Test Definition: ALDEF

Alpha Defensin, Lateral Flow Assay, Synovial Fluid

Overview

Useful For

Detection of alpha defensins 1-3, human host response proteins, in synovial fluid of adults with a total joint replacement who are being evaluated for revision surgery

This test is **not intended to be used** to determine timing for reimplantation in 2-stage procedures.

Method Name

Lateral Flow Assay (LFA)

NY State Available

Yes

Specimen

Specimen Type

Synovial Fluid

Ordering Guidance

This test should **only be used** for patients with a total joint prosthesis. For specimens that are **not** from a prosthetic joint, order JIP / Joint Infection Panel, PCR, Synovial Fluid.

Necessary Information

Specimen source and type of joint are required. If not obtained from a prosthetic joint, testing will be canceled.

If ordering electronically, answers must be provided for the order entry questions.

If not ordering electronically, specimen source and type of joint must be provided on the request form.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Red-top tube without preservative or clot activators
Submission Container/Tube: Plastic vial
Specimen Volume: 0.6 mL

Specimen Minimum Volume

0.1 mL

Reject Due To

Gross hemolysis	Reject
Specimens collected in tubes with preservatives or clot activators	Reject
Specimens not from a prosthetic joint	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Synovial Fluid	Refrigerated (preferred)	7 days	
	Ambient	7 days	

Clinical & Interpretive

Clinical Information

Diagnosis of prosthetic joint infections (PJI) may be challenging in certain clinical scenarios. Multiple societies have defined criteria for establishing the presence of a PJI, including results from laboratory tests, clinical findings, and tissue histopathology. The challenge, however, is that results of these tests are frequently not available at the time of or after surgery. As an alternative, synovial fluid cell count and differential are frequently used biomarkers for PJI; however, there is a lack of consensus on the optimal thresholds to use for a PJI diagnosis. Additionally, cell count and differential results require clinician interpretation as laboratories do not report abnormal levels correlating with PJI.

Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection and served as part of the host-defense innate immune system with broad antimicrobial activity against gram-positive and gram-negative bacteria, mycobacteria, fungi, and viruses. The presence of alpha defensins in synovial fluid may therefore be used by clinicians as a marker of PJI.

Reference Values

Negative
Reference values apply to all ages.

Interpretation

Negative:
No alpha defensin detected in synovial fluid; this suggests the absence of prosthetic joint infection.

Positive:
Alpha defensin detected in synovial fluid suggests prosthetic joint infection. Additional microbiologic studies (eg, culture,

molecular detection) are recommended.

Cautions

Alpha defensin testing should be used to evaluate for the presence of a prosthetic joint infection if other clinical and diagnostic test findings (ie, synovial fluid cell count and differential) are inconclusive.

Test results should be utilized in conjunction with other clinical and diagnostic findings to aid the diagnosis of prosthetic joint infection.

This kit has been developed for use with freshly collected synovial fluid only. The use of this test kit with any other specimen type may lead to inaccurate test results. The use of synovial fluid diluted with saline, blood, contrast agent, or any substances injected into the joint may lead to false-negative results.

Presence of greater than 1 million/mcL red blood cells in the synovial fluid specimen may lead to false-negative results. This represents dilution of the synovial fluid specimen with greater than 20% blood.

The performance of this test has only been validated for conditions evaluated by the Musculoskeletal Infection Society criteria.

A decrease in sensitivity (an increased likelihood of false-negative results) has been observed in the presence of a sinus tract communicating with the prosthesis. Since the presence of a sinus tract is definitive evidence of PJI, use of this test under those circumstances is **not** recommended.

False-positive results have been reported in the presence of metallosis.

A negative test result does **not** preclude the possibility of infection.

Synovial fluid obtained after repeated aspirations within a short time period might lead to false-negative results due to the lack of buildup of alpha defensin.

Clinical Reference

Bonanzinga T, Ferrari MC, Tanzi G, Vandenbulcke F, Zahar A, Marcacci M. The role of alpha defensin in prosthetic joint infection (PJI) diagnosis: a literature review. EFORT Open Rev. 2019;4(1):10-13

Performance

Method Description

The Alpha Defensin Lateral Flow Test Kit is an immunoassay test system comprised of a single use device, a premeasured vial of dilution buffer, a disposable Microsafe tube, and a sample cup.

Each device contains a reagent strip with all the critical components for the assay. Dilution is performed by collecting a sample from an aspirated synovial fluid specimen using the disposable Microsafe tube and adding the sample to the

premeasured dilution buffer. Three full, free-falling drops of the diluted sample are then added to the test device to begin the testing process. Cellular material is removed by the first pad. The solution then migrates to the buffering pad and mixes with the gold conjugate that has been labelled with an anti-alpha defensin antibody. The test mixture then migrates across the test line and the control line. A test result line will form if the level of alpha defensin in the sample is greater than the cut-off concentration. A control line will form to confirm that the solution has properly flowed across the device. Results can be read between 10 to 20 minutes.(Package insert: Synovasure Alpha Defensin Lateral Flow Test Kit. Zimmer Biomet; M40004 V 8, 01/2024)

PDF Report
No

Day(s) Performed
Monday through Friday, Sunday

Report Available
Same day/1 day

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
83518

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ALDEF	Alpha Defensin, Synovial Fluid, LFA	94718-4

Result ID	Test Result Name	Result LOINC® Value

607711	Alpha Defensin, Synovial Fl, LFA	94718-4
JOINT	Is this for a prosthetic joint?	107578-7
ADSRC	Alpha Defensin Source	72923-6