Development of Group B Streptococcus Multiplex PCR Panel Amendable to Bead-Based and Microarray Detection Systems

Introduction/Background:

Streptococcal infection, also known as Group B Streptococcus (GBS), is a common bacterial infection of the vaginal and/or genitourinary tract of between 15-40% of healthy women. Typically, this organism is only pathogenic when carried by pregnant women who can then pass the bacteria to their offspring during the birth process. GBS has been implicated as causing sepsis and meningitis, as well as respiratory and necrotizing fasciitis in newborns. This fact has led to increased awareness and identification of this organism in newborns and women of childbearing age. GBS is a commensal organism in the vagina and GI tract of between 15-40% of healthy women. Typically, GBS is not pathogenic until it is introduced into the bloodstream (e.g., during birth). In 2002, the CDC recommended that all pregnant women be screened for Group B Streptococcus. The CDC guidelines state that women who are GBS PCR-positive should be treated with intravenous penicillin or ampicillin through IV during labor. The ‘gold standard’ method for GBS detection is culture on selective media, followed by biochemical testing for specific identification. Currently, several rapid molecular methods are available for detecting GBS. These methods vary in sensitivity, speed and specificity and may require specialized equipment and expertise to perform.

Materials & Methods:

Development and Validation of TEM-PCR™ GBS Panel

Results:

<table>
<thead>
<tr>
<th>Culture</th>
<th>NEGATIVE</th>
<th>DETECTED</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>256</td>
<td>0</td>
<td>256</td>
</tr>
<tr>
<td>Positive</td>
<td>77</td>
<td>0</td>
<td>77</td>
</tr>
</tbody>
</table>

Table 1. Reference strains for inclusivity testing. All strains were evaluated at approximately 1000 CFU/mL.

Evaluation of Microarray Detection Platform

Table 2. Clinical comparison of Luminex vs. Microarray platforms for GBS detection. Concordance was determined using ROC analysis. "GBS Detected" and "Microarray Not Detected" are represented as 100% sensitivity and specificity, respectively.

Results (continued):

Evaluation of Bead-Based Detection Platform

Table 3. List of fluorophores used in evaluation.

Conclusions:

For the first time, a GBS microarray panel was validated for detection in clinical samples.

References:


Acknowledgments:

The authors appreciate the support of research funds provided by Diatherix Laboratories, Inc. Leslie Malone

Leslie Malone
leslie.malone@diatherix.com

Cheryl Sesler
Stefan Brzezinski
Donna Hockman
Elena Grigorenko, Ph.D.
Diatherix Laboratories, Huntsville, AL

Diatherix Laboratories

www.diatherix.com