



Clinical Impact of the BIOFIRE® Joint Infection (JI) Panel



PIONEERING DIAGNOSTICS

What's the Problem?

Joint infections cause a tremendous burden for patients and society.^{1,2}

Septic arthritis is a medical emergency requiring prompt diagnosis and treatment.

Delayed diagnosis is associated with permanent disability and increased mortality, which can be as high as 15%.³

Prosthetic joint infections (PJIs) are costly to treat and on the rise.⁴

The cost to treat a PJI is 3 to 6 times more expensive than the initial arthroplasty.⁴ When missed or undertreated, PJIs can lead to unnecessary surgical revisions causing poor function or disability, considerably impacting quality of life.⁵

Diagnosis of Joint Infections is Complicated

- Joint infection diagnostics lack standardization of specimen type and preparation, test media, and methods.⁴
- Culture negative PJIs occur in up to 35% of infections.⁶
- Joint infections are associated with difficult fastidious organisms, anaerobes, biofilm-forming organisms, and polymicrobial specimens.⁴
- Complex society-developed diagnostic criteria vary considerably in diagnostic agreement.⁶

The Right Test, The First Time

BIOFIRE's syndromic approach combines several potential targets into one rapid test, helping clinicians identify pathogens that produce non-specific symptoms like red, hot, swollen joint(s) in a clinically actionable timeframe.

Faster Than Traditional Methods

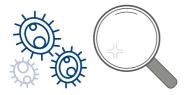
Traditional methods require multiple tests and can take up to two weeks to provide a pathogen identification result. The BIOFIRE[®] Joint Infection (JI) Panel identifies target pathogens in about an hour using a single test.

Syndromic Testing



Improved Diagnostic Yield

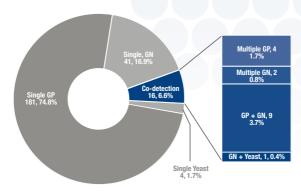
In prospective clinical trials, the BIOFIRE JI Panel detected an additional 76 confirmed organisms missed by routine culture. The BIOFIRE JI Panel detects fastidious organisms and difficult-to-grow anaerobes.⁷



Detected an additional 76 confirmed organisms missed by routine culture⁷

Polymicrobial Detections

The BIOFIRE JI Panel prospective clinical trial demonstrated polymicrobial detections. Of the 242 positive specimens detected by the BIOFIRE JI Panel, 16 involved co-detections.⁷



Demonstrated polymicrobial detections

Pathogen Guided Patient Management

Pathogen identification is a central component of septic arthritis and PJI treatment guidelines. The BIOFIRE JI Panel may aid in appropriate surgical decision making and reduce time to effective therapy through rapid pathogen identification.⁸⁻¹¹



May aid in clinical decision making

BIOFIRE® Joint Infection Panel Targets

GRAM-POSITIVE BACTERIA

Anaerococcus prevotii/vaginalis Clostridium perfringens Cutibacterium avidum/granulosum Enterococcus faecalis Enterococcus faecium Finegoldia magna Parvimonas micra Peptoniphilus Peptostreptococcus anaerobius Staphylococcus aureus Staphylococcus lugdunensis Streptococcus spp. Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes

GRAM-NEGATIVE BACTERIA

Bacteroides fragilis Citrobacter Enterobacter cloacae complex Escherichia coli Haemophilus influenzae Kingella kingae Klebsiella pneumoniae group Morganella morganii Neisseria gonorrhoeae Proteus spp. Pseudomonas aeruginosa Salmonella spp. Serratia marcescens

Sample Requirements

0.2mL of synovial fluid

Overall Performance

- 91.7% Sensitivity¹²
- 99.8% Specificity¹²

YEAST

Candida spp. Candida albicans

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases IMP KPC NDM OXA-48-like VIM

ESBL CTX-M

Methicillin Resistance mecA/C and MRF L

Vancomycin Resistance vanA/B



FDA-cleared | C €2797



References

- 1. Kurtz SM. J Arthroplasty. 2012 27:61-65.e61. doi:10.1016/j.arth.2012.02.022 dfd
- 2. Singh JA, Yu S, PLoS One. 2017; 12(8): e0182577.
- 3. Carpenter CR, et al. Acad Emerg Med. 2011 Aug; 18(8): 781-796.
- 4. Tande JT, Patel R, Clin Microbiol Rev. 2014 Apr; 27(2): 302–345.
- 5. Zimmerli W, Trampuz A, Ochsner PE, N Engl J Med. 2004 Oct 14; 351(16):1645-54.
- Parvizi J, J Arthroplasty. 2018 May;33(5):1309-131. doi: 10.1016/j.arth.2018.02.078. Epub 2018 Feb 26.4.e2.
- Graue C, et al. Evaluation of the BIOFIRE® Bone and Joint Infection (BJI) Panel for the Detection of Microorganisms and Antimicrobial Resistance Genes in Synovial Fluid Specimens. IDWeek 2020; Virtual.
- McNally M, et al. Bone Joint J. 2021 Jan;103-B(1):18-25. doi: 10.1302/ 0301-620X.103B1.BJJ-2020-1381.R1, PMID: 33380199; PMCID: PMC7954183.
- 9. Bauer TW, Bedair H, Creech JD et al, J Arthroplasty. 2019 34:S351–S359.
- Parvizi J, Tan TL, Goswami K, et al. J Arthroplasty. 2018; 33(5):1309-1314.e2. doi:10.1016/j.arth.2018.02.07
- 11. Osmon DR, Berbari EF, Berendt AR et al, Clin Infect Dis. 2013 56:e1-e25.
- 12. Overall performance based on prospective clinical study for the BIOFIRE® Joint Infection Panel, data on file, BIOFIRE Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.

Contact Us

bioMérieux S.A. 69280 Marcy l'Etoile France Tel.: +33 (0) 4 78 87 20 00 Fax: +33 (0) 4 78 87 20 90 biomerieux.com Manufactured by: BIOFIRE Diagnostics, LLC 515 Colorow Drive Salt Lake City, UT 84108 USA biofiredx.com

PIONEERING DIAGNOSTICS