M40036 V7

Synovasure®
Comprehensive Infection Panel
Test Requisition

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

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

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

See "Required Volume" for amount and tube type for each test option. Tubes are provided within the Synovasure Infection Specimen Transportation Kit.

☐ **Synovasure® Comprehensive Periprosthetic Joint Infection (PJI) Test Panel with SynTuition™* and Culture**** ***Note: Test is not available in New York State***

*Includes: Synovasure Alpha Defensin, Synovasure Microbial Identification (*Staphylococcus, Enterococcus, Candida, and P. acnes antigen*), Synovial Fluid CRP, and WBC Count w/ Differential and RBC count

***Includes Aerobic and Anaerobic Culture*

***Required Volume**: 3.0mL (No Additive Tube), 3.0mL (No Additive Tube) & 0.5mL (EDTA tube)*

☐ **Add-on: Crystal Analysis** *(+0.5mL to EDTA tube)*

☐ **Synovasure® Comprehensive Native Septic Arthritis (NSA) Test Panel**

Note: Test is not available in New York State

Includes: Synovasure Alpha Defensin for NSA (alpha defensin and lactate), Synovasure Microbial Identification (*Staphylococcus, Enterococcus, Candida, and P. acnes antigen*), WBC Count w/ Differential and RBC count, Culture (Aerobic and Anaerobic), and Crystal Analysis

***Required Volume**: 3.0mL (No Additive Tube), 3.0mL (No Additive Tube) & 1.0mL (EDTA tube)*

☐ **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 (Aerobic and Anaerobic)

***Required Volume**: 3.0mL (No Additive Tube), 3.0mL (No Additive Tube) & 0.5mL (EDTA tube)*

☐ **Add-on: Crystal Analysis** *(+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**

Note: Test is not available in New York State

Includes testing for Staphylococcus, Enterococcus, Candida and P. acnes antigen

Exclusively Serviced by:

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Phone: (888) 981-8378 | Fax: (410) 415-1951 | customerservice@cdlaboratories.com
A subsidiary of CD Diagnostics, a division of Zimmer Biomet

CD Laboratories®

Note: All testing at CD Laboratories is intended for synovial fluid obtained from an intraarticular joint space. All other specimens will be rejected at CD Laboratories.

Synovasure® Comprehensive PJI Test Panel with SynTuition™

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 adult patients experiencing joint pain and/or inflammation following a total joint arthroplasty. The panel includes the following tests:

- Synovasure® Alpha Defensin for PJI
- Synovasure® Microbial Identification
- Synovial Fluid C-Reactive Protein (CRP)
- WBC Count with Differential and RBC count
- Specimen Integrity

The SynTuition™ Score* is generated utilizing a validated, machine-learning algorithm comprised from the test results included in the Synovasure® Comprehensive PJI Panel. The SynTuition™ Score is presented via a colorimetric scale and numerical score from >1% to <99% to aid in the test result interpretation and diagnosis of PJI.

Note: Culture (Aerobic and Anaerobic) is tested alongside the Synovasure® Comprehensive PJI Panel but is not included in the SynTuition™ Score.

***The Synovasure® Comprehensive PJI Test Panel with SynTuition™ is not currently available in New York State. A modified version of the comprehensive panel is available as noted on the front of this form.**

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 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 (Aerobic and Anaerobic)
- 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 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 a panel of assays intended for the early detection of microbial antigens in synovial fluid. The panel can detect microbial antigens in some samples where an organism is present but was not able to be cultured. The 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* 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 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 up to 7 days. Includes organism identification and antibiotic susceptibilities. Shoulder specimen cultures are supplemented to enhance growth and incubated for up to 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
M25.551 **(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	T84.51XD **(Infection and inflammatory RX due to internal right hip prosthesis, subsequent encounter)**
Primary Dx required	T84.52XD **(Infection and inflammatory RX due to internal left hip prosthesis, subsequent encounter)**
Primary Dx required	T84.53XS **(Infection and inflammatory RX due to internal right knee prosthesis, sequential encounter)**
Primary Dx required	T84.54XS **(Infection and inflammatory RX due to internal left 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 a complete listing of related diagnosis codes, please refer to the ICD-10 code database

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