport systems containing a non-nutritive transport medium (e.g. Amies or Stuart). The swab is removed from the transport medium and placed into selective Lim Broth. After ≥ 18 h incubation at 35 ± 2 °C, a 15 µL aliquot of the broth is mixed with BD MAX™ GBS Sample Preparation Reagent and processed on the BD MAX™ System using the BD MAX™ GBS Assay. The BD MAX™ System automates and integrates DNA extraction and concentration, reagent preparation, and nucleic acid amplification and detection of the target sequence using real-time PCR. The target nucleic acid is a 124 bp region of the *cfb* gene sequence of the *Streptococcus agalactiae* chromosome. The *cfb* gene encodes for CAMP factor, a diffusible protein that is present in virtually all GBS isolates. An Internal Process Control is also incorporated into the lysis, extraction, concentration and amplification steps to monitor for the presence of potential inhibitory substances as well as system or reagent failures.

The BD MAX™ System uses a combination of lytic and extraction reagents to perform cell lysis, DNA extraction and removal of inhibitors. Following cell lysis, with a combination of heat and lytic enzymes, the released nucleic acids are captured by magnetic affinity beads. The beads, with the bound nucleic acids, are washed and the nucleic acids are eluted using release solution and prepared for PCR by addition of neutralization reagent. The BD MAX™ System then uses the PCR-ready DNA solution to rehydrate a freeze-dried PCR pellet containing all the reagents necessary for amplification of the GBS-specific target. The freeze-dried PCR pellet also contains reagents to amplify a section of the Internal Process Control sequence to enable simultaneous amplification and detection of both target and Internal Process Control DNA sequences. After reconstitution of the freeze-dried amplification reagents, the BD MAX™ System dispenses the prepared PCR-ready solution into one lane (per specimen) of the BD MAX™ Microfluidic PCR Cartridge. Microvalves in the BD MAX™ Microfluidic PCR Cartridge are sealed by the system prior to initiating PCR to prevent evaporation as well as amplicon contamination.

The amplified targets are detected in real time using Scorpions® chemistry-based fluorogenic oligonucleotide probe molecules specific to the amplicons for the respective targets. Scorpions® chemistry features a bi-functional molecule which includes a PCR primer covalently attached to a probe. The Scorpions® primers used in the BD MAX™ GBS Assay have a fluorophore and quencher held together by an internal stem loop. Figure 1 is a diagrammatic representation of Scorpions® functionality.

A Scorpions® probe labeled with a fluorophore (Excitation: 490 nanometers and Emission: 521 nanometers) at the 5’ end, and a dark quencher at the 3’ end, is used to detect GBS DNA. For detection of the Internal Process Control, the Scorpions® probe is labeled with an alternate fluorescent dye (Excitation: 590 nanometers and Emission: 610 nanometers) at the 5’ end, and a dark quencher at the 3’ end. The BD MAX™ System monitors the fluorescent signal emitted by the Scorpions® probes at the end of each amplification cycle. When amplification is complete, the BD MAX™ System analyzes the data and provides a final result (POSITIVE, NEGATIVE, or INDETERMINATE).

Figure 1: Mechanism of action of Scorpions® chemistry



2.0 Clinical Significance

Group B *Streptococcus* is found in the lower intestinal tract of 10-30% of all healthy adults. Colonization can lead to transmission to newborns during birth by vertical (mother-to-baby) transmission. GBS can cause severe invasive disease in newborns and is a leading cause of life threatening bacterial infections in this age group. The current standard of care for preventing neonatal GBS disease is screening pregnant women at 35-37 weeks of gestation to determine their GBS colonization status. Colonized women are given antibiotic prophylaxis during labor to help prevent transmission to the newborn.

3.0 Scope

This procedure is classified under CLIA as Moderately Complex. It should be carried out by technical personnel familiarized and trained on all levels of the operation of the BD MAX™ testing platform. Testing includes but is not limited to: instrument start up, shutdown, routine maintenance, performance checks, basic troubleshooting, QC checks, administrative tasks and record keeping of information vital to verification of instrument and technical proficiency in accordance with the department SOP. Records are to be kept within the employee's record in the department of continued competence and proficiency on the equipment. Performance reviews of technical personnel are to be carried out annually.

4.0 Safety - Personal Protective Equipment

Performance of this procedure will expose testing personnel to biohazardous material. All specimens must be handled as potentially infectious material as outlined in the Microbiology Biohazards and Safety document. Follow proper handling, storage, and disposal of specimens and items that come into contact with specimens. Place contaminated materials in a

biohazardous waste container.

