

technical update

Anti-Beta 2 Glycoprotein I Proposal for Interpretive Ranges

For *in vitro* diagnostic use

With many new semi-quantitative diagnostic tests, reporting results as positive or negative with a unit value included, may not provide enough information for a physician to assess a patient's current clinical status. This may be even more important with autoimmune testing, including anti-phospholipid antibody ELISAs. Previously, documents have been published suggesting interpretive ranges for the Anti-Cardiolipin (aCL) assays. Now, with the use of the DiaPharma Anti-Beta 2 Glycoprotein I (aB2GPI) IgG, IgM, and IgA assays, laboratorians are requesting interpretive ranges in a similar format for these tests. In response, a large number of samples (n = 393) from various groups of patients were tested, both with and without clinical history (based on physician diagnosis and patient history of thrombosis), for anti-B2GPI antibodies to determine appropriate interpretive ranges. Patient groups included in this study are as follows:

- Healthy blood donors (n=121)
- Syphilis (n = 41)
- Progressive Systemic Sclerosis (PSS) (n = 42)
- Rheumatoid Arthritis (RA) (n = 42)
- Miscellaneous Autoimmune (n = 86)
- Unselected SLE (n = 40)
- SLE with thrombosis (Secondary APS) (n = 12)
- Primary antiphospholipid syndrome (APS) (n = 9)

These samples were tested for IgG, IgM, and IgA autoantibodies using the DiaPharma Anti-B2GPI ELISA test kits. Assays were performed per package insert instructions. Results were reported in G, M, and A units respectively. Each assay has a cutoff of 20 units and a reportable range of 0 to 200 units. Based on the results from this testing, the following interpretive ranges are proposed:

Ranges	Units
Normal	0 - 20
Low Positive (+)	21 - 50
Moderate Positive (+)	51 - 100
High Positive (+)	>100

The distribution of test results showed good discrimination between the patient groups. The results for each isotype, including the number of positives in each test population are presented in the following tables:

IgG aB2GPI population	Mean Value G units	Total % positive	Recovery (%) by Range			
			normal	low positive	moderate positive	high positive
Healthy	2.1	0	100%	0	0	0
Syphilis	3.9	2%	98%	0	2%	0
PSS	2.1	2%	98%	2%	0	0
RA	2.0	0	100%	0	0	0
Autoimm.	31.9	27%	73%	7%	3%	17%
Uns. SLE	24.5	23%	77%	8%	0	15%
SLE w/ throm.	69.0	58%	42%	8%	8%	42%
Primary APS	111.0	89%	11%	0	22%	67%

IgM aB2GPI population	Mean Value A units	Total % positive	Recovery (%) by Range			
			normal	low positive	moderate positive	high positive
Healthy	7.7	8%	92%	7%	1%	0
Syphilis	9.7	4%	96%	2%	0	2%
PSS	10.1	8%	93%	5%	2%	0
RA	11.1	12%	88%	7%	5%	0
Autoimm.	18.6	22%	78%	10%	7%	5%
Uns. SLE	12.8	18%	82%	13%	5%	0
SLE w/ throm.	24.5	42%	58%	25%	17%	0
Primary APS	32.7	33%	67%	0	22%	11%

IgA aB2GPI population	Mean Value M units	Total % positive	Recovery (%) by Range			
			normal	low positive	moderate positive	high positive
Healthy	6.9	4%	96%	4%	0	0
Syphilis	3.9	5%	95%	5%	0	0
PSS	2.1	5%	95%	5%	0	0
RA	2.0	15%	85%	13%	2%	0
Autoimm.	49.1	27%	73%	5%	4%	18%
Uns. SLE	42.6	36%	64%	13%	5%	18%
SLE w/ throm.	105.6	67%	33%	17%	0	50%
Primary APS	132.4	78%	22%	0	11%	67%

As shown in these tables, the mean value and positive rate for all three isotypes, IgG, IgM, and IgA, is higher in clinically relevant patient groups. In addition, more samples were recovered in the moderate and high positive ranges in these groups.

In the study, test results showed a high clinical association with the IgA anti-B2GPI isotype, consistent with literature reports and with previous studies. This data supports the

importance of IgA anti-B2GPI testing. Hopefully the data shown here and the proposed interpretive ranges will provide useful guidelines for the clinical interpretation of anti-B2GPI results.

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