


**MICROGEN DIAGNOSTICS**

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<b>PATIENT</b>		<b>SPECIMEN</b>	LT KNEE	<b>PHYSICIAN</b>	
<b>DOB</b>		<b>RECEIVED</b>		<b>PHONE</b>	
<b>PATIENT ID</b>		<b>COMPLETED</b>		<b>FAX</b>	
<b>GENDER</b>		<b>ACCESSION</b>		<b>COLLECTED</b>	

**SUMMARY OF RESULTS**

BIOMARKER RESULTS	
MARKER	RAW VALUE
Synovial CRP	5.18 mg/L
Synovial WBC	13752 cells/uL
Synovial PMN	94.9 % PMN
NGS RESULTS	
POSITIVE	

RISK FOR INFECTION*	
<b>HIGH PROBABILITY OF INFECTION</b>	Based on the information provided, the sample has a high probability for infection. While further work-up in keeping with the criteria listed in Figure 1 are needed, the organism(s) isolated by NGS most likely represent pathogen(s).

\*Risk calculated from 2018 ICM definition with positive NGS results as proxy for a single positive culture. NGS is not part of the ICM definition.

CUTOFF	ICM 2018 SCORE ATTRIBUTED
Chronic PJI threshold = >4.2 mg/L CRP	1 point
Chronic PJI threshold = >2,000 cells/uL WBC	3 points
Chronic threshold = >70% PMN	2 points

<b>BACTERIAL LOAD(16S)</b>	10 <sup>5</sup> -10 <sup>7</sup>
<b>SUMMARY OF MULTIPLEX PCR RESULTS (LEVEL 1)</b>	
<b>BACTERIA:</b>	
Cutibacterium acnes	1.63 x 10 <sup>9</sup>
<b>FUNGI:</b>	
None	
<b>SUMMARY OF NGS PATHOGEN IDENTIFICATION (LEVEL 2)</b>	
<b>BACTERIA:</b>	
Escherichia coli	75%
Enterococcus faecalis	24%
Cutibacterium acnes	1%
<b>FUNGI:</b>	
None	
<b>RESISTANCE GENES DETECTED</b>	
None	

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### RESULT DETAIL

**Figure 1.** 2018 ICM Definition

MAJOR CRITERIA (AT LEAST ONE OF THE FOLLOWING)	DECISION
Two positive cultures of the same organism	Infected
Sinus tract with evidence of communication to the joint or visualization of the prosthesis	

PREOPERATIVE DIAGNOSIS	MINOR CRITERIA		POSSIBLE SCORE	PATIENT SCORE	DECISION
	Serum	Elevated CRP or D-Dimer	2		
	Elevated ESR	1			
Synovial	Elevated synovial WBC count or LE	3	3		
	Positive alpha defensin	3			
	Elevated synovial PMN (%)	2	2		
	Elevated synovial CRP	1	1		

INTRAOPERATIVE DIAGNOSIS	INCONCLUSIVE PRE-OP SCORE or DRY TAP		POSSIBLE SCORE	PATIENT SCORE	DECISION
		Preoperative Score	-		≥6 Infected  4-5 Inconclusive  ≤3 Not Infected
	Positive Histology	3			
	Positive Purulence	3			
	Single Positive Culture	2			
	Positive NGS *	2	2		

<b>CUMULATIVE PATIENT SCORE</b>	<b>8</b>	<b>INFECTED</b>
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The above table was developed at the 2018 International Consensus Meeting. Bolded tests are included in the MicroGenDX OrthoKey and can contribute up to 8 points to the patients cumulative score satisfying the criteria for evidence-based diagnosis of PJI. As these criteria were not designed to include molecular methods such as quantitative PCR and/or Next-Generation Sequencing, these tests have been included in the MicroGenDX OrthoKey and contribute the same diagnostic points as a single positive culture in the criteria.

qPCR TESTS FOR BACTERIA			FUNGI	STIs	RESISTANCE GENES		
Enterococcus faecalis	Klebsiella pneumoniae	Streptococcus agalactiae	Candida albicans	None	Vancomycin	Methicillin	
Streptococcus pyogenes	Enterococcus faecium	Pseudomonas aeruginosa			Extended-Spectrum Beta-Lactamase	Beta-lactam	
Staphylococcus aureus	Cutibacterium acnes				Aminoglycoside	Tetracycline	
					Carbapenem	Macrolide	
					Quinolone	Bactrim	

DISCLAIMER: (i) This test was developed and performance characteristics have been determined by Southwest Regional PCR Laboratory dba MicroGen DX. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA), however, the FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Its use should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing. (ii) A negative result does not rule out the presence of PCR inhibitors, or DNA extraction inhibitors such as lidocaine, in patients' specimens or microbial DNA concentrations below the level of detection of the assay. (iii) This test is performed pursuant to an agreement with Roche Molecular Systems, Inc. (iv) Relative quantitation of swabs refers to analyte load levels of  $< 10^5$ ,  $10^5$  to  $10^7$ , and  $> 10^7$  for low, medium and high respectively. Southwest Regional PCR Laboratory dba MicroGen DX licenses are CLIA 45D1086390 and CAP 7214171.



To help you better interpret the enclosed results of Next Generation Sequencing, please visit <https://icmphilly.com/ortho-applications/>

