



Test Name	Joint Infection Multiplex PCR (Biofire FilmArray)
Specimen Type	Joint fluid, synovial fluid
Special Instructions For Laboratory	Minimum vol: 1 ml
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	1 ml
Test Method	PCR
Expected Result	-
Reference Ranges	n/a
Turn Around Time	1-2 days
Days Of Testing	Daily
Hospital	CGH
Laboratory	Microbiology Lab
Discipline	Microbiology
Contact Details	68504935
Clinical Information	<p>The Joint Infection Multiplex PCR (abbreviated as JI) 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 in joint/synovial fluid.</p> <p>Organism targets which are NOT present in the JI 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 JI panel:</p> <p>GRAM-POSITIVE BACTERIA</p> <p>Anaerococcus prevotii/vaginalis Clostridium perfringens Cutibacterium avidum/granulosum Enterococcus faecalis Enterococcus faecium Fingoldia magna Parvimonas micra Peptoniphilus Peptostreptococcus anaerobius</p>



	<p>Staphylococcus aureus Staphylococcus lugdunensis Streptococcus spp. (incl. differentiation of Streptococcus agalactiae, Streptococcus pneumonia, Streptococcus pyogenes)</p> <p>GRAM-NEGATIVE BACTERIA</p> <p>Bacteroides fragilis Citrobacter Enterobacter cloacae complex Escherichia coli Haemophilus influenzae Kingella kingae Klebsiella aerogenes Klebsiella pneumoniae group Morganella morganii Neisseria gonorrhoeae Proteus spp. Pseudomonas aeruginosa Salmonella spp. Serratia marcescens</p> <p>YEAST</p> <p>Candida spp. Candida albicans</p> <p>ANTIMICROBIAL RESISTANCE GENES</p> <p>ESBL genes: CTX-M Carbapenemase genes: KPC; NDM; OXA-48-like Vancomycin resistance genes: vanA/B Meticillin resistance (<i>Staphylococcus aureus</i>): mecA/C and MREJ (MRSA)</p> <p>APPROPRIATE CLINICAL USAGE</p> <ol style="list-style-type: none"> Urgent testing of samples from joint fluids with suspected infection, e.g. septic arthritis (<i>S. aureus</i>, streptococci) Testing of joint fluid samples where microbial growth is suppressed by preceding antibiotic therapy
<p>Link Out For Additional Information</p>	<p>-</p>
<p>Reporting format (no organisms detected)</p>	<p>GRAM-POSITIVE ORGANISMS Gram-POS DNA: All target Gram-positive DNA not detected</p> <p>GRAM-NEGATIVE ORGANISMS Gram-NEG DNA: All target Gram-negative DNA not detected</p> <p>YEASTS Yeast DNA: All target Yeasts DNA not detected</p>



	(target organisms detected by the assay will be listed at the end of the laboratory report)																											
Reporting format (relevant organisms detected)	<p>GRAM-POSITIVE ORGANISMS Gram-POS DNA (1): Staphylococcus aureus DETECTED</p> <p>GRAM-NEGATIVE ORGANISMS Gram-NEG DNA: All target Gram-negative DNA not detected</p> <p>YEASTS Yeast DNA: All target Yeasts DNA not detected</p> <p>ANTIMICROBIAL RESISTANCE GENES mecA/C gene: ***DETECTED***</p> <p>(target organisms detected by the assay will be listed at the end of the laboratory report)</p>																											
Remarks	<p>BIOFIRE JI Panel test performance</p> <p>A published study¹ was conducted at 13 geographically distinct U.S. and E.U. sites. During the study period, 1,544 samples from unique subjects were enrolled and tested. 850 samples were collected from native joints, and 442 samples were from prosthetic joints.</p> <p>202 specimens were positive by culture for at least one on-panel organism, and 242 specimens were positive by the BIOFIRE JI Panel for at least one organism. The overall performance of the BIOFIRE JI Panel for organisms was 90.5% sensitivity and 99.6% specificity.</p> <p>For the commonest pathogens isolated from joint fluids in CGH, the summarized published performance specifications of the JI Panel are as follows:</p> <table border="1"> <thead> <tr> <th>Organism</th> <th>Sensitivity (95% confidence intervals)</th> <th>Specificity (95% confidence intervals)</th> </tr> </thead> <tbody> <tr> <td><i>Staphylococcus aureus</i></td> <td>93.3 (86.9%–96.7%)</td> <td>98.5 (97.7%–99.0%)</td> </tr> <tr> <td><i>Streptococcus</i> species</td> <td>86.4 (73.3%–93.6%)</td> <td>99.2 (98.6%–99.5%)</td> </tr> <tr> <td><i>Streptococcus agalactiae</i></td> <td>90.9 (62.3%–98.4%)</td> <td>99.9 (99.6%–100%)</td> </tr> <tr> <td><i>Streptococcus pyogenes</i></td> <td>91.7 (64.6%–98.5%)</td> <td>100 (99.7%–100%)</td> </tr> </tbody> </table> <p>For the commonest AMR genes in CGH, the summarized published performance specifications of the JI Panel are as follows:</p> <table border="1"> <thead> <tr> <th>Antimicrobial resistance gene</th> <th>Sensitivity (95% confidence intervals)</th> <th>Specificity (95% confidence intervals)</th> </tr> </thead> <tbody> <tr> <td><i>mecA/C and MREJ</i> (MRSA)</td> <td>100 (83.2%–100%)</td> <td>95.7 (89.6%–98.3%)</td> </tr> <tr> <td>vanA/B</td> <td>100 (43.9%–100%)</td> <td>100 (78.5%–100%)</td> </tr> <tr> <td>CTX-M</td> <td>100 (56.6%–100%)</td> <td>100 (89.6%–100%)</td> </tr> </tbody> </table>	Organism	Sensitivity (95% confidence intervals)	Specificity (95% confidence intervals)	<i>Staphylococcus aureus</i>	93.3 (86.9%–96.7%)	98.5 (97.7%–99.0%)	<i>Streptococcus</i> species	86.4 (73.3%–93.6%)	99.2 (98.6%–99.5%)	<i>Streptococcus agalactiae</i>	90.9 (62.3%–98.4%)	99.9 (99.6%–100%)	<i>Streptococcus pyogenes</i>	91.7 (64.6%–98.5%)	100 (99.7%–100%)	Antimicrobial resistance gene	Sensitivity (95% confidence intervals)	Specificity (95% confidence intervals)	<i>mecA/C and MREJ</i> (MRSA)	100 (83.2%–100%)	95.7 (89.6%–98.3%)	vanA/B	100 (43.9%–100%)	100 (78.5%–100%)	CTX-M	100 (56.6%–100%)	100 (89.6%–100%)
Organism	Sensitivity (95% confidence intervals)	Specificity (95% confidence intervals)																										
<i>Staphylococcus aureus</i>	93.3 (86.9%–96.7%)	98.5 (97.7%–99.0%)																										
<i>Streptococcus</i> species	86.4 (73.3%–93.6%)	99.2 (98.6%–99.5%)																										
<i>Streptococcus agalactiae</i>	90.9 (62.3%–98.4%)	99.9 (99.6%–100%)																										
<i>Streptococcus pyogenes</i>	91.7 (64.6%–98.5%)	100 (99.7%–100%)																										
Antimicrobial resistance gene	Sensitivity (95% confidence intervals)	Specificity (95% confidence intervals)																										
<i>mecA/C and MREJ</i> (MRSA)	100 (83.2%–100%)	95.7 (89.6%–98.3%)																										
vanA/B	100 (43.9%–100%)	100 (78.5%–100%)																										
CTX-M	100 (56.6%–100%)	100 (89.6%–100%)																										