The reagent(s) and/or chemical(s) that are used in this procedure may be hazardous to your health if handled incorrectly. A brief listing of precautions for each chemical hazard is included in the reagent section of this procedure.

More extensive information concerning the safe handling of the reagents and/or chemicals used in this procedure, as well as other important safety information may be obtained by consulting the Material Safety Data Sheet (MSDS). Before performing any part of this procedure, the technologist must take any and all precautions and adhere to all prescribed policies.

This procedure may expose you to:

- Bloodborne pathogens
- Airborne pathogens
- Slightly hazardous reagents

To perform this procedure, you must use:

- Gloves
- Laboratory Coat
- Biological safety cabinet (for specimen processing)

Disinfectant following procedure:

- Bleach dilution sprayers can be used for on demand disinfectant.
- Ethyl Alcohol (70%)

Reference for spill/decontamination

- MSDS
- Chemical hygiene plan

5.0 Specimen Collection, Handling and Storage

1. Collect the vaginal and rectal swab specimen. Wipe away excessive amount of secretion or discharge from the vaginal area. Carefully insert the swab into the lower one-third part of the vagina, and sample secretions from the mucosa. Carefully insert the same swab approximately 2.5 cm beyond the anal sphincter, and gently rotate to sample anal crypts.
2. Transport the specimen to the laboratory in a non-nutritive transport medium (e.g. Amies or Stuart). Specimens should be kept between 2-30 °C during transport. Specimens processed within 24 h may be kept at room temperature. If transport will delay processing beyond 24 h, specimens should be refrigerated. Specimens stored between 2 and 8 °C are stable for up to 6 d.

6.0 Materials

6.1 Equipment and/or Testing System

- BD MAX™ System
- Multi-vial vortex
- Micropipettor (accurate between 10-100 µL)

6.2 Consumables

- BD MAX™ PCR Cartridges REF 441770. Store at 2-25 °C
- Aerosol-resistant, extended length micropipette tips
- BBL™ Lim Broth (Todd Hewitt with CNA) REF 296266

6.3 Reagents

- **BD MAX™ GBS Assay Kit** REF 441772, 24 tests. Store at 4-30 °C.

- BD MAX™ GBS Master Mix: *Freeze-dried PCR Master Mix containing GBS-specific Scorpions® probe and primers along with Internal Process Control-specific Scorpions probe and primers.*
- BD MAX™ DNA Unitized Reagent Strips: *Unitized reagent strip containing all the liquid reagents and disposable pipette tips necessary for DNA Extraction.*
- BD MAX™ GBS Extraction Reagent: *Freeze-dried DNA magnetic affinity beads, Freeze-dried Mutanolysin, Freeze-dried Protease reagents, Freeze-dried Internal Process Control*
- BD MAX™ GBS Sample Preparation Reagent

6.4 Control Materials and Usage

Perform Quality Control using external controls with each new lot or shipment of BD MAX™ GBS Assay kits.

- **Positive external control**: *S. agalactiae* ATCC 13813 Lim Broth culture (incubate for ≥ 18 h at 35 ± 2 °C in ambient air or 5% CO_2.) Broth may be frozen in aliquots at -70 °C and thawed prior to use.
- **Negative External Control**: use an uninoculated GBS Sample Preparation Reagent tube.

6.5 Interfering Substances

The manufacturer performed studies with the BD MAX™ GBS Assay in the presence of both endogenous and exogenous interfering agents to characterize the ability of the assay to detect GBS DNA under these conditions. A complete description of the study can be found in the manufacture's package insert.

Interference (1/3 replicates) was observed in the presence of *Corynebacterium xerosis, Serratia marcescens* and EBV when tested at a GBS target concentration of 300 CFU/mL of Sample Preparation Reagent.

The BD MAX™ GBS Assay was able to detect GBS at a concentration of 300 CFU/mL of Sample Preparation Reagent in the presence of all interfering agents tested except body powder and feces where one of the three replicates was called negative. At 3000 CFU/mL of Sample Preparation Reagent no interference was observed with these agents.

