CD Laboratories®
Confidence in Diagnostics
810 Gleneagles Court, Suite 100
Baltimore, Maryland 21286
Office: 410-296-1400 | Fax: 410-296-1403
Laboratory Director: Paul Endres, M.D.

FINAL

Patient:	**TEST, PATIENT**			**Accession #:**	**1657049**
Provider:	PROVIDER , UNSPECIFIED	Birth:	1/1/1955		
		Age:	69 years	Collection Date:	2/27/2024
		Gender:	Male	Received Date:	2/27/2024 1:31 PM
Organization:	CD LABORATORIES				
				Specimen Site	Left Knee

Test Name	Result	Units	Flag	Clinical Decision Limits
SYNOVASURE® PJI				*Run by SG on 2/27/2024 1:34:34 PM*
SYNOVASURE® ALPHA DEFENSIN PJI	POSITIVE		**ABNORMAL**	
SYNOVIAL FLUID C-REACTIVE PROTEIN (CRP)				*Run by SG on 2/27/2024 1:34:09 PM*
CRP-SF	5.6	mg/L	**HIGH**	> 4.45
CELL COUNT/DIFF, SYNOVIAL FLUID				*Run by SG on 2/27/2024 1:34:54 PM*
RED BLOOD CELL COUNT	4000	/uL		
TOTAL NUCLEATED CELL COUNT	4567	/uL	**HIGH**	
NEUTROPHILS	85.0	%	**HIGH**	
MONONUCLEAR CELLS	15.0	%		

Clinical Decision Limit: Total nucleated cells: > 3000 cells/µL or Neutrophils: > 80%
Based on Musculoskeletal Infection Society (MSIS) recommended criteria for PJI

CRYSTAL ID, SYNOVIAL FLUID				*Run by SG on 2/27/2024 1:35:28 PM*
CRYSTAL ID, SYNOVIAL FLUID	NO CRYSTALS FOUND			
SYNOVASURE MICROBIAL ID PANEL				*Run by SG on 2/27/2024 1:35:42 PM*
P. ACNES	NEGATIVE			
STAPHYLOCOCCUS PANEL	POSITIVE		**ABNORMAL**	
CANDIDA PANEL	NEGATIVE			
ENTEROCOCCUS PANEL	NEGATIVE			

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				Specimen Site	Left Knee

Test Name	Result	Units	Flag
CULTURE, FLUID			*Run by SG on 2/27/2024 1:30:38 PM*
Site	Left Knee		
Organism:	**Staphylococcus epidermidis**		
Growth	In Aerobic and Anaerobic Bottle		
Sensitivities	Staphylococcus epidermidis		
Ciprofloxacin	R, >=8		
Clindamycin	S, <=0.12		
Erythromycin	S, <=0.25		
Gentamicin	S, <=0.5		
Levofloxacin	R, >=8		
Linezolid	S, 2		
Nitrofurantoin	S, <=16		
Oxacillin MIC	S, <=0.25		
Rifampicin	S, <=0.5		
Tetracycline	S, 2		
Tigecycline	S, <=0.12		
Vancomycin	S, 1		

S = Susceptible R = Resistant I=Intermediate

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				Specimen Site	Left Knee

Synovasure® Periprosthetic Joint Infection (PJI) Comprehensive Lab Panel consists of laboratory tests intended for clinical use to aid in the diagnosis of periprosthetic joint infection in synovial fluid (SF) of patients experiencing pain and/or inflammation after total joint arthroplasty. Test performance for joints other than the knee and hip joint, or in joints with spacers or partial joint replacements, has not been established. Test results are intended to be used in conjunction with other diagnostic information, such as patient's clinical history and imaging techniques. Results do not preclude an alternative diagnosis.

The laboratory-developed tests (LDTs) used in this panel were developed and their performance characteristics were determined by CD Laboratories. CD Laboratories is certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing. The LDT tests comprising this panel have not been reviewed by the U.S. Food and Drug Administration.

For Technical Assistance regarding the Synovasure® PJI Comprehensive Lab Panel, call 1-888-981-8378.

SYNOVASURE® PJI LABORATORY DEVELOPED TESTS – DESCRIPTION AND INTERPRETATION	
Test	**Description**
Specimen Integrity	The accuracy of synovial fluid diagnostics tests can be significantly impacted by the quality of the specimen that is submitted for evaluation. As part of specimen analysis, specimen integrity tests are performed. Clinicians are notified when a suboptimal specimen has been submitted, and the test results should be interpreted with caution. The specimen integrity tests assess: • Absorbance at 280 nm (A280) – Specimens that fall outside the normal range for synovial fluid may be diluted by saline or contrast agents • Red Blood Cell Count – Specimens that have elevated levels of RBCs may be diluted by blood
Synovial Fluid CRP	Synovial Fluid CRP has been demonstrated to be comparable to serum CRP for the detection of PJI. The Synovasure PJI LDT diagnostic algorithm utilizes CRP results in conjunction with other biomarkers to aid in the diagnosis of PJI. A CRP cut-off of 4.45 mg/L is recommended.
Synovasure Alpha Defensin ELISA	Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection. The Synovasure Alpha Defensin (AD) ELISA is a qualitative in vitro test developed to detect human alpha defensins 1-3 in the synovial fluid of a person with a suspected joint infection. This test is covered by U.S. patent 7598080. The results are intended to be used in conjunction with other clinical and diagnostic findings to aid in the diagnosis of infection.
Synovasure Microbial ID Panel	The Synovasure Microbial Identification (MID) Test is a qualitative in vitro diagnostic test intended for the early detection of microbial antigen in synovial fluid. The test measures antigens from Staphylococcus sp., Candida sp., Enterococcus sp. and Cutibacterium acnes (formerly called P. acnes) in the synovial fluid. The results are intended to be used as an adjunct to synovial fluid culture and to detect the presence of an organism in culture negative samples.