Synovasure® Diagnostics
Diagnostic Solutions for The Infected Joint

Exclusively available from CD Diagnostics, now part of Zimmer Biomet

ZIMMER BIOMET
Your progress. Our promise.
Synovasure®
Alpha Defensin Test
Proven Accuracy and Performance

First and only test specifically designed and validated to aid in the diagnosis of Periprosthetic Joint Infection (PJI)

Identifies elevated levels of Alpha Defensin, a critical protein in the innate immune response to infection.

Unparalleled accuracy
97% sensitive and 96% specific using the MSIS criteria for diagnosing PJI

Performance backed by data
• Alpha Defensin results not influenced by
  - Prior antibiotic administration
  - Samples that culture negative by traditional methods
  - Comorbidities related to inflammation
  - Type and/or virulence of the organism
• Intended for use as an adjunct to current diagnostics methods for the diagnosis of PJI

<table>
<thead>
<tr>
<th>Study*</th>
<th># Patients</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rothman Institute1</td>
<td>149</td>
<td>97%</td>
<td>96%</td>
</tr>
<tr>
<td>Mayo Clinic4</td>
<td>61</td>
<td>100%</td>
<td>95%</td>
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<tr>
<td>Cleveland Clinic5</td>
<td>78</td>
<td>100%</td>
<td>98%</td>
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<tr>
<td>Rush University6 (Abstract)</td>
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<td>100%</td>
<td>95%</td>
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<tr>
<td>ENDO Klinik7</td>
<td>156</td>
<td>97%</td>
<td>97%</td>
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<tr>
<td>Combined</td>
<td>591</td>
<td>99%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Alpha Defensin Performance in Independent studies vs MSIS criteria for diagnosing PJI

CD Diagnostics Exclusive Comprehensive Infection Panels
Additional information to guide diagnosis and treatment

- One stop comprehensive orthopedic diagnostic workup
- Over 60,000 synovial fluids tested so far, with more than 500 results being reported every week
- Results usually available within 24 hours
- Simple, easy-to-read reports designed specifically for orthopedics

✓ Alpha Defensin
✓ Microbial Identification
✓ Culture
✓ Cell Count and Differential
✓ Neutrophil Elastase
✓ Crystal Analysis
Synovasure®
Microbial ID Test
Identification of Microbial Species

Identification of infectious organisms even when culture is negative

- Zimmer Biomet’s innovative diagnostic technology enables identification of common microbial species through direct detection of microbial antigens.
- Identifies microbial organisms that may not culture.
- Designed to identify the organisms responsible for >65% of PJIs*

Staphylococcus Species Assay is sensitive to known S. aureus infection and also detects specific microbial antigen in some culture negative infections

Panel validated to detect the following microbes:

- **Staphylococcus Species**
  - S. aureus, S. epidermidis, S. lugdunensis
- **Candida Species**
  - C. albicans, C. glabrata, C. parapsilosis, C. parapsilosis sp. Complex, C. tropicalis
- **Enterococcus faecalis**

* CD Diagnostics Data on File

Proper Management of Diagnostics on Synovial Fluid Samples is Key in Proper Diagnosis:

- Insights generated by running more than 60,000 samples have shown that false positive White Blood Cell (WBC) counts can occur in greater than 7% of elevated WBC counts from automated counters

- At CD Laboratories, all synovial fluid WBC counts greater than 3000 cells/µl are confirmed via manual counts

Graph illustrates all samples with a cell count >3000 on the automated cell counter. Of interest are the high automated (Sysmex) cell counts with a low manual count. These samples are elevated due to artifacts.

**Correlation Plot of Sysmex vs Manual Count for Automated Counts >3000**

Remnants of bacteria remain in synovial fluid after bacteria are destroyed.
From diagnosis to re-implantation
Zimmer Biomet provides the most comprehensive portfolio for the continuum of care.

Therapy
Once infection has been diagnosed, defeating the organism is vital. In conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection), Zimmer Biomet’s modular and monoblock spacer molds and lavage systems are designed to help meet these needs.

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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 has been developed for use with synovial fluid only. The use of this test kit with any other specimen type may lead to inaccurate test results.

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References
6. Kayupov E., et al. ABSTRACT Alpha-Defensin is an Accurate Test for PJI. AAOS presentation Control/Tracking Number: 16-P-5723-AAOS.

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