M40036 V6

Synovasure®
Comprehensive Infection Panel
Test Requisition

*** Indicates required field. Failure to provide information will delay results.**

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

CD Laboratories Account

Account Number*

Ordering Provider* (Physician accounts only)

Provider NPI* (Physician accounts only)

Practice/Laboratory Name & Address*

Phone*

Fax*

Email

Patient

Name* *(Last, First)*

Date of Birth*

Gender* ☐ Male ☐ Female

Patient Address*

Phone

Specimen

Specimen Obtained in* ☐ Hospital ☐ ASC ☐ Clinic

Collection Date* (mm/dd/yyyy) _____ / _____ / _____

Aspiration Site*

Knee	Hip	Other _____
☐ Right	☐ Right	☐ Right
☐ Left	☐ Left	☐ Left

For Physician Accounts Only

Note: A front/back scan of insurance card(s) may be submitted

Patient Insurance

Insurance Type* ☐ Medicare ☐ Commercial ☐ VA/Govt ☐ Medicaid ☐ Other

Primary Insurer*

Address*

Member ID*

Group ID*

Name of Insured*

Relationship to Patient* ☐ Self ☐ Spouse ☐ Other _____

Secondary Insurer *(if applicable)*

Member ID

Group ID

Diagnosis/ICD-10-CM Coding *(see reverse for example codes)*

Primary Code*

Secondary Code *(if applicable)*

Patient Acknowledgment

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*

Date*

Test Information – Comprehensive Panel

*Synovasure® Comprehensive Test Panels require three (3) tubes of synovial fluid: **(2) No Additive tubes** (BD 366703 or equivalent) AND **(1) EDTA tube** (BD367856 or equivalent). Refer to Test Submission Instructions within kit for equivalent tube options.*

☐ **Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel**
Includes: Synovasure Alpha Defensin, Synovasure Microbial Identification, Synovial Fluid CRP, WBC Count w/ Differential and RBC count, and Culture
***Required Volume**: 3.0mL (No Additive Tube), 2.5mL (No Additive Tube) & 0.5mL (EDTA tube)*
☐ **Add-on: Crystal Analysis** *(add addt'l 0.5mL to EDTA tube)*

☐ **Synovasure® Comprehensive Native Septic Arthritis (NSA) Test Panel**
Includes: Synovasure Alpha Defensin for NSA (alpha defensin and lactate), Synovasure Microbial Identification, WBC Count w/ Differential and RBC count, Culture, and Crystal Analysis
***Required Volume**: 3.0mL (No Additive Tube), 2.5mL (No Additive Tube) & 1.0mL (EDTA tube)*
Not available in New York State

☐ **Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel – NEW YORK STATE PATIENTS**
Includes: Synovasure Alpha Defensin, Synovial Fluid CRP, WBC Count w/ Differential, and RBC count, and Culture
***Required Volume**: 3.0mL (No Additive Tube), 1.5mL (No Additive Tube) & 0.5mL (EDTA tube)*
☐ **Add-on: Crystal Analysis** *(add addt'l 0.5mL to EDTA tube)*

Test Information – Individual Tests *(select only if Comprehensive Panel is NOT desired)*

☐ **Synovasure® Alpha Defensin for PJI**
***Required Volume**: 0.5mL (No Additive Tube)*

☐ **Synovasure® Microbial Identification** ***(Not available in New York State)***
***Required Volume**: 1.0mL (No Additive Tube)*

CD Laboratories®
810 Gleneagles Court, Suite 100 | Baltimore, MD 21286
Phone: (888) 981-8378 | Fax: (410) 415-1951
customerservice@cdlaboratories.com
CLIA Registration No.: 21D0216863

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 ELISA
- Synovasure® Microbial Identification
- Synovial Fluid C-Reactive Protein (CRP)
- Synovial Fluid Culture
- WBC Count with Differential and RBC count
- Specimen Integrity

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
- Synovial Fluid Culture
- WBC Count with Differential and RBC count
- Crystal Analysis
- Specimen Integrity

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 an assay for synovial fluid alpha defensin ELISA 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 acnes*.
Synovial Fluid C-Reactive Protein (CRP)	The C-Reactive Protein (CRP) test is a quantitative *in vitro* laboratory developed test (LDT) to measure CRP in synovial fluid of patients experiencing pain and/or inflammation in a joint. This assay is a component of the multi-analyte diagnostic algorithm used to aid in the detection of periprosthetic joint infection (PJI). The measurement of CRP in synovial fluid is used in conjunction with other biomarkers as a component of the Synovasure® PJI Panel to aid the diagnosis of PJI.
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 (>3000 cells/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 Diagnosis Codes *(not all inclusive)*

Primary Diagnosis Code	Secondary Diagnosis Code
M25.469 **(Effusion, unspecified knee)**	*secondary diagnosis allowed*
M25.551 **(Pain in right hip)**	*secondary diagnosis allowed*
M25.552 **(Pain in left hip)**	*secondary diagnosis allowed*
M25.561 **(Pain in right knee)**	*secondary diagnosis allowed*
M25.562 **(Pain in left knee)**	*secondary diagnosis allowed*
Primary Dx required (identify infection)	T84.50XA **(Infection and inflammatory RX due to unspecified internal joint prosthesis, initial encounter)**
Primary Dx required (identify infection)	T84.52XD **(Infection and inflammatory RX due to internal left hip prosthesis, subsequent encounter)**
Primary Dx required (identify infection)	T84.53XS **(Infection and inflammatory RX due to internal right knee prosthesis, sequential encounter)**
Primary Dx required	Z96.641 **(Presence of artificial hip joint, right)**
Primary Dx required	Z96.642 **(Presence of artificial hip joint, left)**
Primary Dx required	Z96.651 **(Presence of artificial knee joint, right)**
Primary Dx required	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 at 1-800-348-2759, Option 1