For full performance of all the analytes, the following table is abstracted from the reference.

Analyte	Sensitivity			TN/(TN + FP)
	TP/(TP + FN)	%	95% CI	
Gram-positive bacteria				
<i>Anaerococcus prevotii/vaginalis</i>	1/1	100	–	1543/1543
<i>Clostridium perfringens</i>	0/0	–	–	1544/1544
<i>Cutibacterium avidum/granulosum</i>	0/0	–	–	1544/1544
<i>Enterococcus faecalis</i>	10/10	100	72.2%–100%	1529/1534
<i>Enterococcus faecium</i>	1/1	100	–	1541/1543
<i>Finegoldia magna</i>	3/3	100	43.9%–100%	1540/1541
<i>Parvimonas micra</i>	0/1	0	–	1543/1543
<i>Peptoniphilus</i>	1/1	100	–	1542/1543
<i>Peptostreptococcus anaerobius</i>	0/0	–	–	1541/1544
<i>Staphylococcus aureus</i>	98/105	93.3	86.9%–96.7%	1417/1439
<i>Staphylococcus lugdunensis</i>	2/2	100	34.2%–100%	1539/1542
<i>Streptococcus</i> spp.	38/44	86.4	73.3%–93.6%	1488/1500
<i>Streptococcus agalactiae</i>	10/11	90.9	62.3%–98.4%	1532/1533
<i>Streptococcus pneumoniae</i>	3/3	100	43.9%–100%	1541/1541
<i>Streptococcus pyogenes</i>	11/12	91.7	64.6%–98.5%	1532/1532
Gram-negative bacteria				
<i>Bacteroides fragilis</i>	0/0	–	–	1543/1544
<i>Citrobacter</i>	2/2	100	34.2%–100%	1542/1542
<i>Enterobacter cloacae</i> complex	2/4	50.0	15.0%–85.0%	1538/1540
<i>Escherichia coli</i>	14/14	100	78.5%–100%	1529/1530
<i>Haemophilus influenzae</i>	1/1	100	–	1542/1543
<i>Kingella kingae</i>	1/1	100	–	1537/1543
<i>Klebsiella aerogenes</i>	0/0	–	–	1544/1544
<i>Klebsiella pneumoniae</i> group	4/5	80.0	37.6%–96.4%	1538/1539
<i>Morganella morganii</i>	1/1	100	–	1541/1543
<i>Neisseria gonorrhoeae</i>	2/2	100	34.2%–100%	1539/1542
<i>Proteus</i> spp.	4/4	100	51.0%–100%	1536/1540
<i>Pseudomonas aeruginosa</i>	2/2	100	34.2%–100%	1539/1542
<i>Salmonella</i> spp.	0/0	–	–	1544/1544
<i>Serratia marcescens</i>	2/2	100	34.2%–100%	1541/1542
Yeast				
<i>Candida</i>	4/7	57.1	25.0%–84.2%	1536/1537
<i>Candida albicans</i>	3/5	60.0	23.1%–88.2%	1539/1539

REFERENCE

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 performance of the test may be affected by inappropriate sample collection, handling and transportation.

Bacterial and yeast nucleic acids may persist in vivo independent of organism viability. Detection of organism nucleic acid does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.

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.