Synovasure®
Diagnostics

Comprehensive PJI Test Panel Offering

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Demand More From Your Diagnosis

The Synovasure® Comprehensive PJI Test Panel offers physicians a wide variety of test options to aid in the diagnosis of Periprosthetic Joint Infection (PJI). Our test panel includes three unique laboratory tests only available through Zimmer Biomet:

- Synovasure Alpha Defensin ELISA
- Synovasure Microbial Identification
- Synovasure Neutrophil Elastase

In addition, our laboratories offer standard synovial fluid tests such as White Blood Cell (WBC) count, Crystal analysis and Culture. With this comprehensive offering, a physician can obtain sufficient information to determine if a patient's joint pain is a result of an infection, based on utilizing the Musculoskelatal Infection Society (MSIS) minor criteria for diagnosing PJI.

Synovasure Comprehensive PJI Tests

Test	Description
Synovasure Alpha Defensin ELISA	The Synovasure Alpha Defensin (AD) ELISA Test is a qualitative, in vitro diagnostic device intended as an adjunct for the detection of PJI in synovial fluid of patients experiencing pain and/or inflammation in a replacement joint. The test measures human alpha defensins 1-3 in the synovial fluid of persons with a total joint replacement. Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection. The results are intended to be used in conjunction with other clinical and diagnostic findings to aid in a patient's diagnosis of infection.
Synovasure Neutrophil Elastase	The Synovasure Neutrophil Elastase ELISA Test is a qualitative *in vitro* test that measures the neutrophil elastase protein within synovial fluid of patient experiencing joint pain and/or inflammation.
Synovasure Microbial Identification	The Synovasure Microbial Identification (MID) 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 test measures antigen from *Staphylococcus spp., Candida spp., Enterococcus spp.* and *Cutibacterium acnes* (formerly called *P. acnes*) in the synovial fluid. The results are intended to be used as an additional test to microbial culture and to detect the presence of an organism in culture negative samples.
Sample Integrity	Sample integrity tests are performed on synovial fluid samples to evaluate for high percentages of blood, as well as dilution by saline, lavage or contrast dye. Physicians are notified when a suboptimal specimen has been submitted. Our sample integrity tests assess: • Absorbance at 280 nm (A280) – Samples that fall outside the normal range for synovial fluid may be diluted by saline or contrast agents • Red Blood Cell Count – Samples are evaluated for elevated levels of RBCs
Synovial Fluid WBC Count (PMN%)	An automated, high-performance cell count test with differential and RBC count. Elevated white blood cells (>3000c/mm^3) are confirmed with a manual count.
Synovial Fluid Crystal Analysis	An assessment of synovial fluid for the presence of CPPD (Calcium pyrophosphate dehydrate) and/or MSU (Monosodium urate) crystals. The presence of crystals does not rule out a potential infection.
Synovial Fluid Culture	Anaerobic and aerobic culture bottles are incubated for 7 days to determine organism identification and antibiotic susceptibilities. Shoulder samples are supplemented to enhance growth and incubated for 14 days.

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

Check for country product clearances and reference product specific instructions for use. Not for distribution in France.

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