

Test Name	BACTERIA / CANDIDA MULTIPLEX PCR
Specimen Type	<p>ACCEPTABLE SAMPLES Fluid samples from normally sterile sites For Joint fluids, please order Joint Infection Multiplex PCR.</p> <p>INAPPROPRIATE SAMPLES 1. Cerebrospinal fluid Please order Meningitis/encephalitis PCR instead (see exception below). 2. Lower respiratory tract samples Please order Respiratory Pathogen PCR or Pneumonia PCR 3. Samples from contaminated sites, where multiple organisms are likely e.g. bowel perforation, appendicitis, pus from infected lower extremities</p> <p>Under special circumstances, where hospital-onset meningitis is suspected and there are concerns about bacterial viability (e.g. prior antibiotic administration) AND the possible pathogens are included in the target pathogen list, CSF samples may be accepted for testing. Please note that this will be an unvalidated sample type.</p>
Special Instructions For Laboratory	Transport to CGH laboratory as quickly as possible.
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® Joint Infection PCR) (laboratory modified, to accept sample types listed above)
Expected Result	<p>The assay report has three reportable components:</p> <p>Gram positive bacteria: DETECTED, not detected, Inhibitory</p> <p>Gram negative bacteria: DETECTED, not detected, Inhibitory</p> <p>Candida DETECTED, not detected, Inhibitory</p> <p>Antimicrobial resistance genes: (this is only reportable if a RELEVANT organism is detected) DETECTED, not detected</p>
Reference Ranges	n/a
Turn Around Time	1-2 days
Days Of Testing	Daily
Hospital	CGH

Laboratory	Microbiology Lab
Discipline	Microbiology
Contact Details	68504935 / 36
Clinical Information (to copy all)	<p>SUMMARY OF TEST</p> <p>The Bacterial / Candida Multiplex PCR (abbreviated as BCID) is a CGH-validated test, which uses a commercial PCR multiplex test (Biofire® JI panel) validated for detection of nucleic acids from multiple bacteria and candida species.</p> <p>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).</p> <p>Organism targets which are NOT present in the test panel will not be detected by the PCR assay. Please interpret the results of negative PCR results in the context of the clinical infection, the likeliest causative organism(s), and the results of other clinical data and investigations.</p> <p>The following organisms are detected by the test panel:</p> <p>Gram-Positive Bacteria <i>Anaerococcus prevotii/vaginalis</i> <i>Clostridium perfringens</i> <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i> <i>Finegoldia magna</i> <i>Parvimonas micra</i> <i>Peptoniphilus</i> <i>Staphylococcus aureus</i> <i>Staphylococcus lugdunensis</i> <i>Streptococcus</i> spp. (incl. differentiation of <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i>)</p> <p>Gram-Negative Bacteria <i>Bacteroides fragilis</i> <i>Citrobacter</i> spp. <i>Enterobacter cloacae</i> complex <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae</i> group <i>Morganella morganii</i> <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> spp. <i>Serratia marcescens</i></p> <p>Yeast <i>Candida</i> spp. <i>Candida albicans</i></p> <p>Antimicrobial Resistance Genes ESBL genes: CTX-M Carbapenemase genes: KPC; NDM; OXA-48-like Vancomycin resistance genes: vanA/B</p>

