PROGRAM Standard Operating Procedure – Laboratory Services		
Title: MIC31200 -	Policy Number:	
GBS Screen		
Program Name: Laboratory Services		
Applicable Domain: Lab, DI and Pharmacy Services		
Additional Domain(s): NA		
Effective Date:	Next Review Date:	
Issuing Authority:	Date Approved:	
Director, Laboratory and Diagnostic Imaging Services		
Accreditation Canada Applicable Standard: NA		

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GUIDING PRINCIPLE:

10-35% of women are asymptomatic carriers of Group B *Streptococcus* (*Streptococcus agalactiae*, GBS) in the genital and gastrointestinal tracts. GBS may be transmitted to the neonate at birth and remains a leading cause of serious illness and death in newborn populations.

PURPOSE/RATIONALE:

This standard operating procedure describes the screening for Group B *Streptococcus* (GBS) in vaginal/rectal specimens.

SCOPE/APPLICABILITY:

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) processing specimens for GBS screen.

Туре	Swab Amie's with or without charcoal 	
Source	 Combined introital (vaginal and anorectal area) swab Vaginal swabs are not the specimen of choice but will be processed 	
Stability	 If the sample is received in the laboratory and processed greater than 48 hours from collection: Add specimen quality comment: "Delayed transport may adversely affect pathogen recovery" 	
Storage Requirements	Room temperature	

SAMPLE INFORMATION:

Criteria for rejection	 Unlabeled/mislabeled swab Specimen container label does not match patient identification on requisition Duplicate specimens obtained with same collection method within 24 hours
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REAGENTS and/or MEDIA:

- LIM Broth (LIM), StrepBSelect agar (GBS) and Blood agar (BA)
- Identification reagents: Strep latex test

SUPPLIES:

- Disposable inoculation needles
- Wooden sticks
- Glass test tubes
- Sterile pipettes

EQUIPMENT:

- Biosafety cabinet
- 35° CO₂ incubator
- 35° ambient air incubator
- VITEK 2 and supplies

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures:

- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is
 unavoidable
- Eye protection must be used when there is a known or potential risk of exposure of splashes
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC)
- The use of needles, syringes and other sharp objects should be strictly limited

All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:

- Refer to MIC60040-Culture Media Quality Control procedure
- Refer to Test Manual for reagent quality control procedures

PROCEDURE INSTRUCTIONS: Action Step Processing swabs for GBS screen Place swab in LIM broth, break off leaving the swab in the broth medium 1 and loosely recap. Leave broth in the rack in the BSC. The evening technologist will incubate the rack of LIM broths in the CO_2 2 incubator before leaving for the evening. At 14:00, after 18 to 24 hours incubation, subculture the broth to StrepBSelect agar: Remove the required number of StrepBSelect plates from the refrigerator and bring to room temperature Saturate a sterile swab in the broth and rotate against the wall 3 of the tube above the liquid to remove excess inoculum Inoculate StrepBSelect agar with the swab Ensure all surfaces of the swab make contact with the agar Streak for isolated growth using a disposable inoculation needle Label the GBS plate with: R (Date + 2 date). 4 Incubate the media: 5 Place GBS plate in the O₂ incubator on the "GBS SCREEN" section on the old cultures shelf

INTERPRETATION OF RESULTS:

Step	Action		
1	Observe GBS plate at 38 to 48 hoursExamine for blue colonies		
3	 If no blue colonies are seen at 38 to 48 hours: Record observations in the LIS Workup complete GBS not isolated 		
4	 If blue colonies are seen: Record observations in the LIS Subculture colonies to BA plate if no isolated colonies are present If isolated colonies are present, perform Strep latex test for Group B 		
	IF	THEN	
5	Strep B latex test NEGATIVE	Record observations in the LISWorkup completeGBS not isolated	
	Strep B latex test POSITIVE	Record observations in the LISGBS isolated	

NOTE: Each Streptococcus grouping latex test should be tested with at least one extra grouping latex suspension as a negative control

REPORTING INSTRUCTIONS:

IF	REPORT	
GBS not isolated	 Report: "No Streptococcus agalactiae (Group B) isolated" A copy will automatically print to STH OBS (SOBS) 	
GBS isolated and no	 Choose key 9 on STRB keypad to add isolate:	
penicillin allergy indicated	"Streptococcus agalactiae (Group B)" List quantitation as "Isolated" The following isolate comments will be added:	
in clinical history	&A336 and &IAPO A copy will automatically print to STH OBS (SOBS)	
GBS isolated and clinical	 Choose key A on the STRB keypad to add isolate:	
history indicates penicillin	"Streptococcus agalactiae (Group B)" List quantitation as "Isolated" The following isolate comment will be added:	
allergy	&A336 VITEK AST-ST03 panel will be ordered Report susceptibility results as per ASTM A copy will automatically print to STH OBS (SOBS)	

LIMITATIONS:

- 1. If an inoculum contains a high density of *Streptococcus agalactiae*, the medium around the deposit may be coloured.
- 2. The colonies of some species, other than *Streptococcus agalactiae* (for example, *Streptococcus pyogenes*, *Streptococcus porcinus* and *Streptococcus gallolyticus*) may appear blue.
- 3. Prenatal GBS screening should be done between 35-37 weeks gestation as GBS colonization can be transient and colonization early in pregnancy is not predictive of early-onset GBS disease. Late third trimester colonization status has been used as a proxy of intrapartum colonization. The negative predictive value of GBS cultures performed ≤5 weeks before delivery is 95%-98%; however, the clinical utility decreases when a prenatal culture is performed more than five weeks before delivery because the negative predictive value declines.

CROSS-REFERENCES:

• MIC60040-Culture Media Quality Control

REFERENCES:

- 1. Leber, A. (2016). *Clinical microbiology procedures handbook.* (4thed.) Washington, D.C.: ASM Press
- Jorgensen, J. H., Pfaller, M. A., Carroll, K. C., Funke, G., Landry, M. L., Richter, S. S., Warnock, D. W. (2015). *Manual of clinical microbiology* (11thed.). ASM Press
- 3. BioRad Laboratories. (2009/08). *StrepBSelect* package insert

APPROVAL:

Date

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 May 17	Initial Release	L. Steven
2.0	22 Oct 18	Updated to include new chromogenic agar StrepB <i>Select</i>	L. Steven
3.0	30 Dec 21	Procedure reviewed and added to NTHSSA policy template	L. Steven
4.0	05 Jun 23	Procedure reviewed and updated to add new VITEK AST-ST03 card	L. Steven
5.0	19 Dec 24	Updated to reflect removal of 24 hour read	L. Steven