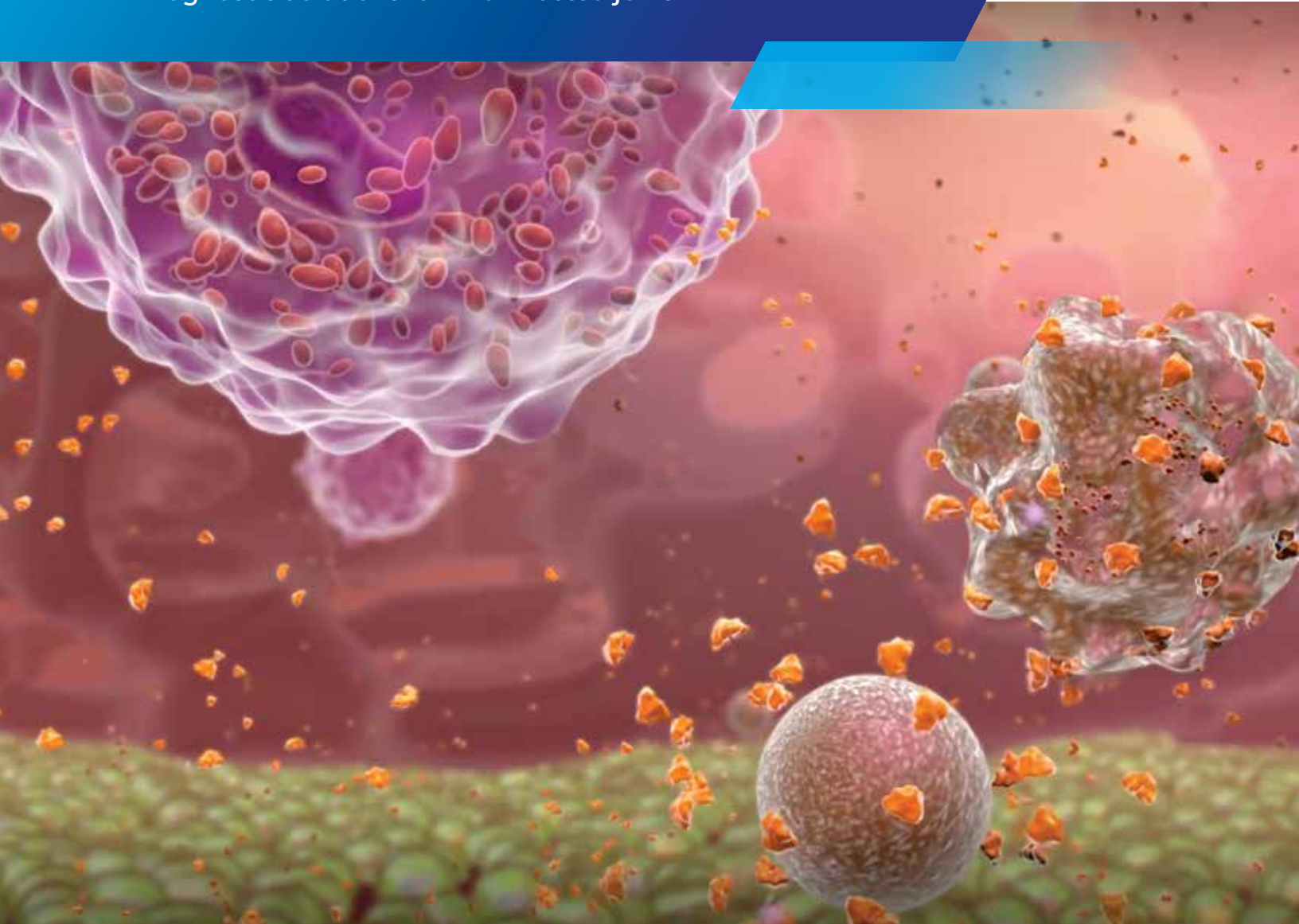


# Synovasure<sup>®</sup> Diagnostics

Diagnostic Solutions for The Infected Joint



**CD Diagnostics<sup>®</sup>**  
Confidence in Immunoassays

Exclusively available from CD Diagnostics,  
now part of Zimmer Biomet



**ZIMMER BIOMET**  
Your progress. Our promise.™

# Synovasure<sup>®</sup>

## 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)**

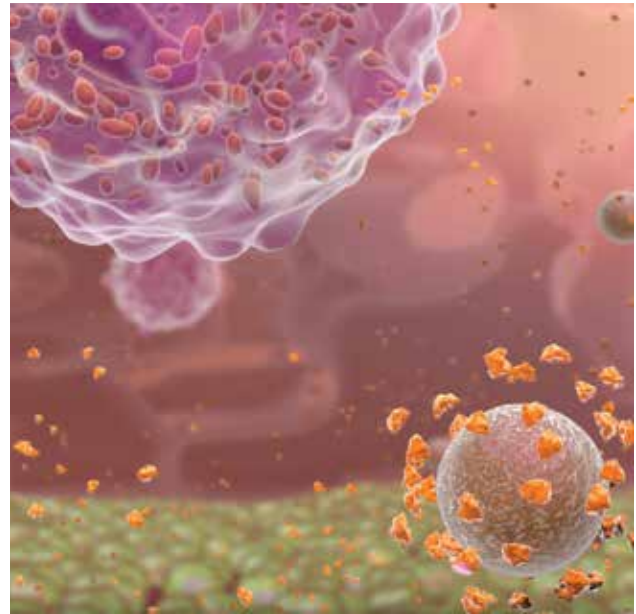
Identifies elevated levels of Alpha Defensin, a critical protein in the innate immune response to infection.

#### Unparalleled accuracy

97% sensitive and 96% specific using the MSIS criteria for diagnosing PJI<sup>1</sup>

#### Performance backed by data

- Alpha Defensin results not influenced by
  - Prior antibiotic administration<sup>1,2</sup>
  - Samples that culture negative by traditional methods
  - Comorbidities related to inflammation<sup>1</sup>
