Synovasure® RISC™ Panel

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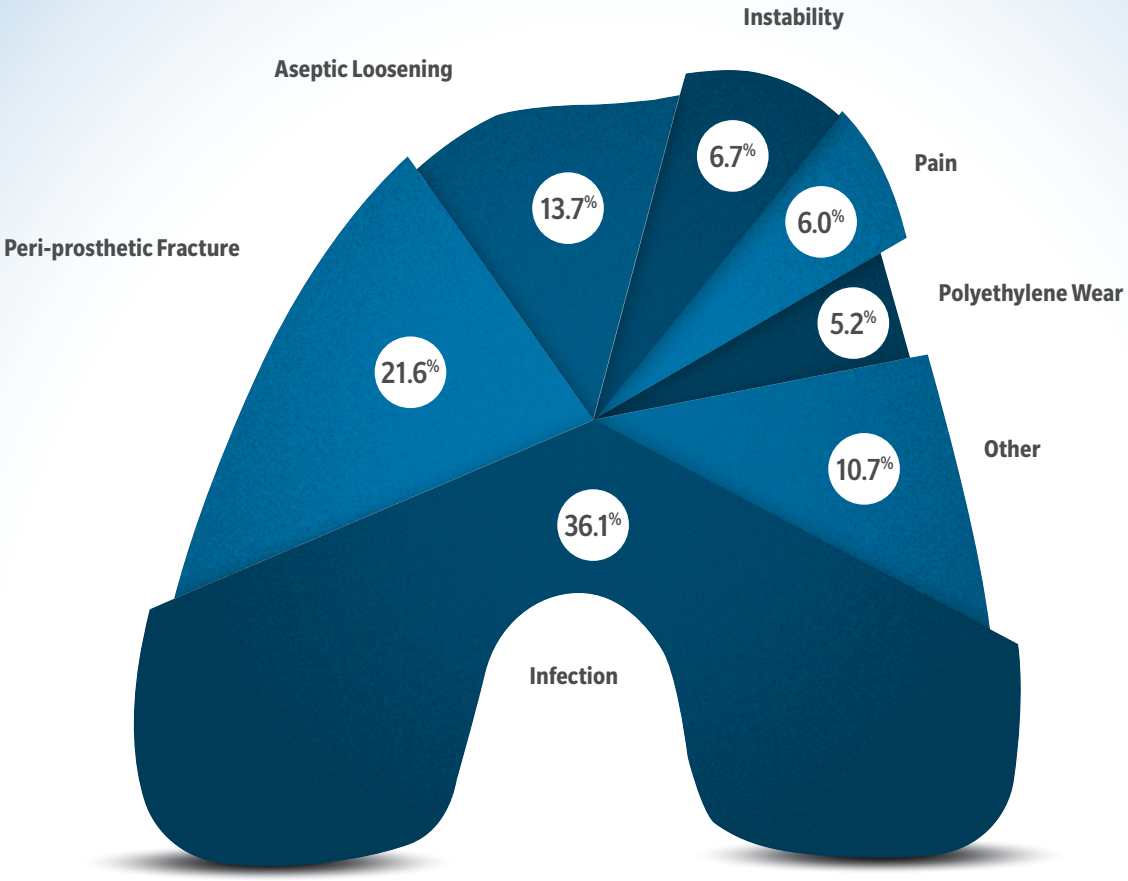


Causes of TKA Revision Surgery[1]

THE BURDEN OF REVISION:
3% OF KNEE REPLACEMENTS ARE REVISED[2]

Total knee arthroplasty has become one of the most common orthopedic procedures for treatment of knee, with over 1 million total knee replacements performed each year in the United States, and is expected to grow to nearly 3.4 million by 2040[3]. Though a highly successful surgical procedure, nearly 3% of knee replacements are revised within the first 5 years for reasons such as infection, loosening, pain and instability[2]. Ultimately, revisions place a burden on patients and the healthcare system through the potential increase in costs, readmissions and morbidity[2]. If patients with a higher risk of post-operative complications are identified before surgery, proper treatment plans may be able to be developed to mitigate the risks.

A SINGLE ASPIRATION
FOR A MORE INFORMED TREATMENT PLAN

Getting an accurate arthritis diagnosis is critical in optimizing a patient treatment plan to maximize satisfaction and minimize postoperative risks. Historically, individual laboratory tests have been utilized to diagnosis or rule out specific arthritis conditions through serum and joint fluid samples.

The Synovasure® Relative Inflammatory Status Classification (RISC) Panel is the first of its kind panel test offering a one stop, comprehensive panel of synovial fluid tests to aid in diagnosing different arthritis conditions that may correspond to relative level of inflammation and post-operative complications. The panel includes biomarker tests for:

- Osteoarthritis (OA)
- Rheumatoid Arthritis (RA)
- Crystalline Arthritis
- Native Septic Arthritis (NSA)

An accurate arthritis diagnosis helps identify which treatment options are best for the patient, including implant selection, venue, and pre- and post-operative care plans.

KEY FEATURES

Single, synovial fluid test panel for common arthritis types

Streamlined submission process

Every specimen tested for integrity

Easy-to-read results report

First and only test panel for diagnosis of OA

Quick turnaround within 72 hours

OSTEOARTHRITIS

First and Only Laboratory Test to Aid in OA Diagnosis

Historically, laboratory tests were used to exclude OA from a diagnosis. The Synovasure® RISC™ Panel includes the first test specifically designed for OA diagnosis.

