Beta-2 Glycoprotein 1 Antibodies

September 2011

B2GP1 antibodies can aid in the diagnosis of certain autoimmune disease thrombotic disorders.

Legacy Laboratory Services commenced testing for Beta-2 glycoprotein 1 antibodies (B2GP1) on August 15, 2011. The presence of B2GP1 antibodies can be used in conjunction with clinical findings and other laboratory tests as an aid in the diagnosis of certain autoimmune disease thrombotic disorders including those secondary to systemic lupus erythematosus or primary antiphospholipid syndrome. Performed in the proper clinical context, positive B2GP1 IgG and/or IgM results, on at least two occasions and at least 12 weeks apart, suggests antiphospholipid syndrome. Because transient positive tests may occur, diagnosis should NOT be based on a single specimen.

Testing is performed using INOVA QUANTA Lite™ B2GP1 enzyme-linked immunosorbent assays (ELISA) for the detection of B2GP1 antibodies. Results are reported semi quantitatively in standard B2GP1 units (SGU for IgG and SMU for IgM and, if desired, SAU for IgA).

The manufacturer's reported test performance characteristics are summarized in Table 1. For ordering options and specimen requirements, please see Table 2.

Table 1 Manufacturer's Reported Test Performance

Patient Group	% Positive B2GP1 Ab (Persons tested)		
	IgG	IgM	IgA
SLE + APS	97.2 (37)	72.8 (81)	71.4 (14)
Primary APS	93.3 (15)	60.0 (80)	54.2 (48)
Sensitivity	***96.2***	***66.5***	***58.1***
SLE (No APS)	5.8 (34)	11.7 (60)	29.2 (24)
Rheumatoid Arthritis	0 (17)	0 (15)	ND
Infectious group	0 (81)	3.0 (133)	0 (30)
Polyhypergammaglobulinemia	0 (7)	ND	ND
Normal	0.4 (256)	2.6 (313)	3.2 (215)
Specificity	***99.6***	***96.4***	***94.8***

SLE = Systemic Lupus Erythematosus.
APS = Antiphospholipid syndrome.
Infectious group was mostly those with positive syphilis serology.
ND = Not done

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Table 2 Ordering Options

Test Name	Antibodies Detected	Specimen Requirements	Testing Performed	Turnaround	Normal Range
Beta-2 Glycoprotein 1 IgG IgM	IgG and IgM, detected and reported separately	2.0 mL serum collected in gold SST. Transport refrigerated.	Tuesday, Thursday	Same day as performed	IgG: 0-20 SGU IgM: 0-20 SMU
Beta-2 Glycoprotein 1 IgA	IgA	2.0 mL serum collected in gold SST. Transport refrigerated.	Tuesday, Thursday	Same day as performed	IgA: 0-20 SAU

For specific collection, transport and testing information, refer to Beta-2 Glycoprotein on our website at www.legacyhealth.org

References:

Miyakis, S., et al., International consensus statement on an update of classification criteria for definite antiphospholipid syndrome (APS). Journal of Thrombosis and Haemostasis, 4: 295-306

INOVA QUANTA Lite™ Beta 2 GPI ELISA package inserts (IgG, IgM, and IgA).