Clinical performance of the WASP Lab AI/IA-PhenoMATRIX™ software in detection of GBS from LIM-enriched cultures plated to CHROMID® Streptoc B Chromogenic Media.

Karen Timm1, Justin Baker, Karissa Cublaube1
1TriCore Reference Laboratories, Albuquerque NM, Department of Pathology, University of New Mexico School of Medicine, Albuquerque NM

Abstract

Group B Streptococcus (GBS) can be found colonizing about 25% of all healthy adult women and is the leading infectious cause of early neonatal morbidity and mortality in the United States. The rate of early-onset neonatal infection is ~0.22 cases per 1,000 live births (2016) and can cause sepsis resulting in neurological sequelae such as sight/hearing loss and cerebral palsy. The CDC recommends that vaginal/rectal swabs be collected between 35 to 37 weeks gestation to test the mother for carriage and prophylactic measures taken for colonized women.

This study was undertaken to evaluate the clinical performance of the WASP lab™ Artificial Intelligence/Interpretative Algorithm (PhenoMATRIX™) with specific emphasis on the detection of GBS. A total of 486 vaginal/rectal swab samples were collected for the study. Specimens were determined to be positive if they had a positive molecular result and/or a confirmed GBS culture result. The overall sensitivity of 95.7% for a sensitivity of the ChromGBS plus PM of 95.7%, but specificity of 93.6% and 79.9% for the PhenoMATRIX. Morphologies consistent with GBS were confirmed using Gram stain, catalase reaction and latex Lancefield grouping. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) was determined by comparing the result of each method to the consensus result.

Methods

**Samples:** 486 residual vaginal/rectal swabs in LIM broth were enrolled in the study. LIM broth was incubated at 35-37°C for 18-24 hours. Culture of the Lim-broth enriched specimen is the gold-standard for detection of GBS. The CDC recommends universal culture-based screening for GBS on all pregnant women at less than 33 weeks gestation.

**Specimen Collection:** A total of 486 vaginal/rectal swab samples were collected for the study. Specimens were determined to be positive if they had a positive molecular result and/or a confirmed GBS culture result. The overall detection of GBS was considered to be 94/486 (19.3%). The ChromGBS plus PM algorithm detected 84/94 (93.6%) GBS samples at 24 hours demonstrating a sensitivity and specificity of 93.6% and 79.9%, respectively.

**Results:** A total of 486 vaginal/rectal swab samples were collected for the study. Specimens were determined to be positive if they had a positive molecular result and/or a confirmed GBS culture result. The overall detection of GBS was considered to be 94/486 (19.3%). The ChromGBS plus PM algorithm detected 84/94 (93.6%) GBS samples at 24 hours demonstrating a sensitivity and specificity of 93.6% and 79.9%, respectively.

**Introduction**

Group B Streptococcus (GBS) has been recognized as a leading cause of infectious early neonatal morbidity and mortality in the United States. Early onset GBS disease in infection in newborns occurs within the first week of life. Patients typically present with respiratory distress, apnea or other constitutional signs of sepsis with mortality from early-onset GBS can range from 2-30%, with the highest rates among infants less than 33 weeks gestation.

Culture of the Lim-broth enriched specimen is the gold-standard for detection of GBS. However, culture lacks sensitivity and requires 24-48 hours following enrichment for detection. There are several rapid, fully-automated nucleic acid amplification tests available for the detection of GBS that increase sensitivity and provide a faster result, but may suffer from a lack of specificity.

**Conclusion**

- The use of ChromGBS in combination with Phenomatrix is equivalent to the use of ChromGBS plus PhenoMatrix in screening GBS.
- ChromGBS with PhenoMatrix lacks specificity due to overlap in color spectra for GBS and non-GBS isolates.
- ChromGBS plus PhenoMatrix provides an efficient method for rapid screening of GBS negative cultures.

**Acknowledgements**

This work was supported by COPAN Diagnostics and bioMerieux.