Progentec Diagnostics, Inc.
655 Research Parkway, Suite #538
Oklahoma City, OK 73104
Phone: (833) 587-8739
Fax: (833) 335-3314

CLIA#: 37D2153168 CAP#: 8352739

Final Report

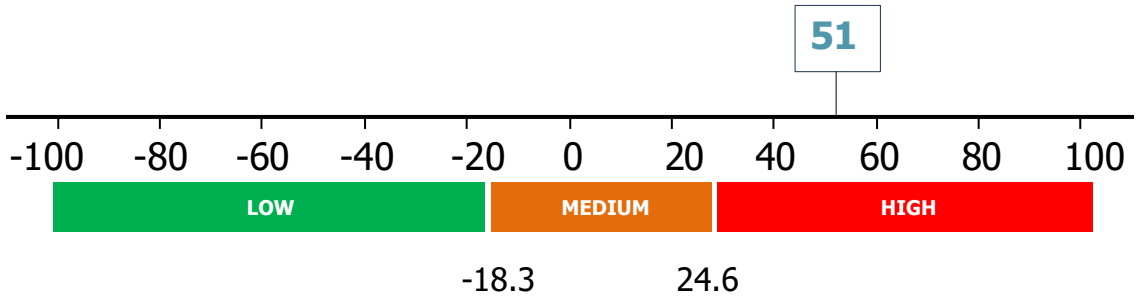
PATIENT INFORMATION:		SPECIMEN INFORMATION:		CLINIC INFORMATION:	
Name:	Sample, Patient	Accession#:	4777 (O118000355)	Organization:	Rheumatology Clinic
Patient ID:	080804777	Date Collected:	06/20/2023 10:00 AM	Location Name:	Rheumatology Clinic
DOB:	05/01/1985	Date Accessioned:	06/21/2023 11:20 AM	Provider:	Doctor Doctor, MD
Age:	38	Date Reported:	06/22/2023		
Gender:	F				

Requisition Comments

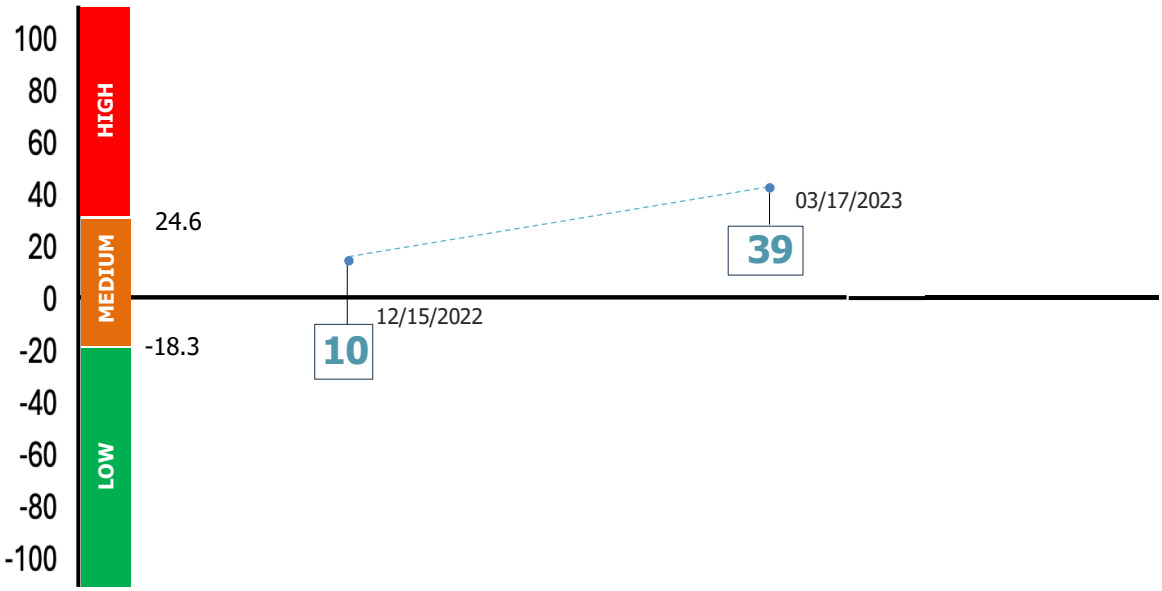
MRN: X100461011

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.

progentec Diagnostics

aiSLE DX

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CLINIC INFORMATION:

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

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)	890	37-343	HIGH
02) Interferon-Gamma (IFN-g)	21.00	0.34-7.80	HIGH
03) Interleukin-15 (IL-15)	51.00	1.00-4.30	HIGH
04) Interleukin-4 (IL-4)	6.00	1.000-3.200	HIGH
05) Interferon-Alpha-2 (IFN-a2)	29.00	3.600-8.300	HIGH
06) Interleukin-10 (IL-10)	19.00	1.20-9.50	HIGH
07) Interleukin-7 (IL-7)	16.00	1.10-12.00	HIGH
08) TNF-Related Apoptosis-Inducing Ligand (TRAIL/TNSF10)	135	26-120	HIGH
09) B Lymphocyte Stimulator (BAFF/BlyS)	4842	370-995	HIGH
10) Osteopontin (OPN)	127988	14958-95972	HIGH
aiSLE DX DAI Score	51		

*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.