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 with 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.
### Test Information

**Test Name**: Synovasure® Alpha Defensin

**Specimen Site**: Left Knee

**Result**: Positive

**Units**: mg/L

**Flag**: ABNORMAL

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

### Hemoglobin

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.

### Test Details

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

**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

For additional information, see the Synovasure® Alpha Defensin assay manual.

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**Test Name** | **Result** | **Ref. Range** | **Flag** | **Run by**
--- | --- | --- | --- | ---
Synovasure® Alpha Defensin NSA | POSITIVE | | | ~LD on 11/8/2017 1:09 PM

### Specimen Site

**SPECIMEN SITE**: LEFT KNEE

**ALPHA DEFENSIN-SF**: POSITIVE

**CRP-SF**: >60 mg/L

**HEMOGLOBIN-SF**: NORMAL

**LACTATE - SF**: 80.0 mg/L
### Test Results

<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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RED BLOOD CELL COUNT, FLUID</td>
<td>241000</td>
<td>/uL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL NUCLEATED CELL COUNT</td>
<td>206000</td>
<td>/uL</td>
<td>HIGH</td>
<td>&lt;150</td>
</tr>
<tr>
<td>NEUTROPHILS</td>
<td>87.9</td>
<td>%</td>
<td>HIGH</td>
<td>&lt;25.0</td>
</tr>
<tr>
<td>MONONUCLEAR CELLS</td>
<td>12.1</td>
<td>%</td>
<td></td>
<td>&lt;75.0</td>
</tr>
</tbody>
</table>

**Note:** Result was verified by manual cell count.

### Interpretation

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**

Periprosthetic Joint Infection (PJI) is currently recommended 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.


### 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 Neutrophil Elastase LDT has been shown to outperform 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.
### CRYSTAL ID, SYNOVIAL FLUID
#### POSITIVE FOR INTRACELLULAR AND EXTRACELLULAR

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRYSTAL ID, SYNOVIAL FLUID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXPANDED SYNOVASURE® MICROBIAL ID PANEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STAPHYLOCCUS PANEL</td>
<td>POSITIVE</td>
<td></td>
</tr>
<tr>
<td>CANDIDA PANEL</td>
<td>NEGATIVE</td>
<td></td>
</tr>
<tr>
<td>P. ACNES</td>
<td>NEGATIVE</td>
<td></td>
</tr>
<tr>
<td>ENTEROCOCCCUS PANEL</td>
<td>NEGATIVE</td>
<td></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

#### Sensitivities

<table>
<thead>
<tr>
<th>Drug</th>
<th>Sensitivity</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.

Assesses for presence of CPPD (Calcium pyrophosphate dehydrate) and/or MSU (Monosodium urate) crystals. The presence of crystals does not rule out infection.
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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Zimmer Biomet does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received. This test kit has been developed for use with synovial fluid only.

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References

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


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


