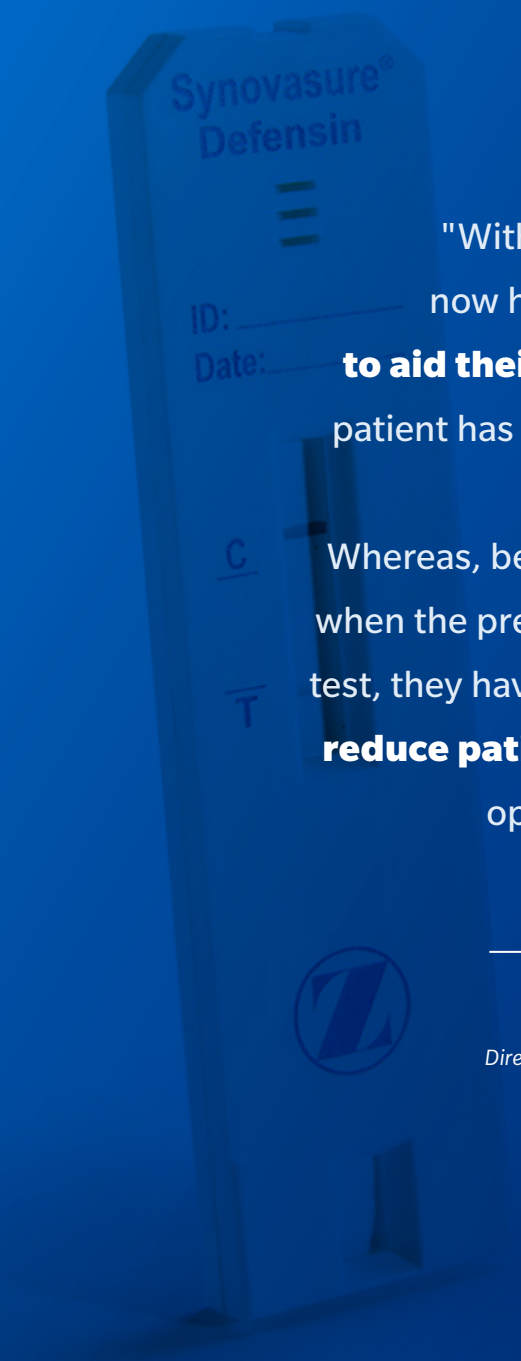
# Synovasure®

## Alpha Defensin Lateral Flow Test

**WHEN YOU NEED TO KNOW NOW**

ZIMMER BIOMET




"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."

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**Tim Stenzel, M.D., Ph.D.,**
*Director, Office of In Vitro Diagnostics and Radiological Health*
*US FDA Center for Devices and Radiological Health*
*FDA News Release, May 23, 2019.*

## PJI - A Serious Complication

Periprosthetic Joint Infection (PJI) 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.[1] Furthermore, PJI places major stress on the healthcare system including patients, payers and hospital systems.

