Changi General Hospital
SingHealth

Tel: (65) 6788 8833
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Changi General Hospital
2 Simei Street 3
Singapore 529889
www.cgh.com.sg
Reg No 198904226R

Test Name	**Bacteria / Candida Multiplex PCR**
Specimen Type	**ACCEPTABLE SAMPLES** Fluid samples from normally sterile sites **INAPPROPRIATE SAMPLES** 1. Cerebrospinal fluid Please order Meningitis/encephalitis PCR instead 2. Respiratory tract samples (e.g. BAL, ETTA) Please order Respiratory Pathogen PCR or Pneumonia PCR Under special circumstances, where hospital-onset meningitis is suspected and there are concerns about bacterial viability (e.g. prior antibiotic administration), CSF samples may be accepted for testing. Please note that this will be an unvalidated sample type.
Special Instructions For Laboratory	-
Specimen Storage And Transport	Minimum sample volume required: 1 ml Transport to laboratory as quickly as possible. Samples should be refrigerated, if delay in specimen transport is anticipated. Refrigerated samples may be stored and tested for up to approximately 7 days.
Specimen Minimum Volume	Minimum vol: 1 ml
Test Method	PCR (Biofire FilmArray Multiplex PCR) (laboratory modified, to accept sample types listed above)
Expected Result	Detected, Not Detected, Inhibitory The PCR assay detects DNA with identification to species level, or at a broader group (genus) level. For positive detections, there is potential cross-reactivity with very closely related species. The most important potential cross-reactivity is annotated in Table 1 below. *I. REPORTED TO SPECIES LEVEL* GRAM-POSITIVE BACTERIA: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae (Group B streptococcus), Streptococcus pneumoniae GRAM-NEGATIVE BACTERIA: Acinetobacter baumannii, Enterobacter cloacae complex, Escherichia coli, Klebsiella pneumoniae group, Klebsiella oxytoca, Proteus spp1, Pseudomonas aeruginosa, Serratia marcescens, Haemophilus influenzae, Neisseria meningitidis (encapsulated) CANDIDA: Candida albicans, Candida krusei, Candida glabrata complex, Candida parapsilosis, Candida tropicalis *II. REPORTED AS A GROUP (GENUS) LEVEL* GRAM-POSITIVE: Staphylococcus spp. (primarily S. caprae, S. cohnii, S. epidermidis, S. haemolyticus, S. hominis, S. lugdunensis, S. xylosus) Streptococcus spp. (primarily S. anginosus, S. bovis, S. constellatus, S. dysgalactiae, S. equinis, S. gallolyticus, S. gordonii, S. intermedius, S. mitis, S. mutans, S. oralis, S. parasanguinis, S. pseudopneumoniae, S. salivarius, and S. sanguinis.) Enterococcus spp. (primarily E. faecalis, E. faecium, E. avium, E. casseliflavus, E. durans, E. gallinarum, and E. hirae.) GRAM-NEGATIVE: Enterobacterales (Cedeceae spp., Citrobacter spp., Cronobacter sakazakii, Enterobacter spp., Escherichia spp., Klebsiella spp., Kluyvera spp., Leclercia adecarboxylata, Proteus spp., Raoultella spp., Salmonella spp., Shigella spp., Serratia marcescens)
Reference Ranges	n/a

