CITRANO MEDICAL
LABORATORIES, INC.
810 Gleneagles Ct., Suite 100
Baltimore, Maryland 21286
(410) 296-1400 FAX: (410) 296-1403

REVISED

Patient: **TEST, PATIENT** **Acc #:** **475200**
Provider: PROVIDER , UNSPECIFIED Birth: 1/1/1955
Home Phone: (888)555-6666 Age: 60 years Collection Date: 7/15/2015
Gender: Male Received in Lab: 7/15/2015 8:30 AM
Organization: Citrano Medical Lab

Test Name	Result	Units	Flag	Ref. Range
				Run by: MAC on 7/15/2015 8:31 AM
SYNOVASURE® PJI	POSITIVE		**ABNORMAL**	
SPECIMEN SITE	LEFT KNEE			
ALPHA-DEFENSINS-SF	POSITIVE			
CRP-SF	4.0	mg/L		
HEMOGLOBIN-SF	NORMAL			

For technical assistance regarding the Synovasure® assay call 1-888-981-8378.

Synovasure® is a laboratory developed test (LDT) intended as an adjunct for the detection of infection in synovial fluid in patients experiencing pain and or inflammation in a joint. Synovasure® LDT utilizes a panel of tests that measure markers, including alpha-defensin, in the synovial fluid of joints that are infected. The alpha-defensin cutoff is adjusted for cell lysis using hemoglobin concentration. Synovasure® LDT results are intended to be used in conjunction with other clinical and diagnostic findings to aid in a patient's diagnosis of infection.

Synovasure® is intended to determine whether there is an infection present in synovial fluid. It is not intended to identify a specific type of infection or to establish the origin or severity of an infection. It is intended to provide the physician with a specific positive or negative result for the presence of biomarkers that are in synovial fluid as a result of the infection.

The Synovasure® LDT test is intended for clinical use. It was developed and its performance characteristics determined by Citrano Medical Laboratories. Citrano Medical Laboratories is certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing. Synovasure® has not been reviewed by the U.S. Food and Drug Administration. This test is covered by U.S. patent 7598080.

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Test Name	Result	Units	Flag	Ref. Range
[C] CELL COUNT/DIFF, SYNOVIAL				*Run by: MAC on 7/15/2015 8:30 AM*
TOTAL NUCLEATED CELL COUNT	20000	/uL	**HIGH**	<150
NEUTROPHILS	90.0	%	**HIGH**	<25.0
MONONUCLEAR CELLS	10.0	%		<75.0

*** Result was verified by manual cell count.

There have been a number of reported cutoffs for both PJI and Native Septic Arthritis (NSA) in the literature. The literature below can be referenced as guidance for the interpretation of your result.

Periprosthetic Joint Infection

The Musculoskeletal Infection Society (MSIS) currently recommends that any:
White cell count over 3000 cells/uL meets a minor criterion for PJI
Percent PMN over 80% meets a minor criterion for PJI

Native Septic Arthritis (NSA)

There is no fixed cutoff for NSA. A number of cutoffs (1700 - 100,000 cells/uL) have been reported with varying sensitivities and specificities. The commonly referenced cutoff of 50,000 white cell count/uL provides only 50% sensitivity for septic arthritis. Elevated white cell counts and %PMNs need to be interpreted along with all other clinical information available.

1) http://www.msis-na.org/international-consensus
2) Carpenter CR, Schuur JD, Everett WW, Pines JM. Acad Emerg Med. 2011Aug;18(8):781-96.

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HUMAN NEUTROPHIL ELASTASE	POSTIIVE	**ABNORMAL**

The Human Neutrophil Elastase (HNE) LDT was designed to be a replacement for the Leukocyte Elastase (LE) test strip which can serve as one of the criteria in the MSIS infection algorithm. The HNE LDT has been shown to outperform the LE test strip in internal studies. The HNE LDT is not prone to the high rate of invalid results that have been reported with the LE test strip. A positive HNE should be interpreted as meeting the MSIS criteria of a positive LE test strip.

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CRYSTAL ID, SYNOVIAL FLUID	NO CRYSTALS FOUND	NONE SEEN

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Test Name	Result	Units	Flag	Ref. Range
FLUID CULTURE SCREEN				**** Results still pending*
PRELIMINARY RESULTS:				**** Results still pending*
NO GROWTH TO DATE				