progentec Diagnostics

aiSLE DX

Final Report

Progentec Diagnostics, Inc.
655 Research Parkway, Suite #538
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CLIA#: 37D2153168 CAP#: 8352739

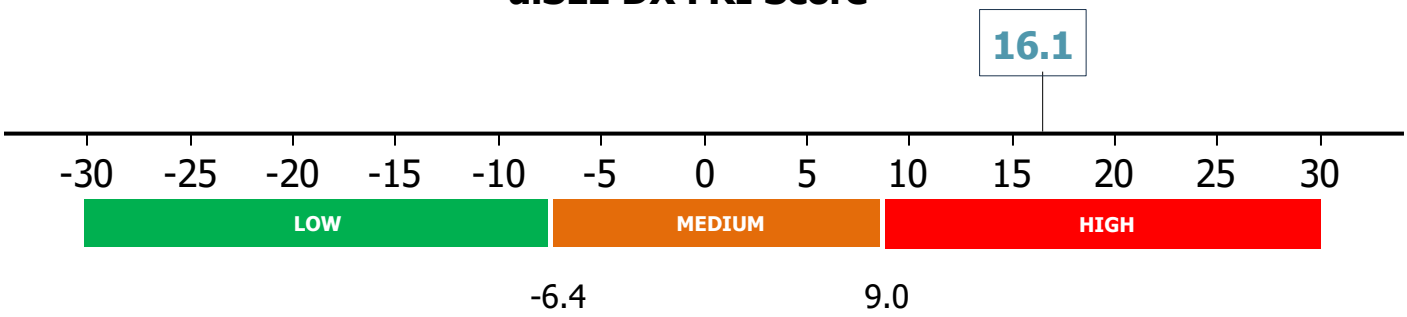
PATIENT INFORMATION:		SPECIMEN INFORMATION:		CLINIC INFORMATION:	
Name:	Sample, Patient	Accession#:	4321 (O118000339)	Organization:	Rheumatology Clinic
Patient ID:	081234777	Date Collected:	06/20/2023 10:00 AM	Location Name:	Rheumatology Clinic
DOB:	05/01/1985	Date Accessioned:	06/21/2023 11:20 AM	Provider:	Doctor Doctor, MD
Age:	38	Date Reported:	06/22/2023		
Gender:	F				

Requisition Comments

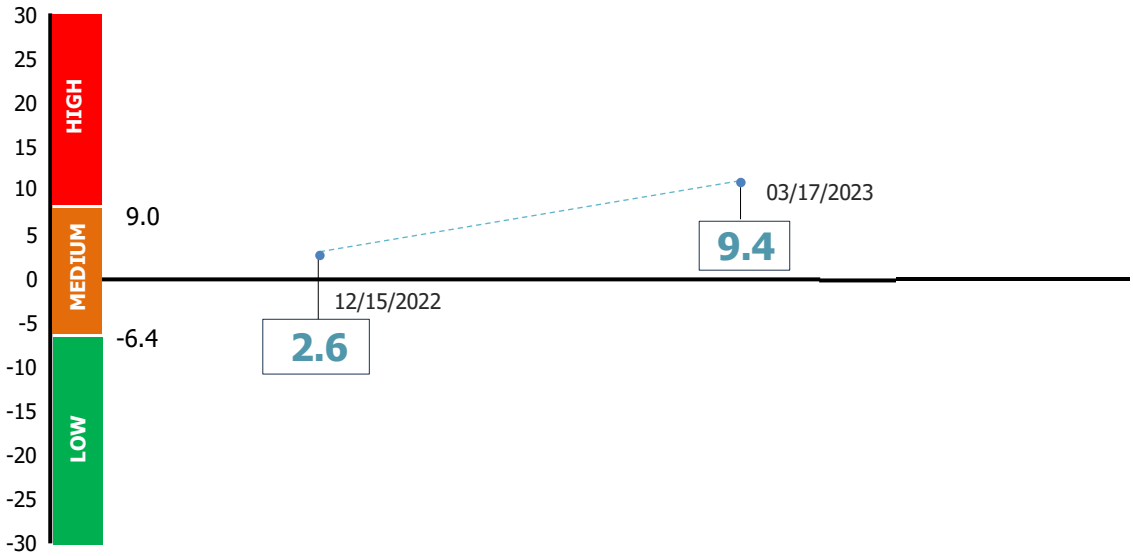
MRN: X10061004

Current Test Result

aiSLE DX FRI Score



aiSLE DX FRI Score History



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Test Description

The aiSLE*DX Flare Risk Index (FRI) test measures the concentrations of 11 blood plasma proteins. A proprietary weighted algorithm is used to calculate a flare risk score that ranges from -30 to +30. The magnitude of the score indicates the likelihood of the patient experiencing a lupus flare in the next 12 weeks.

Decision curve analysis was used to stratify the risk levels as: Low (< - 6.4), Medium (- 6.4 to 9.0), and High (>9.0). Applying these cut-offs:

- A maximum sensitivity of 97% and maximum specificity of 98% was observed for the FRI.
- Additional complementary analyses showed that a patient with a positive score is over 5 times more likely to flare in the next 12 weeks than a patient with a negative score (Odds Ratio = 5.2, p=0.0001).
- A patient with a positive score greater than 9.0 is highly likely to flare (Odds Ratio = 9.3, p=0.0233) while a patient with a negative score less than - 6.4 is not likely to flare (Odds Ratio = 18.0, p = 0.0003).

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

Munroe ME, et al. A Flare Risk Index Informed by Select Immune Mediators in Systemic Lupus Erythematosus. Arthritis Rheumatol. 2023 May;75(5):723-735.

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aiSLE DX FRI Cytokine Panel Summary

Biomarker Name	Results (pg/mL)	Ref. Interval* (pg/mL)	Flag**
01) Monocyte chemoattractant protein-1 (MCP1)/CCL2	600	54-368	HIGH
02) Interleukin-5 (IL-5)	2.500	0.260-2.000	HIGH
03) Interleukin-17A (IL-17A)	15.50	2.100-11.000	HIGH
04) Interleukin-7 (IL-7)	15.00	1.10-12.00	HIGH
05) Interleukin-4 (IL-4)	6.50	1.000-3.200	HIGH
06) Tumor necrosis factor-a (TNF-a)	20.50	1.80-12.00	HIGH
07) Monocyte chemoattractant protein-3 (MCP3)/CCL7	22.50	0.82-16.00	HIGH
08) B Lymphocyte Stimulator (BAFF)/ BLyS	8000	370-995	HIGH
09) Osteopontin (OPN)	127000	14958-95972	HIGH
10) Tumor necrosis factor receptor 1 (TNFR1)/TNFRSF1A	4000	617-1595	HIGH
11) Tumor necrosis factor receptor 2 (TNFR2)/TNFRSF1B	5000	1079-3589	HIGH
aiSLE DX FRI Score	16.1		

*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.