

Synovasure®

Comprehensive Infection Panel

Test Requisition

Place Test Sticker Provided
in Kit Here
(stickers not intended for use on tubes)

Failure to provide all information marked as required will delay results

Account Information

Synovasure Account	(Required)
Ordering Provider (Physician accounts only)	(Required)
Provider NPI (Physician accounts only)	(Required)
Practice/Laboratory Name & Address	(Required)
Phone	(Required)
Fax	(Required)
Email (optional)	

Billing Information – Physician Accounts Only

Insurance Type	(Required)
	<input type="checkbox"/> Medicare <input type="checkbox"/> Commercial <input type="checkbox"/> VA/Govt <input type="checkbox"/> Medicaid <input type="checkbox"/> Other
Insurance Carrier	(Required)
ID#	(Required)
Group#	(Required)
Name of Insured	(Required)
Relationship to Patient	(Required)
	<input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Other _____

Patient Information

Name (Last, First)	(Required)
Date of Birth	(Required)
Gender	(Required) <input type="checkbox"/> Male <input type="checkbox"/> Female
Patient Address	(Required)
Phone	(Required)

Specimen Information

Collection Date	(Required)
Aspiration Site	(Required)
	Knee Hip Other _____
	<input type="checkbox"/> Right <input type="checkbox"/> Right <input type="checkbox"/> Right
	<input type="checkbox"/> Left <input type="checkbox"/> Left <input type="checkbox"/> Left
Diagnosis Code (ICD-10-CM)	(Required) – See reverse for examples

Patient Acknowledgment – Physician Accounts Only

By signing this form, I hereby authorize Zimmer Biomet to furnish my designated insurance carrier the information on this form, if necessary, for reimbursement. I also authorize benefits to be payable to Zimmer Biomet. I understand that I am responsible for any amounts not paid by insurance for reasons including, but not limited to, non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.

Signature	(Required)
Date	(Required)

Test Information – Comprehensive Panel

Synovasure® Comprehensive Test Panels require three (3) tubes of synovial fluid

- Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel**
Specimen integrity, Synovasure® Alpha Defensin for PJI (alpha defensin ELISA & CRP), Synovasure® Microbial Identification, Synovasure® Neutrophil Elastase, Culture, White Blood Cell Count with Differential and Red Blood Cell Count
- Add-on: Crystal Analysis**
- Synovasure® Comprehensive Native Septic Arthritis (NSA) Test Panel**
(Not available for NY State patients)
Specimen integrity, Synovasure® Alpha Defensin for NSA (alpha defensin ELISA & lactate), Synovasure® Microbial Identification, Synovasure® Neutrophil Elastase, Culture, White Blood Cell Count with Differential and Red Blood Cell Count, and Crystal Analysis

- Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel – New York State Patients***
Specimen integrity, Synovasure® Alpha Defensin for PJI (alpha defensin ELISA & CRP), Synovasure® Neutrophil Elastase, Culture, White Blood Cell Count with Differential and Red Blood Cell Count
- Add-on: Crystal Analysis**

*Synovasure Microbial Identification test is not included as part of Synovasure Comprehensive PJI Panel for New York State Patients

Test Information – Individual Tests

Select individual option only if a Comprehensive Test Panel is not desired. Use clear-top, red stopper tube with fluid volumes stated below

- Synovasure® Alpha Defensin ELISA for PJI** – 0.5mL **Synovasure® Microbial Identification** – 1.0mL
(Not available for NY State patients)



Synovasure® Comprehensive PJI Test Panel

The Synovasure® Comprehensive PJI Test Panel is intended as an aid in diagnosing periprosthetic joint infection (PJI) through a combination of proprietary and standard of care (SoC) synovial fluid tests for patients experiencing joint pain and/or inflammation following a total joint arthroplasty. The panel includes the following tests:

- Synovasure® Alpha Defensin for PJI
Includes alpha defensin ELISA and CRP
 - Synovasure® Microbial Identification
 - Synovasure® Neutrophil Elastase
 - Synovial Fluid Culture
 - WBC Count with Differential and RBC count
- Note: Crystal Analysis available as add-on to comprehensive panel**