6.6 Warnings and Precautions

- Do not use the kit if the packaging is damaged upon arrival.
- Do not use the kit after the expiration date.
- Do not use reagents if the protective pouch is open or broken upon arrival.
- Protect reagents against heat and humidity. Prolonged exposure to humidity will affect product performance.
- Avoid microbial and deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile DNase-free disposable filter-blocked or positive displacement pipette tips is recommended. Use a new tip for each specimen.
- To avoid contamination of the environment with GBS amplicons, do not break apart the BD MAX™ Microfluidic PCR Cartridges post-amplification. The seals of the BD MAX™ Microfluidic PCR Cartridges prevent contamination.
- Performing the BD MAX™ GBS Assay outside the time ranges recommended for specimen storage can produce invalid results.
- BD MAX™ Microfluidic PCR Cartridges are not re-usable and should be discarded properly after each use.
- Consult the BD MAX™ System IVD Operation Manual for additional warnings, precautions and procedures.

6.7 Software Instructions

Refer to BD MAX™ System IVD Operation Manual for programming instructions.

7.0 Procedure

7.1 Lim Broth Culture

1. Remove swab(s) from transport medium and inoculate into selective Lim Broth.
2. Incubate inoculated Lim Broth for ≥ 18 h at 35 ± 2 °C in ambient air or 5% CO_2.
3. Proceed to Test Preparation.

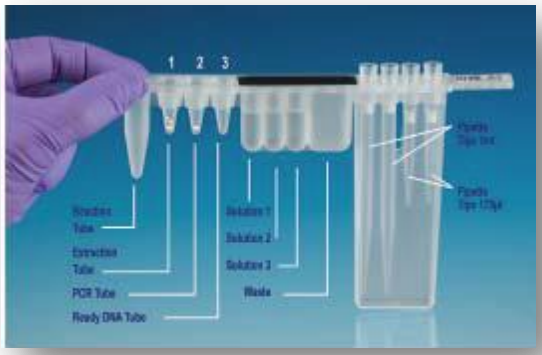
7.2 Test Preparation

1. Vortex the enriched Lim Broth specimen to achieve uniform distribution.
2. Using a calibrated micropipettor and an extended length pipette tip (so as to not contaminate the micropipettor with the enriched specimen) aspirate 15 µL of the enriched specimen into the pipette tip.
3. Remove the cap on a BD MAX™ GBS Sample Preparation Reagent tube and dispense the 15 µL of enriched specimen into the tube, taking care not to aerosolize the specimen. Pipette liquid up and down to ensure complete transfer of specimen.

7.3 BD MAX™ Operation

1. For each specimen to be tested, place one DNA Unitized Reagent Strip on the BD MAX™ System Rack.
2. Snap the BD MAX™ GBS Extraction Reagent tube into the DNA Unitized Reagent Strip in Position 1 as shown in Figure 2.

Figure 2: DNA Unitized Reagent Strip



3. Snap the BD MAX™ GBS Master Mix tube into the Reagent Strip in Position 2 as shown in Figure 2. The rack is color-coded to help guide proper placement of the reagents.

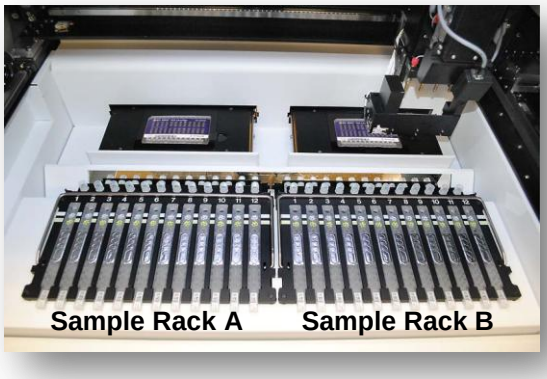
Figure 2: Reagent Placement

4. Select the 'Work List' tab in the 'Run' screen on the BD MAX™ System monitor.
5. Enter the specimen/patient accession number into the BD MAX™ System, using either the barcode scanner or manual entry. Start with Position 1 of Rack A (Rack A is positioned on the left side of the BD MAX™ System and Rack B is on the right).
6. Enter the barcode from each BD MAX™ GBS Sample Preparation Reagent tube using the barcode scanner or manual entry. Start with Position 1 of Rack A and ensure that each patient/specimen accession number and each BD MAX™ GBS Sample Preparation Reagent tube is accurately matched.
7. Place the BD MAX™ GBS Sample Preparation tube (containing the specimen) on the BD MAX™ System Rack according to the Work List location ensuring that no positions are skipped.
8. Repeat Steps (1-7) for all specimens.
9. Define the test to be run by choosing 'GBS' from the pull down menu under the 'Test' tab in the Work List creation window on the BD MAX™ System monitor.
10. Place appropriate number (1 or 2) of BD MAX™ Microfluidic PCR Cartridge(s) into the BD MAX™ System.

