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

**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. A selective enrichment broth must be used for initial processing of prenatal GBS specimens as it significantly improves detection of GBS.

**PURPOSE/RATIONALE:**

To screen for Group B Streptococcus(GBS) in vaginal/rectal specimens.

**SCOPE/APPLICABILITY:**

This procedure applies to Medical Laboratory Technologists processing specimens for GBS screen.

**SAMPLE INFORMATION:**

|  |  |
| --- | --- |
| **Type** | 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 |
| **Criteria for rejection and follow up action** | 1. Unlabeled/mislabeled swab 2. Specimen container label does not match patient identification on requisition 3. Duplicate specimens obtained with same collection method within 24 hours |

**REAGENTS and/or MEDIA:**

* LIM Broth (LIM), StrepB *Select* agar (GBS) and Blood agar (BA)
* Identification reagents: catalase and Strep latex test

**SUPPLIES:**

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

**EQUIPMENT**

* Biosafety cabinet
* 35° CO2 incubator
* 35° ambient air incubator

**SPECIAL SAFETY PRECAUTIONS:**

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

* 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. Universal precautions 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:**

|  |  |
| --- | --- |
| **Step** | **Action** |
| **Processing swabs for GBS screening** | |
| **1** | Place swab in LIM broth, break off leaving the swab in the broth medium and loosely recap. Leave broth in the rack in the BSC. |
| **2** | The evening technologist will incubate the rack of LIM broths in the CO2 incubator before leaving for the evening. |
| **3** | At 14:00, after 18 to 24 hours incubation, subculture the broth to StrepB *Select* agar:   * Remove the required number of StrepB *Select* plates from the refrigerator and bring to room temperature * Saturate a sterile swab in the broth and rotate against the wall of the tube above the liquid to remove excess inoculum * Swab the first quadrant of the agar * Streak for isolated growth using a disposable inoculation needle:     Streak out to cover the whole plate. |
| **4** | Incubate plate in O2 incubator at 35° for 24 hours in the 1:00 pm new urine rack. |

**INTERPRETATION OF RESULTS:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | |
| **1** | Remove culture plates after 24 hours incubation. | |
| **2** | Observe plate for blue colonies: | |
| **3** | **IF** | **THEN** |
| No blue colonies seen at 24 hours | * Record observations in the LIS * Re-incubate plates in O2 incubator on the “Old urine culture” shelf |
| No blue colonies  seen at  38-48 hours | * Record observations in the LIS * Workup complete. * GBS not isolated |
| Blue colonies seen at 24 or 38 hours | * Record observations in the LIS * Subculture colonies to BA plate if no isolated colonies are present * From BA sub-plate or original GBS plate, perform:  1. Catalase |
| **IF** | **THEN** |
| Catalase  POSITIVE | * Record observations in LIS * Workup complete * GBS not isolated |
| Catalase  NEGATIVE | * Record observations in LIS * Perform Strep latex test for Group B |

|  |  |  |
| --- | --- | --- |
| **3** | **IF** | **THEN** |
| Strep B latex test  NEGATIVE | * Record observations in LIS * Workup complete * GBS not isolated |
| Strep B latex test  POSITIVE | * Record observations in LIS * GBS isolated |
| **IF** | **THEN** |
| Group B screen is positive and clinical history does not state penicillin  allergy | * Susceptibility testing not performed |
| Group B screen is positive and clinical history states  penicillin allergy | * Perform susceptibility testing as per ASTM |

**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 penicillin allergy indicated in clinical history | * Choose key 7 on STRB keypad to add isolate:   **“Streptococcus agalactiae (Group B)”**   * List quantitation as **“Isolated”** * The following isolate comments will be added: **&A336** and **&IAPO** * A copy will automatically print to STH OBS (SOBS) |
| GBS isolated and clinical history indicates penicillin allergy | * Choose key 8 on the STRB keypad to add isolate:   **“Streptococcus agalactiae (Group B)”**   * List quantitation as **“Isolated”** * The following isolate comment will be added: **&A336** * KB susceptibility panel for GBS screen is ordered * Report susceptibility results as per ASTM * A copy will automatically print to STH OBS (SOBS) |

**LIMITATIONS:**

1. The selective mixture of antibiotics/antifungal agents inhibits the growth of the majority of microorganisms, with the exception of *Streptococci*, some *enterococci* and *lactobacilli*.
2. As with any chromogenic medium, it is important to streak at closely spaced intervals in order to obtain well-isolated colonies: the morphology and colour of the colonies will then be more typical.
3. If an inoculum contains a high density of *Streptococcus agalactiae*, the medium around the deposit may be coloured.
4. The colonies of some species, other than *Streptococcus agalactiae* (for example, *Streptococcus pyogenes*, *Streptococcus porcinus* and *Streptococcus gallolyticus*) may appear blue.
5. The intrinsic demands of some *Streptococci* can lead to absence or partial inhibition of their growth.
6. 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.

**REFERENCES:**

* Clinical Microbiology Procedures Handbook, 4th edition, ASM Press, 2016
* Jorgensen J.H., Pfaller M.A., Carroll K.C., Funke G., Landry M.L., Richter S.S., WarnockD.W. 2015. Manual of Clinical Microbiology, 11th edition, ASM Press, Washington, D.C.
* StrepB Select agar package insert. 08/2009

**APPROVAL:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**REVISION HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **REVISION** | **DATE** | **Description of Change** | **REQUESTED BY** |
| 1.0 | 15 May17 | Initial Release | L. Steven |
| 2.0 | 8 Feb 19 | Updated to include new chromogenic agar StrepB *Select* | L. Steven |
| 3.0 | 30 Dec 20 | Procedure reviewed and added to NTHSSA policy template | L. Steven |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |