M40032 V5

Synovasure® RISC™ Panel Requisition

Failure to provide all information marked as required will delay results

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

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*

Note: A scan of the front and back of insurance card can be attached to this requisition

Insurance Type	(Required) ☐ Medicare ☐ Commercial ☐ VA/Govt ☐ Medicaid ☐ Other
Insurance Carrier	(Required)
ID#	(Required)
Group#	(Required)
Name of Insured	(Required)
Relationship to Patient	(Required) ☐ Self ☐ Spouse ☐ Other _____

Patient Information

Name *(Last, First)*	(Required)
Date of Birth	(Required)
Gender	(Required) ☐ Male ☐ Female
Patient Address	(Required)
Phone	(Required)

Specimen Information

Specimen Obtained in:	(Required) ☐ Hospital ☐ ASC ☐ Clinic
Collection Date	(Required)
Aspiration Site	(Required) **Knee** ☐ Right ☐ Left **Other** _____ ☐ Right ☐ Left *Note: Performance of Synovasure® RISC™ Panel is not established for applications outside of the knee*
Diagnosis Code (ICD-10-CM)	(Required)

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

Synovasure® RISC™ Panel requires three (3) tubes of synovial fluid: ***(2) No Additive tubes*** *(BD 366703 or equivalent no additive tube) AND* ***(1) EDTA tube*** *(BD367856 or equivalent tube). Refer to Test Submission Instructions include in kit for equivalent tube options.*

☐ **Synovasure® Relative Inflammatory Status Classification (RISC) Panel with reflex***

Includes: Specimen Integrity Analysis, Cartilage Oligomeric Matrix Protein, Interleukin-8, Anti-Cyclic Citrullinated Peptide, Rheumatoid Factor, White Blood Cell Count with Differential * and Red Blood Cell Count, and Crystal Analysis

**If the total nucleated cell count is >3,000 cells/µL or neutrophils percent is >70%, specimen will be reflexed to Synovasure® Alpha Defensin for Native Septic Arthritis (NSA), Lactate, Synovasure® Microbial Identification and Fluid Culture*

Important – New York State Physicians

STOP *Synovasure® RISC™ Panel is not currently available for New York State patient testing.*

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Synovasure® Relative Inflammatory Status Classification (RISC) Panel

Synovasure® RISC™ Panel is a laboratory-developed test (LDT) panel intended to provide indications for diagnosing different types of arthritis that may correspond to higher risk levels for postoperative complications in patients experiencing knee pain and/or inflammation p rior to primary knee arthroplasty.

Synovasure® RISC™ Panel LDT is intended to determine whether there are abnormal levels of markers present in knee synovial fluid and to provide the physician with an objective result for the presence of biomarkers that may be indicative of a certain type of arthritis. Test performance for joints other than the knee joint has not been established. The panel includes the following tests:

- Cartilage Oligomeric Matrix Protein (COMP)
- Interleukin-8 (IL-8)
- Rheumatoid Factor (RF)
- Anti-Cyclic Citrullinated Peptide (Anti-CCP)
- WBC Count with Differential* and RBC count
- Crystal Analysis

**If the total nucleated cell count is >3,000 cells/µL or neutrophils percent is >70%, specimen will be reflexed to Synovasure® Alpha Defensin for NSA (alpha defensin and lactate), Synovasure® Microbial Identification and Fluid Culture.*

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® Osteoarthritis (OA) **COMP** **IL-8**	The COMP ELISA and IL-8 ELISA are quantitative LDTs intended to detect cartilage oligomeric matrix protein (COMP) and interleukin-8 (IL-8), respectively, in the synovial fluid of patients experiencing knee pain or inflammation with suspected arthritis. Results are used in combination to provide clarification in diagnosing OA. • COMP (-) (below 1500 ng/mL) suggests little to no evidence of cartilage damage • COMP (+) (above 1500 ng/mL) suggests cartilage damage • COMP/IL-8 ratio (+) (above 4.3 ng/pg) suggests isolated, idiopathic OA • COMP/IL-8 ratio (-) (below 4.3 ng/pg) suggests cartilage damage and elevated inflammatory status The values for COMP and IL-8 are assigned using purified recombinant proteins and internal analytical procedures and are not metrologically traceable to an international reference standard.
Synovasure® Rheumatoid Arthritis (RA) **Anti-CCP** **RF**	The qualitative Anti-CCP ELISA and quantitative immunoturbidimetric RF Latex are LDTs intended to detect anti-cyclic citrullinated peptide (anti-CCP) and rheumatoid factor (RF), respectively, in the synovial fluid of patients experiencing knee pain or inflammation with suspected arthritis. Results are used in combination to provide further clarification in diagnosing rheumatoid arthritis. **Negative results on the Anti-CCP ELISA and RF Latex should not be used to aid in the exclusion of RA from the differential diagnosis.**
Synovasure® Crystalline Arthritis **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.
Synovasure® Native Septic Arthritis **Synovial Fluid WBC Count w/ Differential**	Current International Consensus Meeting guidelines for periprosthetic joint infection (PJI) recommend a cut-off of 3,000 cells/µL and/or a PMN% of 70%. The same criteria are used to establish the threshold for Synovasure Alpha Defensin NSA reflex testing. All samples with cell counts >3,000 cells/µL are confirmed with a manual cell count. **If the total nucleated cell count is >3,000 cells/µL or neutrophils percent is >70%, specimen will be reflexed to Synovasure® Alpha Defensin for NSA (alpha defensin and lactate), Synovasure® Microbial Identification and Fluid Culture.*
Synovasure® Alpha Defensin for NSA *(includes alpha defensin ELISA and lactate)*	The Synovasure® Alpha Defensin ELISA is a qualitative LDT intended to detect human alpha defensins 1-3 in the synovial fluid of native joints. The quantitative lactate LDT is intended to measure lactate in synovial fluid of patients experiencing joint pain and/or inflammation. The results are used in conjunction to provide further clarification in diagnosing NSA: • Alpha Defensin (-) suggests no evidence of NSA, regardless of L-lactate result • Alpha Defensin (+), lactate (-) or below 70.0 mg/dL is indeterminate for NSA • Alpha Defensin (+), lactate (+) suggests NSA
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 Culture	Anaerobic and aerobic culture bottles incubated for 7 days. Includes organism identification and antibiotic susceptibilities.

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

To order more Synovasure® Arthritis Specimen Transportation kits (00-8888-160-01), contact your local Zimmer Biomet representative or Zimmer Biomet Customer Service