Figure 3: Microfluidic Cartridge Placement

11. Load Rack(s) into the BD MAX™ System (Figure 4). Ensure that the placement of Rack(s) corresponds to the Work List definition.

Figure 4: Sample Rack Placement



12. Close the BD MAX™ System lid to start processing of the test run.
13. Verify that all barcodes have scanned before leaving.

8.0 Interpretation of Results

Results are available on the 'Results' tab in the 'Results' window on the BD MAX™ System monitor. Test results are automatically interpreted by the BD MAX™ System software. A test result may be called as NEG (negative), POS (positive), or IND (Indeterminate) based on the amplification status of the target and Internal Process Control.

In case of an IND (Indeterminate) result, the Lim Broth should be retested. IND results occur due to inhibition of the PCR reaction, reagent failure or system errors. Be sure to check the BD MAX™ System for error messages. If IND results persist for multiple specimens, notify the Technical Specialist or consult Rounds.

9.0 Result Reporting

- Negative Report: **Negative for Beta Strep group B by PCR**
- Positive Report: **Positive for Beta Strep group B by PCR**

10.0 Reflexive Culture and Antimicrobial Susceptibility Testing

When reporting a positive result, always check for notes in LIS indicating that the patient has antimicrobial drug allergies. Isolates from patients allergic to penicillin should be tested for clindamycin susceptibility. Lim broth samples should be saved in a designated location in the refrigerator in case a client calls and requests antimicrobial susceptibility testing after receiving a positive PCR result.

1. Enter into LIS, **Culture in progress to isolate Strep Group B for antimicrobial susceptibility testing. [SBSUS]**
2. The Lim broth should be subcultured and incubated according to protocol for routine GBS culture. After incubation, the plate should be examined for colonies resembling GBS. Additional subculturing may be necessary to ensure isolation.
3. Confirm identification of suspect colonies by performing Lancefield typing (Streptex).
4. Once the identification has been confirmed, define the isolate in LIS as **CULTURE RESULT: Beta Strep Group B** and proceed with antimicrobial susceptibility testing. A D-zone test should be performed to detect inducible clindamycin resistance (refer to the D-Zone Testing for Beta-Hemolytic Strep test procedure).
5. Record workload, report susceptibilities, and bill for the susceptibility test under the same BSBPCR accession number.
6. If Group B Strep cannot be isolated from the Lim broth, report **Unable to isolate Beta Strep Group B by culture to perform antimicrobial susceptibility testing. The organism may be nonviable or present in numbers below the sensitivity of culture methods. [SBNG]**

11.0 Quality Control & Quality Assurance

11.1 External Controls

External control materials must be used to evaluate each new lot or shipment of BD MAX™ GBS Assay kits. External controls must be tested every 30 d while a lot is in use. Quality control results should be entered into the LIS. Notify technical specialist or supervisor if results are not as expected. Do not report any patient results obtained from the failed run. Repeat testing using new external controls and prepare new test samples from the Lim Broth cultures.

- **Positive control**: *Streptococcus agalactiae* ATCC 13813 cultured in Lim Broth for ≥ 18 h at 35 ± 2 °C. Broth may be frozen in aliquots at -70 °C and thawed prior to use. An external positive control that yields a negative or indeterminate test result is indicative of a reagent or BD MAX™ System error. Repeat Quality Control testing with new controls. Check the BD MAX™ System monitor for any error messages. If the problem persists, use unopened reagents or a new BD MAX™ GBS Assay Kit.

- **Negative control**: Use an uninoculated GBS Sample Preparation Reagent tube as an external negative control. An external negative control that yields a positive test result is indicative of a specimen handling and/or a contamination problem.

11.2 Internal Control

An Internal Process Control is provided in each BD MAX™ GBS Assay. This Internal Process Control monitors the efficacy of the DNA extraction and PCR amplification processes. If the internal control fails to be amplified and detected, the Lim Broth culture specimen should be retested.

12.0 Maintenance

12.1 Daily Cleanup

Caution: Do not use any decontamination or cleaning agents that could cause a hazard as a result of a reaction with parts of the equipment. Do not use abrasive or corrosive cleaners on heater boards. Do not spray or pour liquid directly on surfaces.

