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, ATHENA**			**Accession #:**	**1702377**
Provider:	PROVIDER , UNSPECIFIED	Birth:	1/1/1950		
		Age:	75 years	Collection Date:	3/19/2025
		Gender:	Male	Received Date:	3/19/2025 12:18 PM
Organization:	CD LABORATORIES				
				Specimen Site	Left Knee

SynTuition™ Score (1.0.0-RC.7): 86

<20: Low Probability of Infection
20-80: Equivocal sample
>80: High Probability of Infection

Specimen Integrity: PASS

PASS: Specimen optimal for interpretation
FAIL: Interpret results with caution
(see last page for explanation)

Culture*: POSITIVE

Please see below for full culture results

Synovasure® Comprehensive PJI Panel – Individual tests used to determine SynTuition™ Score (1.0.0-RC.7)

Test Name	Result	Units	Flag	Clinical Decision Limit
SYNOVASURE® ALPHA DEFENSIN	NEGATIVE			
SYNOVIAL FLUID C-REACTIVE PROTEIN (CRP)	8.7	mg/L	**HIGH**	> 4.45
CELL COUNT/DIFF, SYNOVIAL FLUID				*Run by MTC on 3/19/2025 12:20:13 PM*
RED BLOOD CELL COUNT	827000	/uL		
TOTAL NUCLEATED CELL COUNT	7692	/uL	**HIGH**	> 3000
NEUTROPHILS	73.4	%		
MONONUCLEAR CELLS	26.6	%		
`Clinical Decision Limit: Total nucleated cells: > 3000 cells/µL or Neutrophils: > 80%`				
`Based on Musculoskeletal Infection Society (MSIS) recommended criteria for PJI`				
SYNOVASURE MICROBIAL ID PANEL				*Run by MTC on 3/19/2025 12:23:47 PM*
P. ACNES	NEGATIVE			
STAPHYLOCOCCUS PANEL	NEGATIVE			
CANDIDA PANEL	POSITIVE		**ABNORMAL**	
ENTEROCOCCUS PANEL	NEGATIVE			

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				Specimen Site	Left Knee

Additional Tests*

CRYSTAL ID, SYNOVIAL FLUID	NO CRYSTALS FOUND	
CULTURE, FLUID		*Run by SG on 3/19/2025 1:16:59 PM*
Site	Left Knee	
Organism:	**Staphylococcus aureus**	
Growth	In Aerobic and Anaerobic Bottle	

Sensitivities	Staphylococcus aureus
Ciprofloxacin	S, <=0.5
Clindamycin	S, 0.25
Erythromycin	S, <=0.25
Gentamicin	S, <=0.5
Levofloxacin	S, <=0.12
Linezolid	S, 2
Moxifloxacin	S, <=0.25
Nitrofurantoin	S, <=16
Oxacillin MIC	S, <=0.25
Rifampicin	S, <=0.5
Tetracycline	S, <=1
Tigecycline	S, <=0.12
Trimethoprim/Sulfamethox	S, <=10
Vancomycin	S, 1
Daptomycin	S, 0.25
Doxycycline	S, <=0.5

S = Susceptible R = Resistant I=Intermediate

* Test results are not included in the generation of the SynTuition™ Score

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				Specimen Site	Left Knee

The Synovasure® Comprehensive PJI Panel with SynTuition™ consists of a panel 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 results are combined into a validated, machine-learning algorithm to generate the SynTuition™ Score. Test performance 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 SynTuition™ Score is available in the United States only as a laboratory-developed test (LDT) performed in conjunction with the Synovasure® Comprehensive PJI Panel. The 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® Comprehensive PJI Lab Panel with SynTuition™, call 1-888-981-8378.

SynTuition™ Score Description and Interpretation
The SynTuition™ Score is a confidence score for PJI diagnosis generated using a proprietary, validated machine-learning algorithm. The results for the Synovasure® Alpha Defensin ELISA, Synovial C-Reactive Protein (CRP), White Blood Cell (WBC) Count with differential, and Synovasure® Microbial Identification tests are combined into the algorithmic software for score generation. The SynTuition™ Score is presented alongside the individual test results for a complete representation of the test results. Additional information is provided regarding the specific biomarkers that contributed to the final score. The SynTuition™ Score should be interpreted as the percent probability that the specific specimen is infected based on the clinical laboratory testing with the Synovasure® Comprehensive PJI Panel.

Individual Test Descriptions and Interpretation	
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
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
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 the diagnosis of PJI. A CRP cut-off of 4.45 mg/L is recommended
WBC Count w/ Differential	Automated cell counts are performed to determine the total cell count and percentage of cells that are neutrophils or mononuclear cells. A clinical decision limit of >3,000 cells/uL or Neutrophils > 70% is utilized based on 2018 International Consensus Meeting (ICM) recommended criteria for PJI. All cell counts > 3,000 are confirmed with a manual count.
Synovasure® Microbial Identification	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.