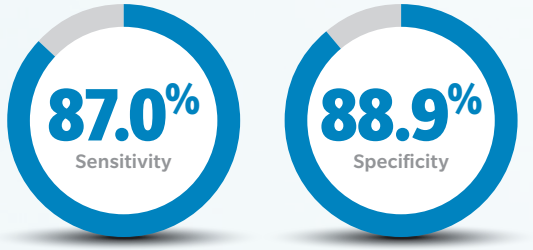
Dual Biomarker Evaluation

Differentiate between primary and secondary OA through assessing levels of:

- Cartilage Oligomeric Matrix Protein (COMP) – Cartilage breakdown biomarker[1,4]
- Interleukin-8 (IL-8) – Inflammatory biomarker[5,6]

Highly Accurate for OA Diagnosis

COMP/IL-8 ratio demonstrates high sensitivity and specificity[7]



RHEUMATOID ARTHRITIS

Testing at the Source

Synovial fluid biomarker testing at the pain source using established serum biomarkers

- Anti-Cyclic Citrullinated Peptide (Anti-CCP) – Biomarker associated with presence of RA[8]
- Rheumatoid Factor (RF) – Biomarker associated with presence of an autoimmune disease[9]

Result Algorithm for Diagnosis Recommendation

Results for Anti-CCP and RF combined to determine if pain potentially caused by RA or other auto-immune condition.

Performance Backed by Data[7]

- Capable of discriminating between RA and Non-RA patients
- Effective “rule-in” test – 100% Specificity

CRYSTALLINE ARTHRITIS

Crystal analysis is performed as part of the Synovasure RISC Panel to detect monosodium urate (MSU) and calcium pyrophosphate dihydrate (CPPD) crystals using high-powered microscopy for gout and CPPD disease.

NATIVE SEPTIC ARTHRITIS

Evaluation of White Blood Cells (WBC) in Fluid

- Automated, high-performance cell count for total cells and breakdown of cell types present.
- A 2020 study shows nearly 4.4% of automated cells counts in native knee specimens resulted in a false positive[10]; therefore, all cell counts >3,000 are confirmed with a manual count.

If final reported WBC count is >3,000 cells/µL or neutrophil percentage is >70%, specimens are reflexed to Synovasure Alpha Defensin for NSA (alpha defensin and lactate), Synovasure Microbial Identification and Fluid Culture.

Synovasure Alpha Defensin for NSA

Laboratory-developed test (LDT) for alpha defensin biomarker and lactate. Alpha defensin demonstrates high level of accuracy in identifying infection[11*] and is unaffected by:

- Prior Antibiotic Administaration[11,12]
- History of Inflammatory Conditions[11,13]
- Type/Virulence of Organism[11,14]

**Validation and performance of alpha defensin is based on cases of PJI and has not been defined for NSA due to no comparative "Gold Standard" criterion.*

Synovasure Microbial Identification

A novel, antigen bead-based test for 24-hour identification of potential infection causing organism including:

	SENSITIVITY[15]	SPECIFICITY[15]
Staphylococcus species	94%	99%
Enterococcus species	97%	99%
Candida species	90%	99%
C. acnes	Due to difficulty culturing C. acnes, performance data not available	

The Synovasure Microbial Identification test is highly accurate and identifies more than 54% of culture-negative PJI specimens.[16]

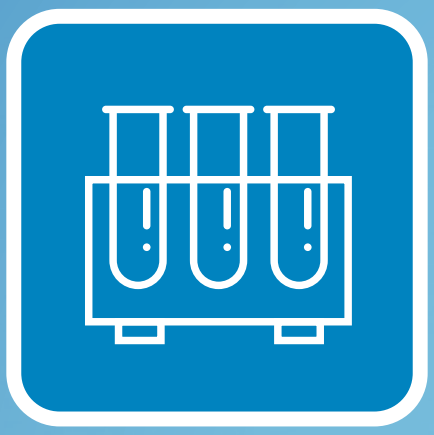
Fluid Culture

Aerobic and anaerobic culture performed to aid in the diagnosis and treatment of infection. All fluid cultures are held for seven (7) days.

STREAMLINED PROCESS

Submitting synovial fluid to CD Laboratories uses a simple, streamlined process from aspiration to result reporting. Results are provided within 72 hours of receipt at CD Laboratories.

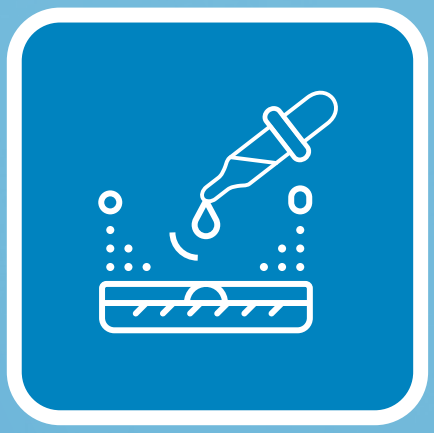
ASPIRATE JOINT



TRANSFER FLUID TO PROVIDED TUBES

PACKAGE TUBES AND REQUISITION IN SHIPPER

OVERNIGHT SHIPMENT TO CD LABORATORIES



TESTS PERFORMED AND RESULTS SENT TO PROVIDER

MANAGING POST-OPERATIVE TOTAL KNEE ARTHROPLASTY COMPLICATIONS

Zimmer Biomet is your partner for assessing and preventing the potential for complications and detecting and treating complications that may arise.

References

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3684.1-US-en-Issue Date 2022-02-02