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

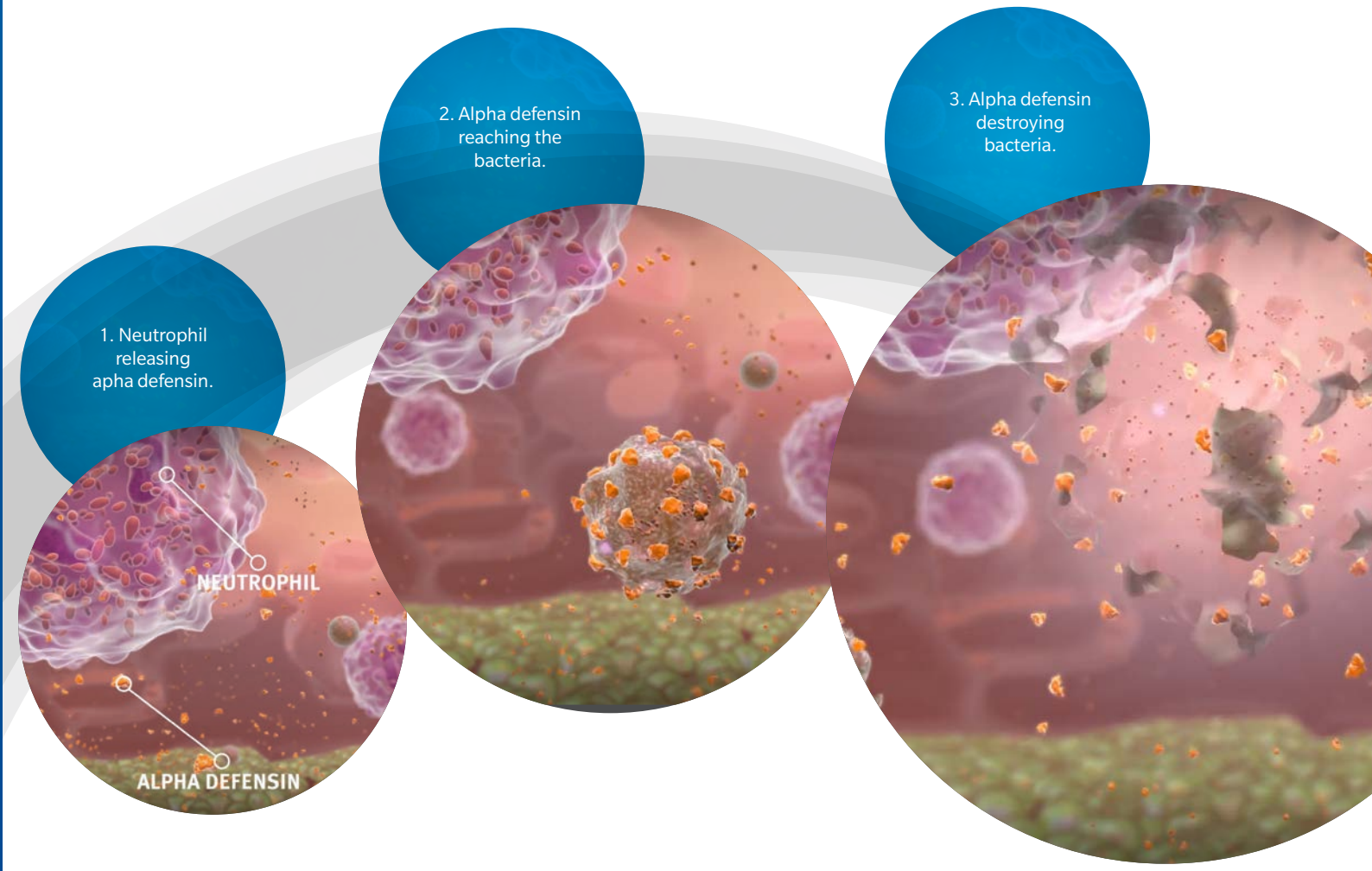
## Alpha Defensin - Aiding Diagnosis of PJI

Alpha defensin is an antimicrobial peptide released into the body through activated neutrophils in response to an infection. In cases of PJI, 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[2,3]
- Comorbidities related to inflammation[2]
- Type and/or virulence of the organism[2,4]

Since discovery, alpha defensin has aided in the diagnosis of PJI following total joint replacement. In 2018, alpha defensin biomarker was included as a minor criteria for diagnosing PJI by the International Consensus Meeting (ICM) on Joint Infection.[5]



