Diatherix | Eurofins Clinical Diagnostics



Group B *Streptococcus* Panel

Application Notes:

Streptococcus agalactiae, more commonly referred to as Group B *Streptococcus* (GBS), is a part of normal flora of the gut and genital tract and carried asymptomatically in 20–40% women. Infection of the neonate during delivery can lead to severe disease or death, primarily from sepsis, pneumonia or meningitis. Such risks can be mitigated by prophylactic antibiotic treatment immediately prior to and during labor. Administration of prophylaxis is generally based on risk factor assessment and by direct screening for GBS on properly collected clinical specimens between 35 -37 weeks of gestation. The Diatherix Eurofins GBS Panel was developed using TEM-PCR™ *(Target Enriched Multiplex Polymerase Chain Reaction)* technology, and is a highly sensitive and specific molecular test for the detection of GBS during pregnancy.

Panel Targets:

The Diatherix Eurofins GBS Panel targets the *pcs*B and *sip* genes. Use of two independent gene targets, with detection of either being taken as indicative of GBS presence in a specimen, allows for increased sensitivity and confidence that a negative test result is not due to a single strain genetic variation.

Specimen Type and Panel Format:

The appropriate specimen for this Panel is a vaginal/rectal swab in Amies medium, as obtained by routine clinical methods that are outlined in our Client Services Manual. The Panel employs patented TEM-PCR technology with documented advantages in sensitivity, specificity, and multiplexing capacity for the qualitative rapid molecular detection of GBS by a two-stage process for maximal sensitivity.

Expected TAT:

Upon receipt, samples are initially tested using the Diatherix Eurofins GBS Panel and positive results are reported that same day. Samples negative by the GBS Panel are further sub-cultured overnight in enrichment medium and then retested. The enrichment step complies with the recommendations set-out by the Centers for Disease Control and ensures the accurate detection of even very low titre positive samples.

Panel Sensitivity:

The GBS Panel has a 95% Limit of Detection (LOD_{95}) of below 100 GBS cfu/ml in incoming samples, as determined on a titered GBS control strain by serial dilution and Reed-Muench method of replicate analysis.

Panel Controls:

This Panel includes process extraction controls, PCR positive controls, PCR negative controls, and individual sample internal controls for reliability and detection of PCR inhibition.

Panel Inclusivity:

The Diatherix Eurofins GBS Panel has been tested for inclusivity on the following 11 reference strains. All strains were evaluated at approximately 1660 GEq/rxn. All strains tested were detected equally well by the Panel.

NOTE: Due to the Panel format (detection of two independent GBS markers), potential rare strain variants with sequence variation in either marker will still be accurately detected.

Strain	*pcsB*	*sip*	RESULT
S. agalactiae ATCC 12386	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 12401	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 12403	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 13813	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 27591	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 31475	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 49446	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC 49447	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC BAA-1138	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC BAA-1177	**DETECTED**	**DETECTED**	**DETECTED**
S. agalactiae ATCC BAA-611	**DETECTED**	**DETECTED**	**DETECTED**

Panel Specificity:

The GBS Panel has been tested for cross reactivity against a wide range of organisms potentially recovered by vaginal-rectal swab. Organisms were tested at high titres (typically 1e6 cfu/ml). None of the 55 organisms tested demonstrated any detectable cross-reactivity thereby assuring a high

Organism*Titre*	*tested*	*pcsB*	*sip*	RESULT
C. trachomatis	1E6 IFU/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. pyogenes	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
N. gonorrhoeae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
MSSA	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. haemolyticus	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. flexneri	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. jejuni	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
L. monocytogenes	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Norovirus Group 2	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Y. enterocolitica	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. difficile	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Rotavirus	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
A. baumannii	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. freundii	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. enterica typhimurium	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
U. urealyticum	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
A. vaginae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**

Organism *Titre*	*tested*	*pcsB*	*sip*	RESULT
M. hominis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
N. meningitidis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
P. aeruginosa	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
K. pneumoniae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
L. pneumoniae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
E. aerogenes	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
E. faecium	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
N. meningitidis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. pneumoniae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. pneumoniae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
P. mirabilis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. maltophilia	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. marcescens	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
E. cloacae	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
E. faecalis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
HSV Type 2	1.72E5 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
T. vaginalis	8.25E5 tro/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. aureus	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Coxsackie virus	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. epidermidis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Adenovirus Type 41	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
S. sonnei	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
M. genitalium	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Adenovirus Type 40	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Echovirus Type 30	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Enterovirus Type 71	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
HSV Type 1	7E4 pfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. albicans	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. parapsilosis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. krusei	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. tropicalis	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**

Organism *Titre*	*tested*	*pcsB*	*sip*	RESULT
H. ducreyi	>1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
C. glabrata	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
E. coli O157	1E6 cfu/mL	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Lactobacillus acidophilus	1.00E+06	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Streptococcus dysagalactiae	1.00E+06	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Streptococcus mitis	1.00E+06	NOT DETECTED	NOT DETECTED	**NOT DETECTED**
Streptococcus sanguinis	1.00E+06	NOT DETECTED	NOT DETECTED	**NOT DETECTED**

Clinical Importance of GBS Detection:

Considerable progress has been made in reducing the incidence of early-onset neonatal sepsis caused by Group B Strep. Nevertheless, GBS remains as the leading cause of infectious mortality and morbidity among newborns.[1] Routine testing of clinical specimens and intra-partum prophylaxis of mothers with positive screens for GBS has produced a decline in the incidence of sepsis and other complications in infants over the past 15 years; from 1.7 cases per 1,000 live births in the 1990s to 0.34-0.37 cases per 1,000 live births in recent years.[2] The rates of maternal colonization has not changed, however, and newer, more sensitive techniques for screening are even more important given the emergence of antibiotic resistant strains and the potential for false negatives when screening with culture techniques alone.[3]

Specimen Collection Requirements:

Significant limitations exist in any Panel where strict specimen collection techniques are not followed. Given the recommendations set out by the CDC and the validation studies on clinical specimens performed in conjunction with the development of the TEM-PCR Panel, the following specimen collection steps should be followed:

1. Use the ESwab Collection Kit (white-top tube supplied by Diatherix).
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Swab the lower vagina (vaginal introitus), followed by the rectum (insert the swab through the anal sphincter) *using the same swab*. Move the swab from side to side, or rotate the swab at the collection site; allowing a few seconds for the organisms to be absorbed by the swab. *Cervical specimens and speculum assisted collections are not recommended.*
4. Without contaminating the swab, place the swab in the white-top transport tube all the way to the bottom. You may either break the swab stick at the colored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube and submit the specimen according to the instructions provided.

Bibliography:

1. Committee Opinion. The American College of Obstetricians and Gynecologists. Number 485. April, 1011.
2. Prevention of Perinatal Group B Streptococcal Disease Revised Guidelines. CDC, 2010. MMWR 59 (No. RR-10):3.
3. Scicchitano and Bourbeau. Comparative Evaluation of the AccuProbe Group B Streptococcus Culture test, the BD GeneOhm Strep B Panel, and Culture for Detection of Group B Streptococci in Pregnant Women. J. Clin. Micro. Sept, 2009, p. 3021-3023.