Synovasure®
Alpha Defensin Lateral Flow Test

WHEN YOU NEED TO KNOW NOW
"With this test, health care professionals now have an additional option available to aid their clinical assessment as to whether the patient has an infection and requires revision surgery.

Whereas, before surgeons may have opted for surgery when the presence of an infection was unclear, with this test, they have more information and could potentially reduce patient risk by avoiding unnecessary revision operations for replacement joints."

Tim Stenzel, M.D., Ph.D.,
Director, Office of In Vitro Diagnostics and Radiological Health
US FDA Center for Devices and Radiological Health
**PJIs - A Serious Complication**

Periprosthetic Joint Infection (PJIs) is one of the most common complications following total joint arthroplasty, accounting for 25% of total knee arthroplasty failures and 16% of total hip arthroplasty failures. Furthermore, PJIs place major stress on the healthcare system including patients, payers and hospital systems.

Making a timely and accurate diagnosis of PJIs is key in the creation of an informed treatment plan and helping to improve patient outcomes.

**Alpha Defensin - Aiding Diagnosis of PJIs**

Alpha defensins are antimicrobial peptides released into the body through activated neutrophils in response to an infection. In cases of PJIs, a patient will have elevated levels of alpha defensin in their synovial fluid.

Clinical findings show that alpha defensin test results are not influenced by:

- Prior antibiotic administration
- Comorbidities related to inflammation
- Type and/or virulence of the organism

Since discovery, alpha defensin has aided in the diagnosis of PJIs following total joint replacement. In 2018, alpha defensin biomarker was included as a minor criteria for diagnosing PJIs by the International Consensus Meeting (ICM) on Joint Infection.
Synovasure® Alpha Defensin Lateral Flow Test
Rapid Results in 10 Minutes

The Synovasure Alpha Defensin Lateral Flow Test is a standalone, rapid device for detecting alpha defensin in synovial fluid.

The first test of its kind, the Synovasure Alpha Defensin Lateral Flow Test offers physicians:

- 94.3% Sensitive and 94.5% Specific vs. standard of care criteria

- Same-day results - Rapid Positive/Negative alpha defensin result in 10 minutes

- Low synovial fluid volume requirement – Only 15 microliters required for test performance

- Control kit availability for proficiency and validation

In a prospective clinical study (n=305), the Synovasure Alpha Defensin Lateral Flow Test demonstrated 94.3% Sensitivity and 94.5%* Specificity when compared to the standard of care criteria. Furthermore, no statistically significant difference was observed between the Synovasure Alpha Defensin Lateral Flow Test compared to the Synovasure Alpha Defensin ELISA.6

*Excluding samples with >20% blood dilution
Rapid Test Process

1. Allow fluid to reach the black fill line
2. Mix with buffer solution
3. Deposit onto device
4. Read results in 10-20 minutes

For complete step descriptions, please refer to the Instructions for Use (IFU)
Synovasure Alpha Defensin Lateral Flow Test is one of many products that make up Zimmer Biomet’s solutions of revision products and services.

It is time to break the revision cycle and focus on the entire patient journey. From diagnostics to patient specific re-implantation, we unite customizable, interconnected and interdependent services and solutions to address each unique episode of care.

In addition to the Synovasure Lateral Flow Test, Zimmer Biomet offers the Synovasure Comprehensive PJI Laboratory Tests Panel – together they offer physicians a wide variety of options to aid in the diagnosis of Periprosthetic Joint Infection (PJI).
Uniting Innovative Solutions
From Diagnosis Aids to Re-implantation

Zimmer Biomet provides a comprehensive portfolio for the continuum of care.

Therapy

Once infection has been diagnosed, defeating the organism is vital. In conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection), Zimmer Biomet’s modular or monoblock cement spacer molds and lavage systems are designed to help meet these needs.

Re-implantation

After the infection has been diagnosed and treated, Zimmer Biomet provides antibiotic loaded cements and revision systems designed to restore joint function. Zimmer Biomet offers a wide range of revision implant systems for re-implantation.

To learn more about our Diagnostic product offerings for PJI, please contact your local Zimmer Biomet representative or visit www.zimmerbiomet.com

Intended Use

The Synovasure® Alpha Defensin Lateral Flow Test Kit is a qualitative, visually read immunochromatographic assay for the detection of human host response proteins, Alpha Defensins 1-3, in the synovial fluid of adults with a total joint replacement who are being evaluated for revision surgery. The Synovasure Alpha Defensin Lateral Flow Test Kit results are intended to be used in conjunction with other clinical and diagnostic findings to aid in diagnosis of periprosthetic joint infection (PJI). The Synovasure Alpha Defensin Lateral Flow Test Kit is not intended to identify the etiology or severity of a PJI.

The Synovasure Alpha Defensin Control Kit is used in the Synovasure Alpha Defensin Lateral Flow Test Kit as assayed quality control samples to monitor performance and reliability of the Synovasure Alpha Defensin Lateral Flow Test Kit.

This assay is for prescription use only in the United States and for laboratory use in Canada and Australia. For all countries outside of the United States, Canada, and Australia, this assay is for professional use only.

References


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For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Zimmer Biomet does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

This test has been developed for use with synovial fluid only. The use of this test kit with any other specimen type may lead to inaccurate test results.

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