	<p>Methicillin resistance (<i>Staphylococcus aureus</i>): <i>mecA/C</i> and MREJ (MRSA)</p> <p>APPROPRIATE CLINICAL USAGE</p> <ol style="list-style-type: none"> Urgent testing of samples from normally sterile fluids, where the most likely pathogens are included in the test panel e.g. spontaneous bacterial peritonitis (<i>S. pneumoniae</i>, <i>streptococci</i>, <i>Enterobacterales</i>) Urgent testing of samples from normally sterile sites e.g. liver abscess (<i>Klebsiella</i> sp, <i>Enterobacterales</i>), prostatic abscess (<i>Enterobacterales</i>) Testing of fluid samples where microbial growth is suppressed by preceding antibiotic therapy. <p>CLINICAL SCENARIOS WHERE TESTING IS UNLIKELY TO BE CLINICALLY HELPFUL</p> <ol style="list-style-type: none"> Specimens where multiple organisms are likely e.g. intra-abdominal diverticular abscess, perforated viscus (rationale: likely to have mixed enteric flora, PCR detection is unlikely to be clinically useful)
Link Out For Additional Information	<p>https://www.cgh.com.sg/patient-care/specialties-services/laboratory-medicine/diagnostic-test-menu</p>
Remarks	<p>The performance of the PCR panel used in the BCID test was originally validated by the manufacturer based on detection of organisms from joint fluids, using the FilmArray® JI Panel.¹</p> <p>The performance of the BCID test from a variety of fluid substrates was validated by CGH laboratory, using both clinical specimens (n=15) and contrived specimens (n=4). The types of fluid substrates utilised for sensitivity testing were as follows: ascitic fluid (n=1), peritoneal fluid (n=3), pleural fluid (n=3), liver abscess (n=2) and other fluids (n=6).</p> <p>BCID test results were concordant with conventional culture results for all the 15 samples. For four samples, the BCID test detected both the bacterial isolates identified by culture, and additional targets (polymicrobial results). The estimated limit of detection for <i>S. aureus</i> and <i>S. agalactiae</i> was ~ 10³-10⁴ cfu/ml.</p> <p>The following are specified limitations of each pathogen or AMR specific assay:</p> <ol style="list-style-type: none"> Nearly all streptococci will be detected by the <i>Streptococcus</i> spp. generic assay, including the <i>Streptococcus milleri</i> group (<i>S. constellatus</i>, <i>S. anginosus</i> and <i>S. intermedius</i>), viridans streptococci, beta-haemolytic streptococci Groups A, C, G and F, <i>Streptococcus bovis</i> group and other streptococci. The <i>Clostridium perfringens</i> assay may cross-react with some members of the <i>Clostridium</i> species group (<i>C. baratii</i>, <i>C. cadaveris</i>, <i>C. disporicum</i>, <i>C. fallax</i>, and <i>C. grantii</i>) The <i>Staphylococcus aureus</i> assay may cross-react with other members of the <i>S. aureus</i> complex (<i>S. argenteus</i> and <i>S. schweitzeri</i>). The <i>Escherichia coli</i> assay will cross-react with <i>Shigella</i> species (<i>S. boydii</i>, <i>S. dysenteriae</i>, <i>S. flexneri</i>, and <i>S. sonnei</i>); which are practically indistinguishable from <i>E. coli</i> by both phenotypic and genetic analyses. Cross-reactivity has also been observed with <i>Escherichia fergusonii</i>, and <i>Escherichia albertii</i> (only at high concentrations). The <i>Haemophilus influenzae</i> assay will cross-react with <i>Haemophilus aegyptius</i>, a species formerly described as a biotype of <i>Haemophilus influenzae</i>.



- (6) The *Candida* species assay will detect most clinically relevant *Candida* species, including *Candida dubliniensis*, *Candida glabrata* (*Nakaseomyces glabrata*), *Candida orthopsilosis*, *Candida parapsilosis*, *Candida krusei* (*Issatchenkia orientalis*), *Candida tropicalis* and *Candida auris*.
- (7) The following cross-reactivity may be noted for AMR gene assays: CTX-M with related blaOXY, blaRAHN, blaKLU genes or some ampC sequences and vanA/B with vanM.

References

1. Esteban, Jaime, et al. "Multicenter evaluation of the BIOFIRE Joint Infection Panel for the detection of bacteria, yeast, and AMR genes in synovial fluid samples." *Journal of Clinical Microbiology* 61.11 (2023): e00357-23.

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.

The results for the antimicrobial resistance gene assays do not specifically link the resistance gene to the applicable bacteria detected. In polymicrobial specimens, the resistance gene may be associated with any of the applicable bacteria detected or an organism that was not detected by the panel.

Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates are required to determine antimicrobial susceptibility.