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Turn Around Time	1-2 days
Days Of Testing	Daily
Hospital	CGH
Laboratory	Microbiology Lab
Discipline	Microbiology
Contact Details	68504935 / 36
Clinical Information	**SUMMARY OF TEST** The Bacterial / Candida Multiplex PCR Panel (abbreviated as BCID) is a CGH-validated test, which uses a commercial PCR multiplex test validated for detection of nucleic acids from multiple bacteria and candida species. A separate sample should ALWAYS be sent for routine microbiological culture (as a minimum, aerobic culture, and the following tests if clinically appropriate: anaerobic culture, fungal culture and mycobacterial culture). Organism targets which are NOT present in the BCID panel will NOT be detected by the PCR assay. Please interpret the results of negative BCID PCR results in the context of the clinical infection, the likeliest causative organism(s), and the results of other clinical data and investigations. The following organisms are detected by BCID panel: **Gram-Positive Bacteria** Enterococcus *Listeria monocytogenes* Staphylococcus *Staphylococcus aureus* Streptococcus *Streptococcus agalactiae* *Streptococcus pneumoniae* *Streptococcus pyogenes* **Gram-Negative Bacteria** *Acinetobacter baumannii* Enterobacteriaceae *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Proteus* *Serratia marcescens* *Haemophilus influenzae* *Neisseria meningitidis* (encapsulated) *Pseudomonas aeruginosa* **Yeast** *Candida albicans* *Candida glabrata* *Candida krusei* *Candida parapsilosis* *Candida tropicalis* **(see below for appropriate clinical usage)**

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APPROPRIATE CLINICAL USAGE

1. Urgent testing of samples from normally sterile fluids, where the most likely pathogens are included in the test panel
e.g.
septic arthritis (*S. aureus*, streptococci)
spontaneous bacterial peritonitis (*S. pneumoniae*, streptococci, Enterobacterales)

2. Urgent testing of samples from normally sterile sites
e.g.
liver abscess (*Klebsiella* sp, Enterobacterales), prostatic abscess (Enterobacterales)

3. Testing of fluid samples where microbial growth is suppressed by preceding antibiotic therapy.

Remarks

The performance of the BCID panel was validated by the manufacturer based on detection of organisms from positive blood culture vials.
The performance of the BCID panel from a variety of fluid substrates was validated by CGH laboratory, using both clinical specimens (n=56) and contrived specimens (n=8).
The types of fluid substrates utilised for sensitivity testing were as follows: joint fluid (n=38), liver abscess fluid (n=6), and other fluids (n=6).
The performance of the assay is as follows: sensitivity 96.3%, specificity 100%.

The estimated limit of detection for *S. aureus*, *S. pyogenes* and *S. dysgalactiae* was ~ 10^3-10^4 cfu/ml.

The two discordant results (not detected by BCID) were from peritoneal fluid (culture positive for *S. haemolyticus*) and joint fluid (culture result positive for *S. aureus*).

Specificity testing was performed on joint fluids (n=14) which were either sterile on aerobic culture, or positive with non-target organisms. All 14 samples were found as negative by BCID panel.

SPECIFIC LIMITATIONS OF POSITIVE RESULTS

For positive detections, there is potential cross-reactivity with very closely related species. The most important potential cross-reactivity is annotated in the table below.

BCID Reports as Detected	Potential cross-reactivity	Unable to detect
Enterobacter cloacae complex	*Enterobacter cancerogenus*	*Enterobacter kobei* *Enterobacter ludwigii* *Enterobacter nimipressuralis*
Escherichia coli	*Shigella species*	
	Escherichia fergusonii	
Klebsiella pneumonia	*Raoultella ornithinolytica*	
Haemophilus influenza	*Haemophilus haemolyticus*	
Proteus species[1]		*Proteus myxofaciens*
Serratia marcescens	*Serratia ficaria*	
	Serratia entomophila	
	Pseudomonas putida	
	Raoultella ornithinolytica	
Enterobacterales		*Morganella morganii*
		Pantoea agglomerans
		Providencia species

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Enterococcus sp.		*Enterococcus raffinosus*
Candida parapsilosis	*Candida orthopsilosis*	

LIMITATIONS OF ASSAY
The BCID test may detect non-viable organisms, or organisms which may represent sample contamination. Results should always be interpreted in the context of clinical history and other diagnostics tests.
In samples with more than one organism present, the BCID test may not detect all targeted organisms.
The performance of the test may be affected by inappropriate sample collection (e.g. poor aseptic technique), handling and transportation.
The performance of the BCID test has not been established for monitoring the treatment of infection.