At the end of each day, perform the following cleaning procedure:

1. Wipe down the following items and areas with disinfecting wipes containing 1% sodium hypochlorite.
   - sample racks (should be cleaned between each run)
   - work surfaces
   - ancillary items such as pipettes, tube racks, etc.
   - all external and internal work surfaces of the BD MAX™ instrument, EXCEPT the monitor screen, the clear part of the instrument door, and the glass surface of the cartridge drawer. External instrument surfaces should be cleaned before internal surfaces.
2. Using a unidirectional motion, thoroughly wipe off all system parts that came into contact with sodium hypochlorite (a known PCR inhibitor) with a lint-free cloth dampened with deionized (DI) water, then with 70% alcohol.
3. Use a new, dampened lint-free cloth for each solution.
4. Dry the system with a lint-free cloth.

12.2 Weekly Cleaning

1. Turn off the BD MAX™ instrument using the On/Off switch.
2. Unplug the BD MAX™ instrument from the Uninterruptible Power Supply (UPS) when performing cleaning and maintenance.
3. Use proper personal protective equipment and follow safety guidelines.
4. Perform routine Daily Cleanup as described above.
5. Inspect the cartridge drawer for foreign objects, dirt, or dust. If any are discovered in the tray, remove and clean the surface with a 70% alcohol solution on a lint-free cloth.
6. Wipe the monitor screen with an alcohol wipe, and then dry the screen with a soft cloth.
7. Use either an alcohol wipe or glass cleaner to clean both the transparent cover of the system and the mirror inside the instrument, using a lint-free cloth to dry.
8. Plug the system back into the UPS and turn on.
9. Put on a clean pair of disposable gloves before beginning instrument operation.

13.0 Instrument Maintenance and Service

13.1 Preventative Maintenance

Preventative Maintenance is performed by a BD field service engineer every 6 months. The engineer checks all of the instrument calibrations and the thermocycler functionality. After the PM is complete, previously tested patient samples should be run to verify the instrument's performance. This should include 5 positive and 5 negative samples for each analyte.

13.2 Service Repairs

If the BD MAX™ instrument malfunctions or operates unusually in any way, initial attempts should be made to solve the problem by following the recommendations in the Troubleshooting section of the System User's Manual. All other servicing attempts will terminate the responsibility of the manufacturer under the terms of the warranty.

If instrument malfunction cannot be corrected, contact BD Technical Services. Technical Services is available Monday through Friday from 5:30 a.m. to 5:00 p.m. Pacific Time. Locate the instrument serial number located on the front of the instrument before placing the call.

Technical Service Information

Telephone Number: 800-638-8663

Email Address:technical_services@bd.com

After major repairs have been made to the instrument, previously tested patient samples should be retested to verify that the instrument is performing as expected.

14.0 Limitations

1. The BD MAX™ GBS Assay does not provide susceptibility results. Cultured isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. Subculture to solid media for additional testing when indicated.
2. The BD MAX™ GBS Assay can only be used on the BD MAX™ System by trained personnel.
3. Performance of the BD MAX™ GBS Assay was established with vaginal and rectal specimens collected from antepartum women using swabs in non-nutritive transport medium (e.g. Amies or Stuart) and enriched in Lim Broth. Use of the BD MAX™ GBS Assay for clinical specimen types other than those specified has not been evaluated and performance characteristics are not established.
4. The BD MAX™ GBS Assay has been validated with Lim Broth media only. Performance of the BD MAX™ GBS Assay with other types of selective broth media has not been evaluated.
5. The BD MAX™ GBS Assay has been validated with Lim Broth cultures incubated for ≥ 18 h. Performance of the BD MAX™ GBS Assay with Lim Broth cultures incubated for less than 18 h has not been evaluated.
6. Erroneous results may occur from improper specimen collection, handling, storage, technical error, sample mix-up, or because the number of organisms in the specimen is below the analytical sensitivity of the test.
7. The presence of feces and body powder can potentially inhibit the detection of GBS at low concentration levels (300 CFU/mL of Sample Preparation Reagent). No interference by these substances was observed at moderate GBS concentration levels (3000 CFU/mL of Sample Preparation Reagent).
8. The presence of *Corynebacterium xerosis, Serratia marcescans* and EBV can potentially inhibit the detection of GBS at low concentration levels (300 CFU/mL of Sample Preparation Reagent).
9. A positive test result does not necessarily indicate the presence of viable organisms. It is, however, presumptive for the presence of Group B *Streptococcus* DNA.
10. While there are no known strains/isolates of GBS lacking the *cfb* gene, the occurrence of such a strain could lead to an erroneous result using the BD MAX™ GBS Assay.
11. If *Moraxella osloensis* is present in the specimen there exists a potential for a false positive result because this organism cross-reacted in four of nine replicates.
12. Mutations in primer/probe binding regions may affect detection using the BD MAX™ GBS Assay.
13. A negative result does not rule out the possibility of GBS colonization. False negative results may occur when the GBS concentration in the specimen is below the LOD of 200 CFU/mL of Sample Preparation Reagent.

