# Test Definition: LDAI

Progentec aiSLE DX Lupus Disease Activity Index, Plasma

## Overview

### Useful For

Aiding in the assessment of current systemic lupus erythematosus disease activity when used in conjunction with standard clinical assessment

### Highlights

This advanced biomarker-based blood test measures current disease activity and helps to support clinicians in the assessment of treatments for patients with systemic lupus erythematosus.

### Method Name

Immunoassay

### NY State Available

No

## Specimen

### Specimen Type

Plasma

### Ordering Guidance

This test is intended to be ordered for adult patients. If the test is ordered for a patient younger than 18 years testing will be canceled.

If ordering this test with LFRI / Progentec aiSLE DX Lupus Flare Risk Index, Plasma, **each test must be on a separate order number**; they **cannot** share an order number.

### Shipping Instructions

**Specimen must be shipped frozen.** Testing will be canceled if received ambient or refrigerated.

### Specimen Required

**Supplies**: Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube**: Yellow top (ACD solution A)
**Submission Container/Tube**: Plastic vial
**Specimen Volume**: 1 mL Plasma
**Collection Instructions:**
1. Centrifuge at 1500 x *g* for 20 minutes.
2. Aliquot plasma into plastic vial.
3. Freeze specimen within 2 hours of collection.

**Note**: Critical frozen. Separate specimens must be submitted when multiple tests are ordered.

### Specimen Minimum Volume

Plasma: 0.5 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Heat-treated specimen | Reject |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Plasma | Frozen | 74 days | |

## Clinical & Interpretive

### Clinical Information

This test measures the concentrations of a set of immune modulatory soluble mediators, including cytokines, chemokines, and soluble receptors shown to be associated with current disease activity in plasma of patients with systemic lupus erythematosus.(1) A proprietary weighted algorithm is used to calculate the patient's disease activity index (DAI) score ranging from -100 to +100. The magnitude of the score indicates the patient's current level of disease activity. Decision curve analysis was used to define cutoff values for low (<-18.3), medium (-18.3 to 24.6), and high (>24.6) activity scores. Applying these cutoff values a maximum sensitivity of 100% and maximum specificity of 93% was observed for the DAI. Additional complementary analyses demonstrated that a patient with a positive score is almost 3 times more likely to have active disease than patient with a negative score (odds ratio =2.9, p<0.0001). A patient with a positive score is over 7 times more likely to have clinically and serologically active (CASA) disease than a patient with a negative score (quiescent disease) with odds ratio of 7.2 (p<0.0001).

The following 10 biomarkers are analyzed and used to calculate the DAI test score: B-lymphocyte stimulator (BLyS/BAFF), CXC motif chemokine ligand 10 (CXCL10/IP-10), interferon alpha-2 (IFN-a2), INF gamma (IFN-y), interleukin-4 (IL-4), IL-7, IL-10, IL-15, osteopontin (OPN), tumor necrosis factor-related apoptosis-inducing ligand (TRAIL). These proteins represent several major immune pathways including chemokine/adhesion (CXCL10/IP-10), homeostasis (IL-7, IL-15), innate (IFN-a2), regulatory (IL-10), Th1-type (IFN-y, OPN), Th-2-type (IL-4), and the TNFR superfamily (BlyS/BAFF, TRAIL).

### Reference Values

C-X-C Motif Chemokine Ligand 10 (CXCL10/IP-10): 37-343 pg/mL
Interferon gamma (IFN-y): 0.34-7.80 pg/mL
Interleukin-15 (IL-15): 1.00-4.30 pg/mL

Interleukin-4 (IL-4): 1.000-3.200 pg/mL
Interferon alpha-2 (IFNa-2): 3.600-8.300 pg/mL
Interleukin-10 (IL-10): 1.20-9.50 pg/mL
Interleukin-7 (IL-7): 1.10-12.00 pg/mL
TNF-Related Apoptosis-Inducing Ligand (TRAIL): 26-120 pg/mL
B Lymphocyte Stimulator (BAFF)/BLys: 370-995 pg/mL
Osteopontin (OPN): 14,958-95,972 pg/mL

### Interpretation

This test measures the concentrations of 10 blood plasma proteins. An algorithm is applied to these concentrations to calculate a disease activity index score that ranges from -100 to +100 with the magnitude indicating the patient's current systemic lupus erythematosus disease activity.

### Cautions

Clinical interpretation of individual biomarker levels has not been established but may be indicative of the pathophysiology of immune, infectious, or inflammatory pathologies.

### Clinical Reference

1. Munroe M, Blankenship D, DeFreese D, et al. Abstract 0554: A refined disease activity immune index informed by select immune mediators that characterizes clinical disease activity in systemic lupus erythematosus. Arthritis Rheumatol. 2023;75(S9):1089-1092
2. Munroe M, DeJager W, Macwana S, et al. Abstract 1803: Ability of innate, adaptive, and TNF-superfamily immune pathways to characterize disease activity and inform a refined lupus disease activity immune index in a confirmatory cohort of SLE patients. Arthritis Rheumatol. 2020;72(S10)
3. Munroe M, Guthridge J, Lu R, et al. Abstract 1693: Innate, adaptive, and TNF-Superfamily immune pathways inform a lupus disease activity immune index that characterizes disease activity in SLE. Arthritis Rheumatol. 2018;70(S9)

## Performance

### Method Description

Analyte specific antibodies are pre-coated onto a microfluidic Simple Plex cartridge. Samples are diluted and added to the cartridge. The sample runs through a microfluidic channel that binds the protein of interest. The Ella platform washes off any unbound analyte and adds a detection reagent. Each channel utilized for analyte capture encompasses three glass nano reactors coated with a capture antibody, providing analyte values in triplicate. A calculated analyte value is then generated from the factory-calibrated standard curve that is built into every cartridge.

### PDF Report

Referral

### Day(s) Performed

Thursday

### Report Available

1 to 14 days

### Specimen Retention Time

7 days

### Performing Laboratory Location

Progentec Diagnostics, Inc

## 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

Progentec Diagnostics developed and characterized this test. It is intended for clinical use and the reported results should be interpreted in relation to each patient's clinical condition and medical history. This test is a laboratory developed test (LDT) and is not cleared by the US Food and Drug Administration (FDA). Progentec Diagnostics Clinical Laboratory is certified under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 and accredited by the College of American Pathologists to perform high complexity clinical testing.

### CPT Code Information

0446U

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| LDAI | Lupus Disease Activity Index, P | Not Provided |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| DA1 | CXC Motif Ligand 10 (CXCL10)(IP-10) | Not Provided |
| DA2 | Interferon gamma (IFN-g) | Not Provided |
| DA3 | Interleukin 15 (IL-15) | Not Provided |
| DA4 | Interleukin 4 (IL-4) | Not Provided |
| DA5 | Interferon alpha 2 (IFN-a2) | Not Provided |
| DA6 | Interleukin 10 (IL-10) | Not Provided |
| DA7 | Interleukin 7 (IL-7) | Not Provided |
| DA8 | TNF-Relat Apop-Induc Ligand (TRAIL) | Not Provided |
| DA9 | B Lymphocyte Stimulator (BAFF) BLyS | Not Provided |
| DA10 | Osteopontin (OPN) | Not Provided |
| DA11 | aiSLE DX DAI Score | Not Provided |

| | | |
|---|---|---|
| DA12 | Comments | Not Provided |