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 CASE 1, PATIENT**			**Accession #:**	**1766625**
Provider:	PROVIDER , UNSPECIFIED	Birth:	1/1/1950		
		Age:	76 years	Collection Date:	8/23/2026
		Gender:	Male	Received Date:	8/23/2026 9:28 AM
Organization:	CD LABORATORIES				
				Specimen Site	Right Knee

SynTuition® Score (v1.1.0-RC.1): 85	<20: Low Probability of Infection 20-80: Equivocal sample >80: High Probability of Infection
Run on 8/23/2026 9:48:00 AM **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 (v1.1.0-RC.1)

Test Name	Result	Units	Flag	Clinical Decision Limit
SYNOVASURE® ALPHA DEFENSIN	NEGATIVE			
Run by MTC on 8/23/2026 9:46:23 AM				
SYNOVIAL FLUID C-REACTIVE PROTEIN (CRP)	18.1	mg/L	**HIGH**	> 4.45
Run by MTC on 8/23/2026 9:45:52 AM				
CELL COUNT/DIFF, SYNOVIAL FLUID				
Run by MTC on 8/23/2026 9:44:32 AM				
RED BLOOD CELL COUNT	19000	/uL		
TOTAL NUCLEATED CELL COUNT	5000	/uL	**HIGH**	> 3000
NEUTROPHILS	56.0	%		> 70
MONONUCLEAR CELLS	44.0	%		

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 CASE 1, PATIENT**			**Accession #:**	**1766625**
Provider:	PROVIDER , UNSPECIFIED	Birth:	1/1/1950		
		Age:	76 years	Collection Date:	8/23/2026
		Gender:	Male	Received Date:	8/23/2026 9:28 AM
Organization:	CD LABORATORIES				
				Specimen Site	Right Knee

Additional Tests*

CRYSTAL ID, SYNOVIAL FLUID — NO CRYSTALS FOUND

Run by MTC on 8/23/2026 9:46:58 AM

CULTURE, FLUID

Run by MF on 8/24/2026 9:35:40 AM

Site	Right Knee
Organism:	**Staphylococcus epidermidis**
Growth	In Aerobic and Anaerobic Bottle

Sensitivities	Staphylococcus epidermidis
Ciprofloxacin	S, <=0.5
Clindamycin	S, 0.5
Erythromycin	S, <=0.25
Gentamicin	S, <=0.5
Levofloxacin	S, <=0.12
Linezolid	S, 1
Nitrofurantoin	S, <=16
Oxacillin MIC	R, >=4
Rifampicin	S, <=0.5
Tetracycline	S, <=1
Tigecycline	S, <=0.12
Vancomycin	S, 1

S = Susceptible R = Resistant I=Intermediate

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

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 CASE 1, PATIENT**			**Accession #:**	**1766625**
Provider:	PROVIDER , UNSPECIFIED	Birth:	1/1/1950		
		Age:	76 years	Collection Date:	8/23/2026
		Gender:	Male	Received Date:	8/23/2026 9:28 AM
Organization:	CD LABORATORIES				
				Specimen Site	Right 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), and White Blood Cell (WBC) Count with differential 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. A CRP cut-off of 4.45 mg/L was validated for use at CD Laboratories.
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.