

Synovasure™ PJI

Alpha Defensin Test for
Periprosthetic Joint Infection

**Demand More
From Your Diagnosis**

Lab Developed Test exclusively serviced by:
Citrano Medical Laboratories, a subsidiary of CD Diagnostics



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Personal Fit. Renewed Life.™

Introducing Synovasure PJI Alpha Defensin Test for Periprosthetic Joint Infection

The *Synovasure*™ PJI Test is the first and only test specifically designed and validated for the diagnosis of Periprosthetic Joint Infection (PJI). Developed to deliver accuracy, performance and ease of use.

Unparalleled accuracy

- The *Synovasure* Test achieves 97% sensitivity and 96% specificity by measuring synovial fluid alpha defensin
- Alpha defensin is an antimicrobial peptide released by neutrophils in response to pathogens
- Alpha defensin is an ideal biomarker for PJI due to the tremendous separation it achieves between positives and negatives

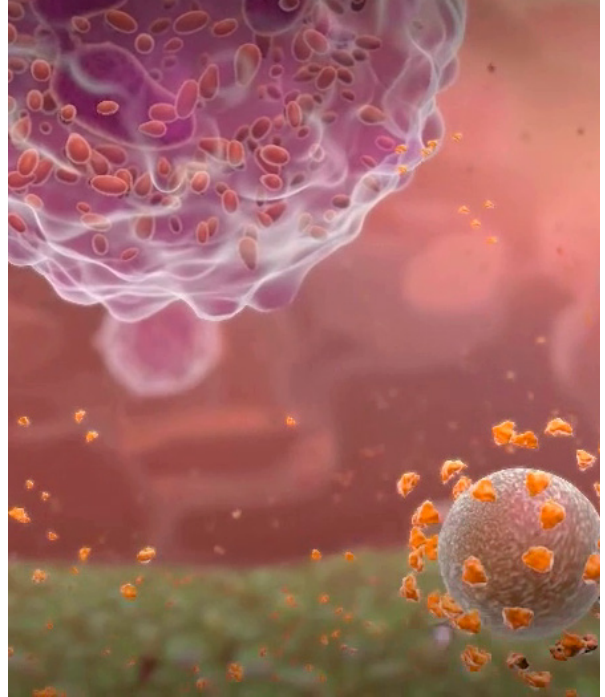
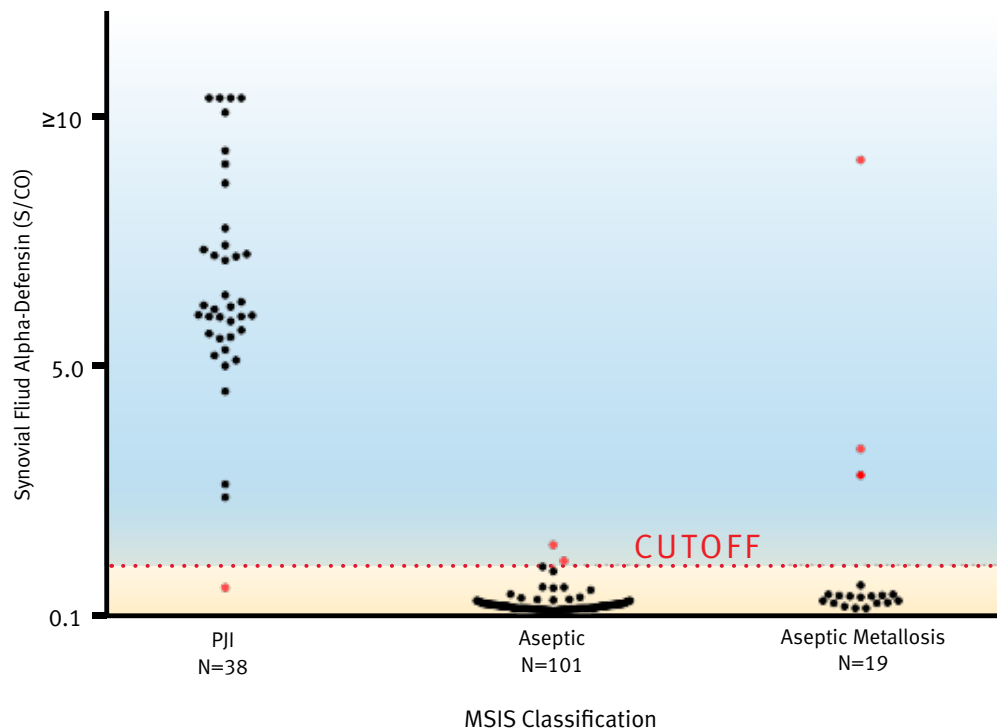