14. The test is not intended to differentiate carriers of Group B *Streptococcus* from those with streptococcal disease.

15.0 Validation Information

The BD MAX™ GBS Assay has been cleared by the FDA for clinical diagnostic testing. No modifications have been made to the FDA-cleared assay. In this evaluation, Lim broth cultures that were tested with the BD GeneOhm™ Strep B Assay were subsequently tested using the BD MAX™ GBS Assay.

Analytical Sensitivity

The Limit of Detection (LoD) of the BD MAX™ GBS Assay, as determined by the manufacturer, is 200 CFU/mL Sample Preparation Reagent (2×10^4 CFU/mL enriched Lim Broth). The data from this evaluation suggest that the LoD of the BD MAX™ GBS Assay is equivalent to, or better than, the LoD of the BD GeneOhm™ Strep B Assay. The GeneOhm™ assay was previously validated in our laboratory using the modification of Lim broth enrichment prior to analysis. That evaluation demonstrated that the LoD was between 10^2 and 10^3 CFU/mL for the BD GeneOhm™ Strep B Assay. Since, no false-negative results were obtained with the BD MAX™ GBS Assay, it is presumed to be as sensitive as the former modified GeneOhm™ Assay.

Analytical specificity

The manufacturer of the BD MAX™ GBS evaluated the assay using samples containing high levels of non-target organisms. A total of 127 organisms were tested (119 viable organisms and 8 genomic DNA), including 11 organisms phylogenetically similar to Group B Streptococcus and a wide variety of other organisms including viruses, fungi and parasites that are known to infect the urogenital tract or are part of urogenital microflora. A complete list of organisms that were tested can be found in the manufacturer's package insert. None of the 11 phylogenetically related streptococcal isolates tested positive with the BD MAX™ GBS Assay. Of the remaining strains tested, only one (*Moraxella osloensis*) was positive in four of nine replicates.

In our evaluation of the BD MAX™ GBS Assay using clinical specimens, no false-positive results were encountered as compared to the BD GeneOhm™ Strep B Assay.

Assay Accuracy

A total of 70 Lim broth culture samples were tested in parallel with the BD MAX™ GBS Assay and the BD GeneOhm™ Strep B Assay. This included 20 positive and 50 negative samples. One (1%) of the BD MAX™ tests produced an indeterminant result. Repeat testing of this sample produced a negative result, which was concordant with the BD GeneOhm™ result. Of the 20 positive results, 1 (5%) sample produced a negative result on the BD GeneOhm™ assay and a positive result on the BD MAX™ assay. Unfortunately, the sample was discarded and no longer available for repeat analysis to confirm the result. Run data from both assays was submitted to BD. BD indicated that there was no evidence of a false-positive result on the MAX. However, the CT value from the MAX indicated that the sample was a low level positive. Since the manufacturer's published LoD for the two assays indicates that the BD MAX™ is more sensitive, the result from the BD MAX™ was considered to be a true positive. Of the 50 negative samples, 1 (2%) of the samples produced a positive result on the BD GeneOhm™ assay and a negative result on the BD MAX™ assay. A review of the run data showed an atypical amplification curve from the BD GeneOhm™ assay. Repeat testing with the BD GeneOhm™ produced a negative result. Review of the second run data showed no indication of the amplification that was detected in the first analysis. The initial BD GeneOhm™ result was considered to be a false-positive and was resolved with the repeat analysis. The table below summarizes the results from this evaluation.

	Positive MAX	Negative MAX	Total
Positive GeneOhm	19	0	19
Negative GeneOhm	1	50	51
Total	20	50	70

Overall Agreement = 98.6%

Positive Agreement = 95%

Negative Agreement = 100%

Precision

A description of the precision studies performed by the manufacturer can be found in the test kit package insert. Our evaluation of the assay's precision consists of 20 days of Quality Control testing using external control materials. This portion of the validation is currently ongoing.

16.0 References

Package insert: BD MAX™ GBS Assay Kit, 03-2012.

17.0 Document Control History

Adopted/Reviewed by director (AR) 04/23/2013 and supervisor (JC) 04/24/2013

Reviewed by J. Schappert: DD/MM/YY