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.

Patient:	TEST, PATIENT			Acc #:	1175296
Provider:	PROVIDER	Birth:	1/1/1955	Specimen Site:	Right Knee
Phone:	(888)555-5555	Age:	63 years	Collection Date:	9/20/2018
		Gender:	Male	Received in Lab:	9/20/2018 7:21 AM
Organization:	CD LABORATORIES			Specimen:	Synovial Fluid

SYNOVASURE® DIFFERENTIAL DIAGNOSIS ARTHRITIS PANEL

Test Name	Result	Units	Flag	Clinical Decision Limits
SYNOVASURE® OSTEOARTHRITIS (OA)	**POSITIVE**		**ABNORMAL**	*Run by: SG on 9/20/2018 7:29 AM*
COMP, SYNOVIAL FLUID	8652	ng/mL	**HIGH**	> 1500
IL-8, SYNOVIAL FLUID	309	pg/mL		
COMP/IL-8*	28.0	ng/pg	**HIGH**	> 4.3
COMP/IL-8 ratio is calculated only when COMP>1500 ng/mL				
SYNOVASURE® RHEUMATOID ARTHRITIS (RA)				*Run by: SG on 9/20/2018 7:29 AM*
ANTI-CCP, SYNOVIAL FLUID	POSITIVE		**ABNORMAL**	
RHEUMATOID FACTOR, SYNOVIAL FLUID	15	IU/mL	**HIGH**	≥ 10
SYNOVASURE® CRYSTALLINE ARTHRITIS	**POSITIVE**		**ABNORMAL**	*Run by: SG on 9/20/2018 7:30 AM*
CRYSTAL ID, SYNOVIAL FLUID POSITIVE FOR INTRACELLULAR AND EXTRACELLULAR MSU CRYSTALS			**ABNORMAL**	
SYNOVASURE® NATIVE SEPTIC ARTHRITIS (NSA)	**POSITIVE**		**ABNORMAL**	
CELL COUNT/DIFF, SYNOVIAL FLUID				*Run by: SG on 9/20/2018 7:29 AM*
RED BLOOD CELL COUNT	1200000	/µL	**HIGH**	> 1000000
TOTAL NUCLEATED CELL COUNT	10770	/µL	**HIGH**	> 3000
NEUTROPHILS	89.4	%	**HIGH**	> 70
MONONUCLEAR CELLS	10.6	%		
SYNOVASURE® ALPHA DEFENSIN NSA*	**POSITIVE**		**ABNORMAL**	*Run by: SG on 9/20/2018 7:28 AM*
ALPHA-DEFENSINS-SF	POSITIVE		**ABNORMAL**	
LACTATE-SF	83	mg/dL	**HIGH**	≥ 70

Alpha Defensin NSA algorithm is tested and reported when Total Nucleated Cell Count or % Neutrophils is high

Notes: ***Specimen Integrity Flag: The RBC count of this specimen was high and represents a significant dilution of the sample with blood. Please interpret results with caution.***

INTENDED USE

Synovasure® Differential Diagnosis Arthritis Panel LDT is intended for use in further clarifying a differential diagnosis including osteoarthritis, rheumatoid arthritis, crystalline arthritis, and septic arthritis in synovial fluid of patients experiencing knee pain and/or inflammation. Test results are intended to be used in conjunction with other diagnostic information such as patient clinical history and imaging techniques.

Synovasure® Differential Diagnosis Arthritis Panel LDT is intended to determine whether there are abnormal levels of markers present in knee synovial fluid and to provide the physician with an objective result for the presence of biomarkers that may be indicative of a certain type of arthritis. Test performance for joints other than the knee joint has not been established.

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Synovasure® Differential Diagnosis Arthritis Panel LDT is intended for clinical use. It was developed by and its 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. Synovasure® Differential Diagnosis Arthritis Panel has not been reviewed by the U.S. Food and Drug Administration.

For technical assistance regarding the Synovasure® Differential Diagnosis Arthritis Panel call 1-888-981-8378.

SYNOVASURE® DIFFERENTIAL DIAGNOSIS ARTHRITIS PANEL- TEST DESCRIPTIONS
* Indicates Laboratory Developed Test (LDT)

Test	Description
Specimen Integrity A280* RBC Count*	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 (0.342-1.190) for synovial fluid may be diluted by saline or contaminated with contrast agents. • Red Blood Cell Count – Specimens that have elevated levels of RBCs >1,000,000 cells/µL may be diluted by blood.
Synovasure® Osteoarthritis (OA) COMP* IL-8*	The COMP ELISA and IL-8 ELISA are quantitative LDTs intended to detect cartilage oligomeric matrix protein (COMP) and interleukin-8 (IL-8), respectively, in the synovial fluid of patients experiencing knee joint pain or inflammation with suspected arthritis. Results are used in combination to provide clarification in diagnosing osteoarthritis. • COMP (-) (below 1500 ng/mL) suggests little to no evidence of cartilage damage • COMP (+) (above 1500 ng/mL) suggests cartilage damage • COMP/IL-8 ratio (+) (above 4.3 ng/pg) suggests isolated, idiopathic OA • COMP/IL-8 ratio (-) (below 4.3 ng/pg) suggests cartilage damage and elevated inflammatory status The values for COMP and IL-8 are assigned using purified recombinant proteins and internal analytical procedures and are not metrologically traceable to an international reference standard.
Synovasure® Rheumatoid Arthritis (RA) Anti-CCP* RF*	The qualitative Anti-CCP ELISA and quantitative immunoturbidimetric RF Latex are LDTs intended to detect anti-cyclic citrullinated peptide (anti-CCP) and rheumatoid factor (RF), respectively, in the synovial fluid of patients experiencing joint pain or inflammation with suspected arthritis. Results are used in combination to provide further clarification in diagnosing rheumatoid arthritis. **Negative results on the Anti-CCP ELISA and RF Latex should not be used to aid in the exclusion of RA from the differential diagnosis.**
Synovasure® Crystalline Arthritis	An assessment of synovial fluid using polarized light microscopy is performed for the presence of CPPD (calcium pyrophosphate dihydrate) and/or MSU (monosodium urate) crystals.
Synovasure® Native Septic Arthritis (NSA) Synovial Fluid WBC Count with Differential Synovasure® Alpha Defensin* Lactate*	Current International Consensus Meeting guidelines for periprosthetic joint infection recommend a cut-off of 3,000 cells/µL and/or a PMN% of 70%. The same criteria are used to establish the threshold for Synovasure® Alpha Defensin NSA reflex testing. All samples with counts >3,000 cells/µL are confirmed with a manual cell count. Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection. The Synovasure® Alpha Defensin (AD) ELISA is a qualitative LDT intended to detect human alpha defensins 1-3 in the synovial fluid of native joints. The quantitative lactate LDT is intended to measure lactate in synovial fluid of patients experiencing joint pain and/or inflammation. The results are used in conjunction to provide further clarification in diagnosing NSA. • Alpha Defensin (-) suggests no evidence of NSA, regardless of lactate result • Alpha Defensin (+), lactate (-) or below 70.0 mg/dL is indeterminate for NSA • Alpha Defensin (+), lactate (+) suggests NSA