CD Laboratories’ Exclusive Comprehensive Infection Panels

CD Laboratories provides healthcare professionals with a simple and comprehensive diagnostic report typically within one business day. Six diagnostic tests are available and can be ordered based on patient need and surgeon preference.

Diagnostic Test Options:

1. Synovasure Alpha Defensin
   - Periprosthetic Joint Infection (PJI)
   - Native Septic Arthritis (NSA)

2. WBC Count w/ Differential

3. Synovasure Neutrophil Elastase

4. Crystal ID

5. Synovasure Microbial ID Panel

6. Synovial Fluid Culture with Antibiotic Susceptibility

The following diagnostic report is an annotated example to provide further explanation of results that can be expected from each test.
Patient: TEST, PATIENT
Provider: PROVIDER, UNSPECIFIED
Home Phone: (888) 555-6666
Organization: CD LABORATORIES

Address: 810 Glenalegus Court, Suite 100
Baltimore, Maryland 21286
Office: (888) 981-8378  |  Fax: (443) 279-2935

Acct#:

Birth: Age: 62 Years
Gender: Male
Collection Date: 3/8/2017
Received in Lab: 3/9/2017 1:05 PM

Run by: MAC on 3/9/2017 1:07 PM

**Test Name** | **Result** | **Units** | **Flag** | **Ref. Range**
--- | --- | --- | --- | ---
SYNOVASURE ALPHA DEFENSIN PJI | POSITIVE |  |  |  
SPECIMEN SITE | LEFT KNEE |  |  |  
ALPHA DEFENSIN-SF | POSITIVE |  |  |  
CRP-SF | >60 | mg/L | ABNORMAL |  
HEMOGLOBIN-SF | NORMAL |  |  |  

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

**Synovasure® Alpha Defensin** 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® Alpha Defensin 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® Alpha Defensin LDT results are intended to be used in conjunction with other clinical and diagnostic findings to aid in a patient’s diagnosis of infection.

Native Septic Arthritis (NSA) Reported Test uses a dual analyte algorithm that combines alpha defensin and lactate. Reported as Positive, Negative, or Indeterminate. Result is 96% Sensitive and 90% Specific.³

**Test Name** | **Result** | **Units** | **Run by:**
--- | --- | --- | ---
SYNOVASURE ALPHA DEFENSIN NSA | POSITIVE |  | ~LD on 11/8/2017 1:09 PM
SPECIMEN SITE | LEFT KNEE |  |  
ALPHA DEFENSIN-SF | POSITIVE |  |  
HEMOGLOBIN-SF | NORMAL |  |  
LACTATE - SF | >60 | mg/L |  

CRP < 3 mg/L combined with positive alpha defensin triggers potential metallosis warning in prosthetic joint samples. Approximately 10% of PJs are CRP negative.²

Hemoglobin is measured as a proxy for cell lysis to adjust results from blood contamination. The Indeterminate range is expanded to adjust for potential white cells present from blood contamination.

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

**Synovasure® Alpha Defensin NSA** 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® Alpha Defensin NSA LDT utilizes a panel of tests that measure markers, including alpha-defensin and lactate, in the synovial fluid of joints that are infected. The alpha-defensin cutoff is adjusted for cell lysis using hemoglobin concentration. Synovasure® Alpha Defensin LDT results are intended to be used in conjunction with other clinical and diagnostic findings to aid in a patient’s diagnosis of infection.

1. Usually reported within 1 business day.
2. Reported as Positive, Negative, or Indeterminate. Result is 97% sensitive and 96% specific for PJI vs MSIS.¹
3. For technical assistance regarding the Synovasure® Alpha Defensin assay call 1-888-981-8378.
<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
<th>Units</th>
<th>Flag</th>
<th>Ref. Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>CELL COUNT/DIFF, SYNOVIAL</td>
<td>241000</td>
<td>/uL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RED BLOOD CELL COUNT, FLUID</td>
<td>206000</td>
<td>/uL</td>
<td>HIGH</td>
<td>&lt;150</td>
</tr>
<tr>
<td>TOTAL NUCLEATED CELL COUNT</td>
<td>87.9</td>
<td>%</td>
<td>HIGH</td>
<td>&lt;25.0</td>
</tr>
<tr>
<td>NEUTROPHILS</td>
<td>12.1</td>
<td>%</td>
<td></td>
<td>&lt;75.0</td>
</tr>
<tr>
<td>MONONUCLEAR CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

