

Synovasure[®] Diagnostics

Laboratory Services



CD Laboratories

A Leader in Synovial Fluid Testing

CD Laboratories, located in Baltimore, Maryland, is a clinical laboratory focused on synovial fluid testing. The lab began accepting synovial fluid samples in 2013 and to date has processed **over 150,000** synovial fluid samples from throughout the United States. The lab is certified under the Clinical Laboratory Improvement Amendments (CLIA) from the Centers for Disease Control (CDC).

A variety of tests are performed utilizing synovial fluid to assist in the diagnosis of joint infection, including three proprietary Synovasure tests only performed at CD Laboratories. Our comprehensive infection panels for Periprosthetic Joint Infection (PJI) and Native Septic Arthritis (NSA) include:

Comprehensive Panel for PJI	Comprehensive Panel for NSA
Synovasure Alpha Defensin for PJI (test includes Alpha Defensin CRP and Hemoglobin)	Synovasure Alpha Defensin for NSA (test includes Alpha Defensin Lactate and Hemoglobin)
Synovasure Neutrophil Elastase	Synovasure Neutrophil Elastase
Synovasure Microbial Identification	Synovasure Microbial Identification
Culture	Culture
White Blood Cell Count w/ Differential and Red Blood Cell Count	White Blood Cell Count w/ Differential and Red Blood Cell Count
Crystal Analysis	Crystal Analysis

Note: All samples received at CD Laboratories are tested for sample integrity to ensure the most accurate results for physicians and their patients.

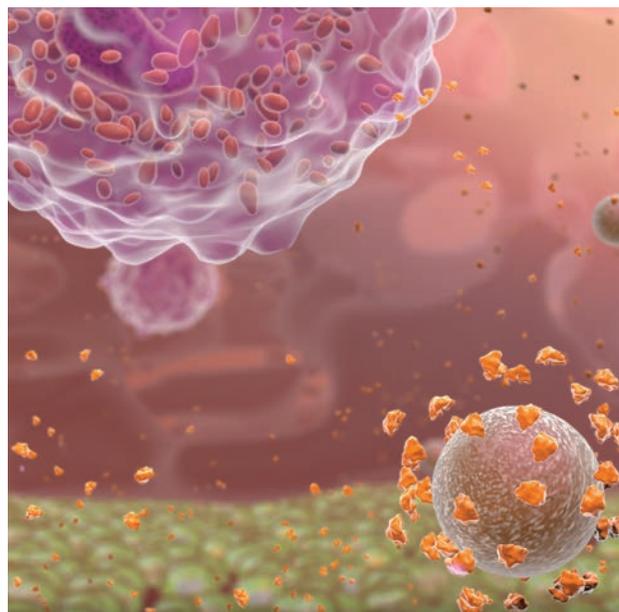


Illustration depicts alpha defensin, released from activated neutrophil, destroying bacteria.

We are dedicated to supporting physicians in their treatment decisions by offering:

- One stop, comprehensive diagnostic workup for infection
- Streamlined sample submission process
- Results usually available within 24 hours
- Simple, easy-to-read reports designed specifically for orthopedics
- No out-of-pocket costs; covered by most insurance companies

Synovasure[®] Alpha Defensin Test*

Proven Accuracy and Performance

*Synovasure Alpha Defensin Test is intended for use as an adjunct test to current methods.

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.

Proprietary Test for Synovial Fluid

Alpha Defensin testing is only available from CD Laboratories.

Unparalleled accuracy

97% sensitive and 96% specific using the 2013 MSIS criteria for diagnosing PJI.¹

Performance backed by data

- Prior antibiotic administration^{1,2}
- Samples that culture negative by traditional methods
- Comorbidities related to inflammation¹
- Type and/or virulence of the organism^{1,3}

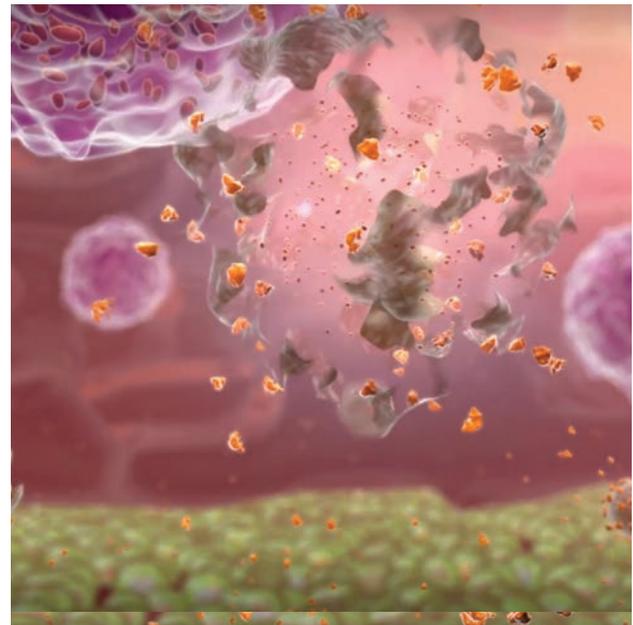


Illustration depicts alpha defensin, released from activated neutrophil, destroying bacteria.

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

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

Synovasure[®] Microbial ID Test

Identification of Microbial Species

Proprietary Test to Detect Microbes

Microbial Identification is only available from CD Laboratories.

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 more than 65% of PJIs.⁸

Panel validated to detect the following microbes:

- Staphylococcus species
- Enterococcus species
- Candida species
- P. acnes

Organism genus	Sensitivity ⁹	Specificity ⁹
<i>Staphylococcus</i>	94.0%	99.0%
<i>Enterococcus</i>	97.1%	99.5%
<i>Candida</i>	90.0%	99.6%

Due to its difficulty to be cultured, sensitivity and specificity data for *P. acnes* is unavailable.

Streamlined Process

- 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
phone: **CD Laboratories Customer Service 888-981-8378**

From Diagnosis Support 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 or monoblock cement spacer molds and lavage systems are designed to help meet these needs.



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.

*Synovasure Alpha Defensin Test is intended for use as an adjunct test to current methods.

All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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.

© 2019 Zimmer Biomet

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.* 96(17):1439-45, 2014.
2. Shahi A, et al. The alpha-defensin Test for periprosthetic Joint Infections Is not Affected by Prior Antibiotic Administration. *Clin Orthop Relat Res* DOI 10.1007/s 11999-016-4726-2.
3. Deirmengian CA., et al. The C-Reactive Protein May Not Detect Infections Caused by Less-Virulent Organisms. *Journal of Arthroplasty.* S152-S155, 2016.
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.
5. Frangiamore S., et al. a-Defensin Accuracy to Diagnose Periprosthetic Joint Infection – Best Available Test? *JOA.* 312:456-60, 2016.
6. Kayupov E., et al. ABSTRACT Alpha-Defensin is an Accurate Test for PJI. AAOS presentation Control/Tracking Number: 16-P-5723-AAOS.
7. Bonanzinga,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.
9. Data on file at CD Diagnostics Laboratories. Technical Report No. 12509-051R Prospective Analysis of Microbial ID Assay at CDL. Feb - Dec 2017.



ZIMMER BIOMET

Your progress. Our promise.®