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EVALUATION OF ENRICHMENT COMBINED WITH PCR OR MALDI-TOF FOR THE DETECTION OF *Streptococcus agalactiae* INFECTION OR CARRIAGE IN LATE PREGNANCY OR IN ELDERLY PATIENTS

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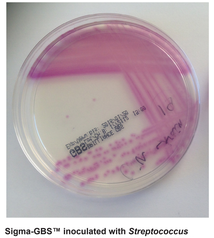
Background

Streptococcus agalactiae is the commonest cause of neonatal infection in the United Kingdom, and also the most frequent cause of meningitis in babies in their first three months of life. In addition, there are reports of increasing incidence in adults over 65 years. When discovered in late pregnancy there is a high risk of infection of the baby which can be life threatening or life-changing, so it is imperative that diagnosis be completed quickly so that treatment can be commenced without delay

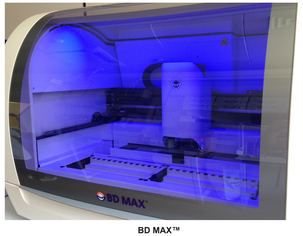
Although many novel diagnostic tests can provide answers within a few hours, the reliability of results is greatly improved by enrichment, and is recommended by CDC Guidelines. A new transport swab device (MWE's Sigma GBS™) allows direct enrichment of *Streptococcus agalactiae* within the primary collection/transport tube, followed by direct testing in various systems. The tubes are designed to be compatible with automated processing platforms, and so following incubation can be directly loaded for plating, for example, onto chromogenic agar. The present study was designed to assess how well the device would perform for culture and in combination with three different rapid confirmatory techniques - PCR (BD Max™), Matrix Assisted Laser Desorption Ionization Time-of-Flight (Vitek™ MS), and direct latex agglutination.

Materials & Methods

Previously confirmed clinical isolates of *Streptococcus agalactiae* were used for the study. Suspensions (0.5 McFarland) were diluted to 10^{-2} and 10^{-3}, and used to inoculate PurFlock® (Sigma GBS™ PF) or Sigma foam-tipped (Sigma GBS™) swabs. The inoculated swabs were then immersed in the Sigma GBS™ medium in their corresponding transport tubes. All tubes were incubated overnight, before testing directly using BD Max™ PCR (BD MAX™ GBS Assay Kit), or plating onto chromogenic agar (Thermo Fisher Brilliance™ GBS Agar). Any growth (pink colonies) was tested by direct latex agglutination (Thermo Fisher Strep Universal Grouping Kit), or identification using MALDI-TOF (Biomerieux Vitek™ MS).



Sigma-GBS™ inoculated with *Streptococcus agalactiae* and plated on (Thermo) Brilliance™ GBS Agar



BD MAX™

Results

Isolate Number	Dilution	Swab Type	GBS Chromogenic Agar	Direct Latex	MALDI-TOF ID	BD MAX PCR
1	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
2	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
3	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
4	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
5	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
6	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
7	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
8	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
9	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
10	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
11	10^{-2}	Foam	Pink Growth	Positive	GBS	Positive
12	10^{-2}	Foam	Pink Growth	Positive	GBS	Fail
13	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Fail
14	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
15	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
16	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
17	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
18	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
19	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
20	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
21	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
22	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
23	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
24	10^{-2}	PurFlock	Pink Growth	Positive	GBS	Positive
25	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
26	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
27	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
28	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
29	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
30	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
31	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
32	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
33	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
34	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
35	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
36	10^{-3}	Foam	Pink Growth	Positive	GBS	Positive
37	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
38	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
39	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
40	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
41	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
42	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
43	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
44	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
45	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
46	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
47	10^{-3}	PurFlock	Pink Growth	Positive	GBS	Positive
48	10^{-3}	PurFlock	No growth	N/A	N/A	Negative

Streptococcus agalactiae (GBS) was recovered from 47 of the 48 swabs inoculated. The single exception was due to a processing error in which the swab may not have been inoculated. Two PCR tests failed due to internal error, but GBS was recovered from these swabs, which also gave positive readings with MALDI-TOF and Direct Latex.

Conclusion & Discussion

Streptococcus agalactiae is a major cause of neonatal infection with consequences including meningitis in babies in the first three months of life. Adults over 65 years are also subject to serious infection from *Streptococcus agalactiae* . Rapid accurate diagnosis is essential. CDC Guidelines recommend enrichment of specimens prior to processing.

In the present study, all inoculated Sigma GBS™ and Sigma GBS™ PF devices allowed the accurate identification of *Streptococcus agalactiae* by culture, and all completed rapid tests such as PCR, Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF), and direct latex agglutination, correctly identified the organism from the same specimen.

Thus routine samples can be plated on chromogenic agar, for example, on an automated processing platform, with confirmation if required using MALDI-TOF, or latex agglutination, while urgent critical specimens could be immediately tested using the rapid PCR test systems which are now available.

By removing the need for a separate enrichment stage at the laboratory, the Sigma GBS™ & Sigma GBS™ PF devices speed up the handling of *Streptococcus agalactiae* specimens, and make universal screening a more practical propostion.

Reference

Centers for Disease Control and Prevention. Prevention of Perinatal Group B Streptococcal Disease: Revised Guideline from CDC. Morbidity and Mortality Weekly Report, November 19, 2010;59(No. RR-10);1-23

BioMerieux Vitek® MS (MALDI-TOF)

Sigma GBS™ & Sigma GBS™PF

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