

Final Report

PATIENT INFORMATION:

Name: Sample, Patient
Patient ID: 080804888
DOB: 06/05/1980
Age: 43
Gender: F

SPECIMEN INFORMATION:

Accession#: 4888 (O118000338)
Date Collected: 06/20/2023 11:35 AM
Date Accessioned: 06/21/2023 11:30 AM
Date Reported: 06/22/2023

CLINIC INFORMATION:

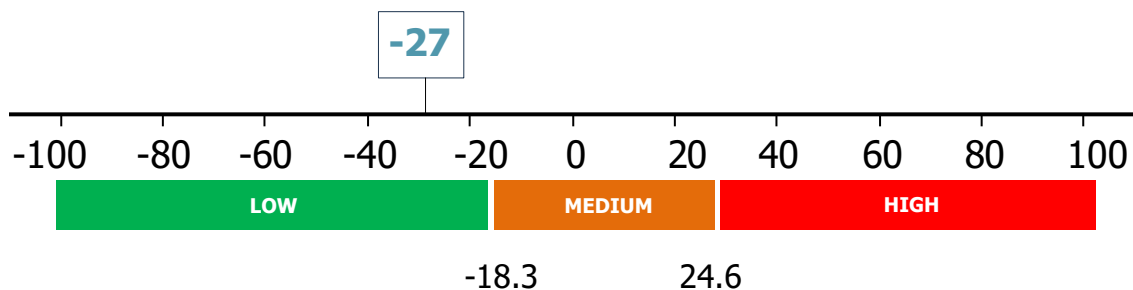
Organization: Rheumatology Clinic
Location Name: Rheumatology Clinic
Provider: Doctor Doctor, MD

Requisition Comments

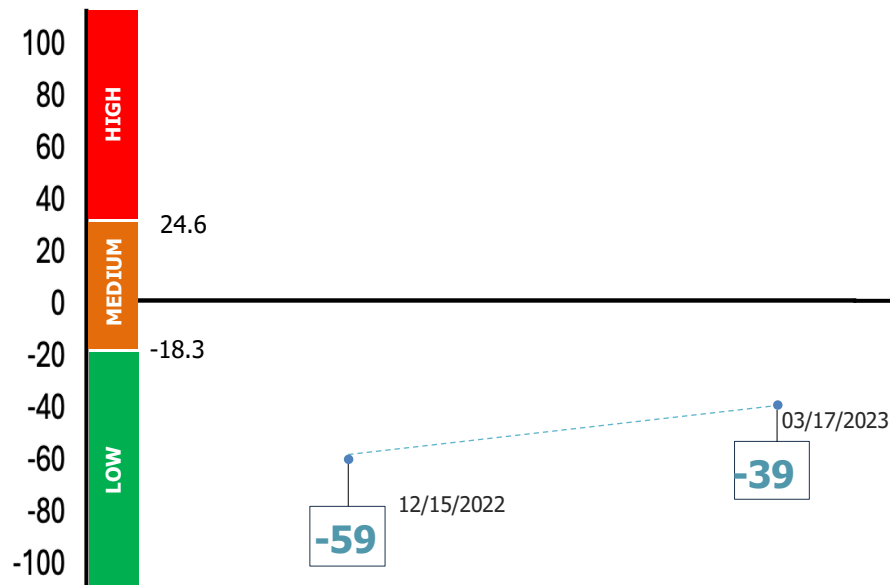
MRN: X100461009

Current Test Result

aiSLE DX DAI Score



aiSLE DX DAI Score History



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Test Description

The aiSLE*DX Disease Activity Index (DAI) test measures the concentrations of 10 blood plasma proteins. A proprietary weighted algorithm is used to calculate a disease activity score that ranges from -100 to +100. The magnitude of the score indicates the patient's current level of disease activity.

Decision curve analysis was used to stratify the risk levels as: Low (<-18.3), Medium (-18.3 to 24.6), and High (>24.6). Applying these cut-offs:

- A maximum sensitivity of 100% and maximum specificity of 93% was observed for the DAI.
- Additional complementary analyses showed that a patient with a positive score is almost 3 times more likely to have active disease than a patient with a negative score (Odds Ratio = 2.9, p=0.0001).
- A patient with a positive score is over 7 time more likely to have clinically and serologically active disease (CASA) than a patient with a negative score (quiescent disease; Odds Ratio = 7.2, p = 0.0001).

Test results are intended to aid in the assessment of disease activity in lupus patients when used in conjunction with standard clinical assessment.

* aiSLE is a registered trademark of Progentec Diagnostics, Inc.

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aiSLE DX DAI Cytokine Panel Summary

Biomarker Name	Results (pg/mL)	Ref. Interval* (pg/mL)	Flag**
01) C-X-C Motif Chemokine Ligand 10 (CXCL10/IP-10)	76	37-343	Normal
02) Interferon-Gamma (IFN-g)	0.60	0.34-7.80	Normal
03) Interleukin-15 (IL-15)	1.30	1.00-4.30	Normal
04) Interleukin-4 (IL-4)	1.80	1.000-3.200	Normal
05) Interferon-Alpha-2 (IFN-a2)	4.00	3.600-8.300	Normal
06) Interleukin-10 (IL-10)	1.50	1.20-9.50	Normal
07) Interleukin-7 (IL-7)	2.40	1.10-12.00	Normal
08) TNF-Related Apoptosis-Inducing Ligand (TRAIL/TNSF10)	52	26-120	Normal
09) B Lymphocyte Stimulator (BAFF/BlyS)	468	370-995	Normal
10) Osteopontin (OPN)	15250	14958-95972	Normal
aiSLE DX DAI Score	- 27		

*Reference intervals were determined from the analysis of 120 apparently healthy control individuals consisting of European Americans (66%), African Americans (23%) and other races and ethnicities (11%) analyzed in Progentec Diagnostics laboratory. **High, Normal and Low is provided as a guide relative to this healthy control population measured with this immunoassay method.

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

Progentec Diagnostics testing uses an Immunoassay to measure the concentrations of plasma proteins. 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). FDA clearance is not currently required for LDTs. 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.