Synovasure® Comprehensive NSA Test Panel

The Synovasure® Comprehensive NSA Test Panel is intended as an aid in diagnosing native septic arthritis (NSA) through a combination of proprietary and standard of care (SoC) synovial fluid tests for patients experiencing joint pain and/or inflammation in a native joint. The panel includes the following tests:

- Synovasure® Alpha Defensin for NSA
Includes alpha defensin ELISA and lactate
- Synovasure® Microbial Identification
- Synovasure® Neutrophil Elastase
- Synovial Fluid Culture
- WBC Count with Differential and RBC count
- Crystal Analysis

Specimen Integrity Testing

The accuracy of diagnostic tests such as synovial fluid white blood cell count, neutrophil percentage, and others, can be significantly impacted by the quality of the specimen that is submitted for evaluation. As part of every analysis, specimen integrity tests are performed. Physicians are notified when a suboptimal specimen has been submitted. Our specimen integrity tests assess:

- **Absorbance at 280 nm (A280)** – Specimens that fall outside the normal range for synovial fluid may be caused by dilution via saline lavage or use of contrast agents
- **Red Blood Cell Count** – Specimens are verified as characteristic of synovial fluid, not blood.

Synovasure® Alpha Defensin for PJI

The Synovasure® Alpha Defensin lab developed test (LDT) for PJI consists of assays for synovial fluid alpha defensin ELISA and CRP and has been validated for use as an adjunct to aid in the diagnosis of periprosthetic joint infection.

Synovasure® Alpha Defensin for NSA

The Synovasure® Alpha Defensin lab developed test (LDT) for NSA consists of assays for synovial fluid alpha defensin ELISA and lactate and has been validated for use as an adjunct to aid in the diagnosis of native septic arthritis.

Synovasure® Microbial Identification

The Synovasure® Microbial Identification LDT is an assay intended for the early detection of microbial antigen in synovial fluid. The assay can detect microbial antigen in some samples where an organism is present but was not able to be cultured. Current panel identifies *Staphylococcus* species, *Enterococcus* species, *Candida* species and *Propionibacterium* species.

Synovasure® Neutrophil Elastase

The Synovasure Neutrophil Elastase (NE) LDT was designed to be a replacement for the Leukocyte Esterase (LE) test strip which can serve as one of the criteria in the MSIS infection algorithm. The NE LDT is designed and validated specifically for synovial fluid, while the LE test strip is designed for urine. The NE LDT is not prone to the high rate of invalid results due to blood contamination that have been reported with the LE test strip. A positive NE result should be interpreted as meeting the MSIS criteria of a positive LE test strip.

Synovial Fluid Culture

Anaerobic and aerobic culture bottles incubated for 7 days. Includes organism identification and antibiotic susceptibilities. Shoulder specimen cultures are supplemented to enhance growth and incubated for 14 days.

Synovial Fluid WBC Count w/ Differential and RBC Count

Automated high-performance cell count system with differential and RBC count. Elevated white blood cells (>3000c/μL) are confirmed with a manual count.

Crystal Analysis

An assessment of synovial fluid using polarized light microscopy is performed for the presence of CPPD (calcium pyrophosphate dihydrate) and/or MSU (monosodium urate) crystals.

Example ICD-10 Codes

M25.469	Effusion, unspecified knee
M25.551	Pain in right hip
M25.552	Pain in left hip
M25.561	Pain in right knee
M25.562	Pain in left knee
T84.50XA	Infection and inflammatory RX due to unspecified internal joint prosthesis, initial encounter
T84.50XD	Infection and inflammatory RX due to unspecified internal joint prosthesis, subsequent encounter
T84.50XS	Infection and inflammatory RX due to unspecified internal joint prosthesis, sequential encounter
Z96.641	Presence of artificial hip joint, right
Z96.642	Presence of artificial hip joint, left
Z96.651	Presence of artificial knee joint, right
Z96.652	Presence of artificial knee joint, left

For customer assistance, contact CD Laboratories Customer Service at 888-981-8378 or email customerservice@CDLaboratories.com

To order more Synovasure® Infection Specimen Transportation kits (00-8888-130-01), contact your local Zimmer Biomet representative or Zimmer Biomet Customer Service