  - Type and/or virulence of the organism<sup>1,3</sup>
- Intended for use as an adjunct to current diagnostics methods for the diagnosis of PJI.<sup>1</sup>



Alpha defensin, released from activated neutrophil, destroying bacteria

Study*	# Patients	Sensitivity	Specificity
Rothman Institute <sup>1</sup>	149	97%	96%
Mayo Clinic <sup>4</sup>	61	100%	95%
Cleveland Clinic <sup>5</sup>	78	100%	98%
Rush University <sup>6</sup> (Abstract)	147	100%	95%
ENDO Klinik <sup>7</sup>	156	97%	97%
<b>Combined</b>	<b>591</b>	<b>99%</b>	<b>96%</b>

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

- ✓ Alpha Defensin
- ✓ Microbial Identification
- ✓ Culture
- ✓ Cell Count and Differential
- ✓ Neutrophil Elastase
- ✓ Crystal Analysis

- 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

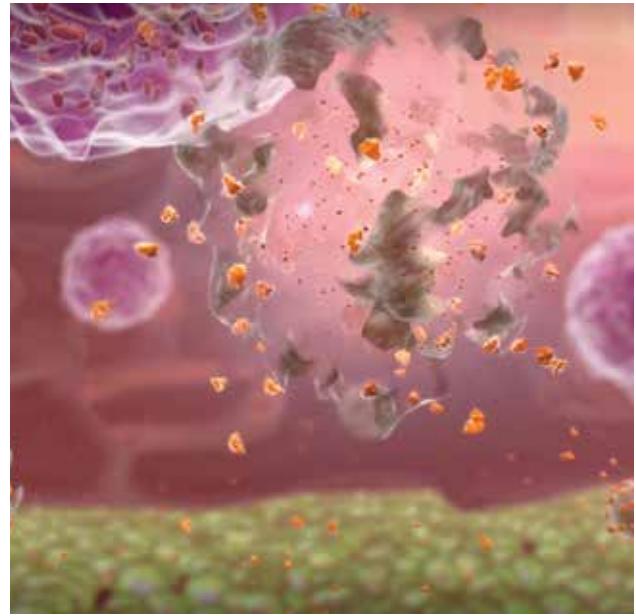
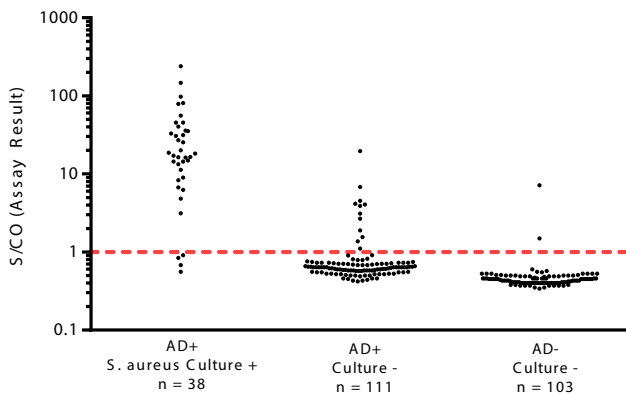
# Synovasure<sup>®</sup> Microbial ID Test