# 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:

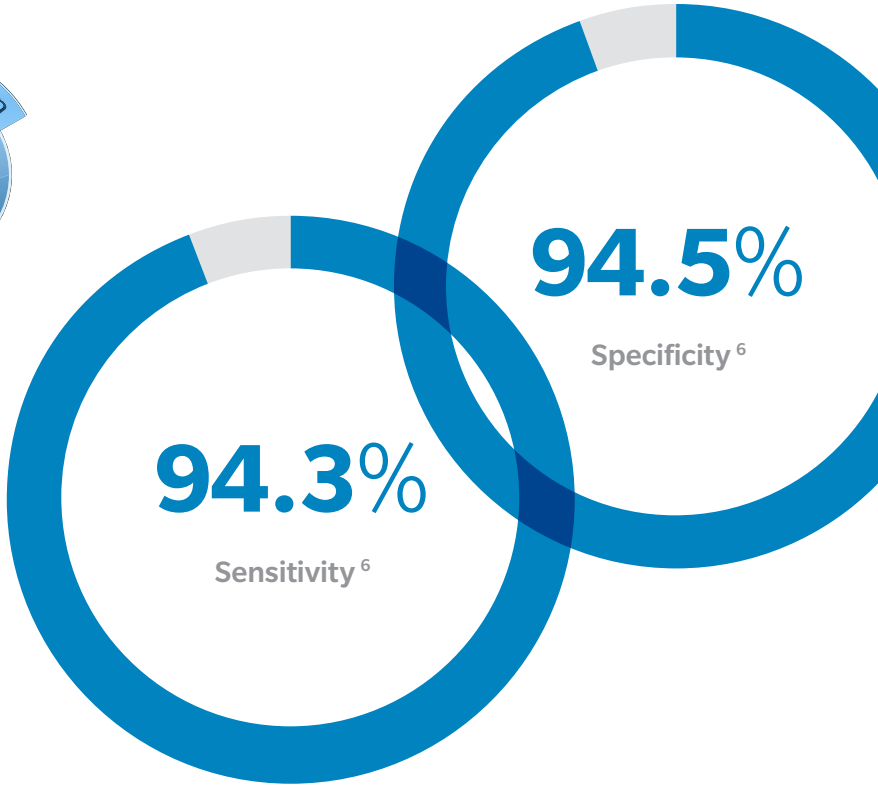
- 94.3% Sensitive and 94.5% Specific vs. standard of care criteria[6]
- Same-day results - Rapid Positive/Negative alpha defensin result in 10 minutes
- Low synovial fluid volume requirement – Only 15 microliters required for test performance
- Control kit availability for proficiency and validation

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


Positive


Negative

# 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)*

# BREAKING THE **REVISION** CYCLE

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.

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. The Synovasure Alpha Defensin Lateral Flow Test Kit and the Synovasure Alpha Defensin Control Kit are non-automated.

This assay is categorized as CLIA moderately complex for prescription use only in the United States. The Synovasure Alpha Defensin Lateral Flow Test Kit and Control Kit is intended for laboratory use in Canada and Australia. In the European Union, the Synovasure Alpha Defensin Lateral Flow Test Kit and Control Kit are intended for laboratory use in a clinical laboratory by laboratory professionals and also for near patient testing in orthopedic clinics by users in routine professional care environments and operating rooms by users in critical care environments.

**References**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2. Diermengian C, *et al.* Combined Measurement of Synovial Fluid a-Defensin and C-reactive Protein Levels: Highly Accurate for Diagnosing Periprosthetic Joint Infection. *JBJS Am.* Sep 3;96(17):1439-45, 2014.
3. Shahi A, *et al.* The alpha-defensin Test for Periprosthetic Joint Infections is Not Affected by Prior Antibiotic Administration. *Clin Orthop Relat Res.* Jul;474(7):1610-5, 2016.
4. Diermengian C, *et al.* The C-reactive Protein May Not Detect Infections Caused by Less-Virulent Organisms. *Journal of Arthroplasty.* 31:152-155, 2016.
5. Shohat N., *et al.* Hip and Knee Section, What is the Definition of a Periprosthetic Joint Infection (PJI) of the Knee and the Hip? Can the Same Criteria be Used for Both Joints?: Proceedings of International Consensus on Orthopedic Infections. Journal of Arthroplasty. 34(2), S325-S327, 2019.
6. Deirmengian C, *et al.* Validation of the Alpha Defensin Lateral FlowTest for Periprosthetic Joint Infection. JBJS Am. 103:115-22, 2020.




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