***Result was verified by manual cell count.

There have been a number of reported cutoffs for Periprosthetic Joint Infection (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](http://www.msis-na.org/international-consensus)

**Synovasure® Neutrophil Elastase**

The Synovasure® Neutrophil Elastase (NE) LDT was designed to be a replacement for the Leukocyte Esterase (LE) test strip which can serve as one of the criteria in the MSIS infection algorithm. The Neutorophil Elastase LDT has been shown to out perform the LE test strip in internal studies. The NE LDT is not prone to the high rate of invalid results due to blood contamination that have been reported with the LE test strip. A positive NE result should be interpreted as meeting the MSIS criteria of a positive LE test strip.

Proprietary immunoassay to measure Neutrophil Elastase (NE), the enzyme detected by the Leukocyte Esterase (LE) test strip.
### CRYSTAL ID, SYNOVIAL FLUID

**POSITIVE FOR INTRACELLULAR AND EXTRACELLULAR**

### EXPANDED SYNOVASURE® MICROBIAL ID PANEL

<table>
<thead>
<tr>
<th>Panel</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus Panel</td>
<td>Positive</td>
</tr>
<tr>
<td>Candida Panel</td>
<td>Negative</td>
</tr>
<tr>
<td>E. Coli</td>
<td>Negative</td>
</tr>
<tr>
<td>S. Mitis</td>
<td>Negative</td>
</tr>
<tr>
<td>P. Acnes</td>
<td>Negative</td>
</tr>
<tr>
<td>Enterococcus Panel</td>
<td>Negative</td>
</tr>
</tbody>
</table>

The Synovasure® Microbial ID Test is a qualitative in vitro diagnostic test intended for the early detection of microbial antigen in synovial fluid of patients experiencing joint pain and/or inflammation. The Synovasure® Microbial ID Test measures antigen from bacterial and fungal species in the synovial fluid from organisms which commonly cause joint infections. The Synovasure® Microbial ID Test results are intended to be used as an additional test to microbial culture and can provide detection of an organism in some samples where there is microbial organism present, but was not able to be cultured.

Notes: Protein A found on cell surface of S. aureus can result in low-level cross-reactivity in Candida and E. faecalis assays.

### CULTURE, FLUID

**Site:** Left Knee

Organism 1: Staphylococcus aureus  
**Growth:** In Aerobic and Anaerobic Bottle

<table>
<thead>
<tr>
<th>Sensitivities</th>
<th>In Aerobic and Anaerobic Bottle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin</td>
<td>&lt;=0.5 S</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>0.25 S</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>0.25 S</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>&lt;=0.5 S</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>&lt;=0.25 S</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>&lt;=0.5 S</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>0.25 S</td>
</tr>
<tr>
<td>Linezolid</td>
<td>2 S</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>0.25 S</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>&lt;=16 S</td>
</tr>
<tr>
<td>Oxacillin MIC</td>
<td>&lt;=0.25 S</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>&lt;=0.5 S</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>&lt;=1 S</td>
</tr>
<tr>
<td>Tigecycline</td>
<td>&lt;=0.12 S</td>
</tr>
<tr>
<td>Trimethoprim/Sulfamethox</td>
<td>&lt;=10 S</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>1 S</td>
</tr>
</tbody>
</table>

**S = Susceptible  R = Resistant  I = Intermediate**

Blood culture bottle is reported to be the most sensitive method for synovial fluid culture. We utilize a BACT/ALERT® system and always run both aerobic and anaerobic bottles.

Upon positive culture and identification of the organism, susceptibility profile is performed.
Easy to Use

- Simple sample submission process, including pre-paid shipping
- No out of pocket costs, covered by most insurance companies
- Experienced customer support team ready to assist

For additional information please phone: CD Laboratories Customer Service 888-981-8378, email: customerservice@cdlaboratories.com or contact your Zimmer Biomet Representative

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References

1. Instructions for use. Synovasure PJ1 ELISA Test. CD Diagnostics. Claymont, DE.


3. Instructions for use. Synovasure L-Lactate LDT. CD Diagnostics. Claymont, DE.