## 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 PJI's\*

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



Remnants of bacteria remain in synovial fluid after bacteria are destroyed

### 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**

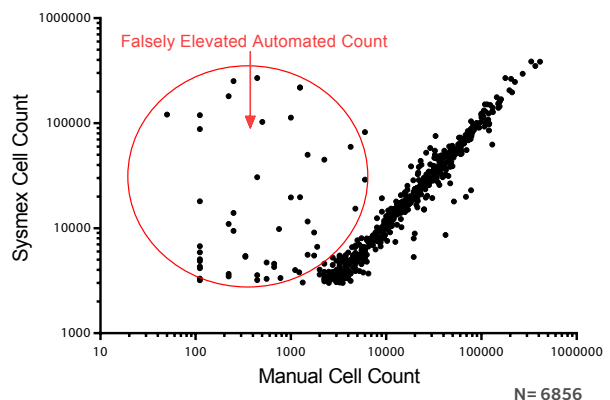
\* CD Diagnostics Data on File

## 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<sup>8</sup>
- At CD Laboratories, all synovial fluid WBC counts greater than 3000 cells/ $\mu$ l are confirmed via manual counts<sup>8</sup>

Graph illustrates all samples with a cell count >3000 on the automated cell counter. Of interest are the high automated (Sysmax) cell counts with a low manual count. These samples are elevated due to artifacts.<sup>8</sup>

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



N = 6856

## 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



Surgeon injects synovial fluid into tubes provided with kit



Complete the sample submission sheet, and package sample using provided instructions and materials



Call for FedEx at 1-800-GOFEDEX for Pre-Paid Package Pick-Up



Testing is performed and results are faxed or emailed directly to the surgeon usually within 24 hours of receipt

For additional information contact your Zimmer Biomet Representative, or email: [customerservice@cdlaboratories.com](mailto:customerservice@cdlaboratories.com) phone: **CD Laboratories Customer Service 888-981-8378**

## 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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### Re-Implantation

After the infection has been diagnosed and treated, Zimmer Biomet's specialized antibiotic loaded cements and your choice of implant should provide symptom relief and restore joint function. Zimmer Biomet offers a wide range of proven revision implant systems for re-implantation.

### References

1. Deirmengian CA., et al. Combined Measurement of Synovial Fluid a-Defensin and C-Reactive Protein Levels: Highly Accurate for Diagnosing Periprosthetic Joint Infection. *JBJS Am.* 2014 Sep 3;96(17):1439-45.
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4. Bingham J., et al. The alpha Defensin-1 Biomarker Assay can be Used to Evaluate the Potentially Infected Total Joint Arthroplasty. *Clin Orthop Relat Res* DOI 10.1007/s11999-014-3900-7.
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7. Bonazinga, T., et al. How Reliable Is the Alpha-defensin Immunoassay Test for Diagnosing Periprosthetic Joint Infection? A Prospective Study. *Clin Orthop Relat Res* DOI 10.1007/s11999-016-4906-0.
8. Technical Bulletin, November 3rd, 2015. Edition 1 Volume 1. CD Diagnostics Data on File.