Image shows alpha defensin attacking a bacteria with an activated neutrophil in the background

Synovasure Performance	95% Confidence Interval
Sensitivity	97.4% 86.1% - 99.6%
Specificity	95.8% 90.5% - 98.6%

Alpha defensin levels for all 158 patients in the study are shown below. Patients with PJI have dramatically elevated levels while patients with aseptic etiologies have levels that are almost undetectable. Musculoskeletal Infection Society (MSIS) criteria were used as the standard for diagnosing PJI.



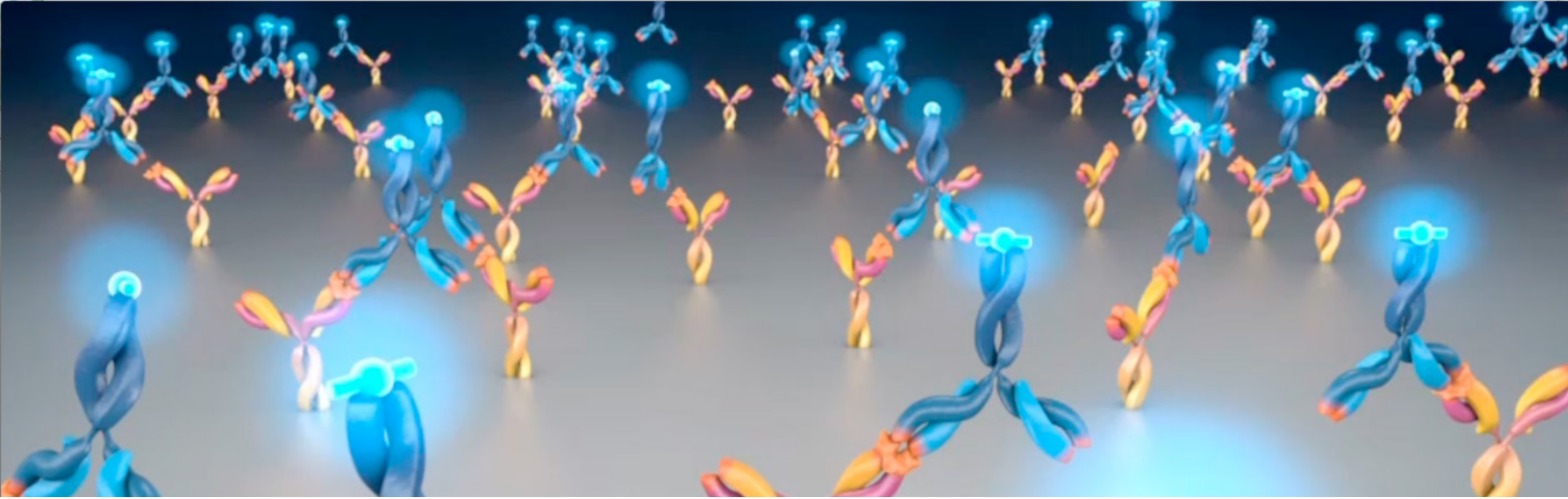


Image shows alpha defensin sandwiched between a proprietary capture antibody and a labeled detection antibody

Performance backed by data

In the 158 patient study, the *Synovasure* PJI Test maintained its performance in typically challenging situations such as:

Culture Negative Infection

- 14 of 38 patients with PJI were culture negative and the *Synovasure* PJI Test correctly identified all 14 as infected

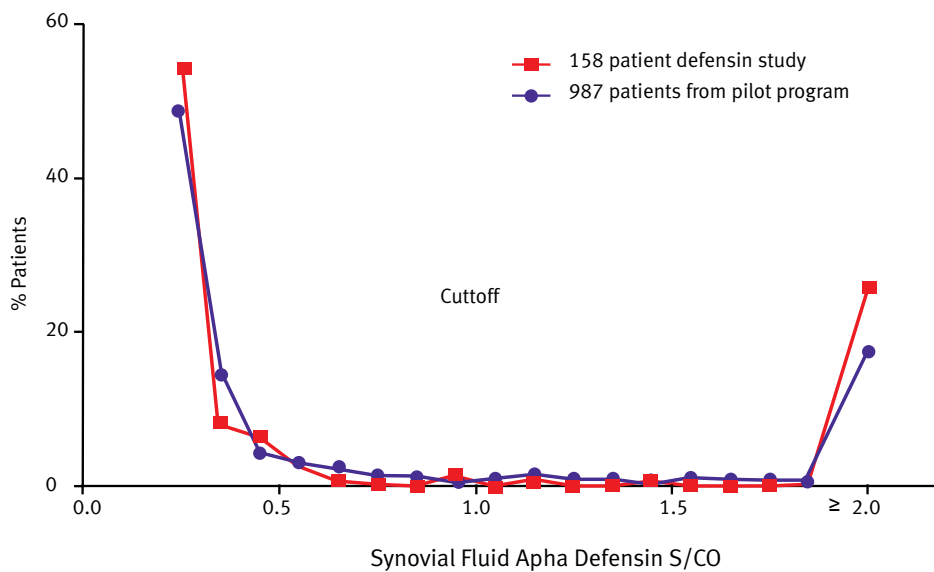
Systemic Inflammatory Conditions

- *Synovasure* PJI Test studies included patients with systemic inflammatory disease and its performance was maintained in this population

Antibiotic Therapy

- 27% of patients with PJI had been treated with antibiotics prior to aspiration and the *Synovasure* PJI was not adversely affected in this population

The graph below demonstrates consistent performance characteristics when comparing the 158 patient study to a Pilot Program where 260 surgeons tested over 980 patient samples



Superior ease of use

Simple sample submission process. Can be sent to Citrano Labs directly from practice or through affiliated hospital lab



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



Citrano Medical Laboratories, Inc.

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

Rapid standardized results

- Results are usually available within 24 hours
- Results do not require complicated interpretation like other tests with poorly defined cutoffs

Covered by most insurance companies

- No out of pocket costs to surgeon or practice

Also available with Culture and Sensitivity Testing

Reference: The data in this brochure can be found in a white paper entitled: A New Paradigm for the Diagnosis of Periprosthetic Joint Infection. CD Diagnostics. September 2013. Contact your Zimmer rep or call CD Diagnostics to receive a copy.

Intended use: The *Synovasure* PJI Alpha Defensin Test for Periprosthetic Joint Infection is intended to be used as an adjunct to current diagnostic methods in the diagnosis of periprosthetic joint infection (PJI). Its results should be interpreted along with the entire clinical picture in order to arrive at a definitive diagnosis.

The *Synovasure* PJI Test is a lab developed test offered through CD Diagnostics' CLIA certified laboratory, Citrano Medical Laboratories (CLIA License# 21D0216863) and has been validated for the detection of PJI. It was developed and its performance characteristics determined by Citrano Medical Laboratories. Citrano Medical Laboratories is certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity testing.

The *Synovasure* PJI Test has not been cleared or approved by the U.S. Food and Drug Administration.

For more information contact your Zimmer Representative,
call CD Diagnostics at 888-981-8378 or visit synovasure.com



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