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 COPY

Patient: **TEST, PATIENT**
Provider: PROVIDER , UNSPECIFIED
Home Phone: (888)555-6666

Birth: 1/1/1955
Age: 65 years
Gender: Male

Accession #: **1508711**
Collection Date: 8/3/2020
Received in Lab: 8/3/2020 2:40 PM

Organization: CD LABORATORIES

Specimen Site Left Knee

Test Name	Result	Units	Flag	Clinical Decision Limits
SYNOVASURE® PJI				*Run by: SG on 8/3/2020 2:46 PM*
SYNOVASURE® ALPHA DEFENSIN PJI	POSITIVE		ABNORMAL	
ALPHA-DEFENSINS-SF	POSITIVE			
CRP-SF	12.5	mg/L	HIGH	>= 3
CELL COUNT/DIFF, SYNOVIAL FLUID				*Run by: SG on 8/3/2020 2:42 PM*
RED BLOOD CELL COUNT	234000	/uL		
TOTAL NUCLEATED CELL COUNT	23450	/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

SYNOVASURE® NEUTROPHIL ELASTASE				*Run by: SG on 8/3/2020 2:43 PM*
SYNOVASURE® NEUTROPHIL ELASTASE	POSITIVE		ABNORMAL	
SYNOVASURE® MICROBIAL ID PANEL				*Run by: SG on 8/3/2020 2:43 PM*
P. ACNES	NEGATIVE			
STAPHYLOCOCCUS PANEL	POSITIVE		ABNORMAL	
CANDIDA PANEL	NEGATIVE			
ENTEROCOCCUS PANEL	NEGATIVE			
FLUID CULTURE SCREEN				*Run by: SG on 8/3/2020 2:44 PM*
AEROBIC CULTURE RESULTS	No growth			
INCUBATION TIME	7	Days		
ANAEROBIC CULTURE RESULTS	No growth			
INCUBATION TIME	7	Days		

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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 Alpha Defensin results for the final result determination. A CRP cut-off of 3 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 Neutrophil Elastase ELISA	The Synovasure Neutrophil Elastase (NE) ELISA is a qualitative in vitro test that measures neutrophil elastase in synovial fluid. The results are intended to be used as a proxy for neutrophil detection in synovial fluid.
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.