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Memo No. 2019-014
Date: 30-Apr-2019
Memo To: Clients
Re: **Test Change – β2 Glycoprotein 1 Antibody, Serum**

Effective Wednesday April 24, 2019, the **β2 Glycoprotein 1 Antibody** assay performed at the Ottawa Hospital has changed from being performed on the Biorad to being performed on the INOVA BioFlash. The assay is a semi-quantitative one step chemiluminescent immunoassay.

Specimen requirements: Serum only; plasma not accepted.

Handling: Unchanged.

Reference ranges and units: both have changed:

	Old Reference Range	Old Units	New Reference Range	New Units
B2GP1 IgG	<= 11	G Units	<= 20	CU
B2GP1 IgM	<= 18	M Units	<= 20	CU

ICL HL7 Setup Codes:

(REF Code) unchanged	(RES Codes) new
Order Code: B2GLYAB	Result Code: 62957 B2GP1 IgG Result Code: 62958 B2GP1 IgM

The testing laboratory offers the following points to keep in mind when interpreting autoantibody assays:

- Results ≤20 CU are considered "Negative"
- Results >20 CU are considered "Positive"
- Positive cut-off limit for these assays was established by using 250-260 healthy controls. The 20 CU positive cut-off corresponds to the upper 99th percentile as recommended by the International Committee in Sydney (*International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). J Thromb Haemost 2006, 4:295-306*).

- Autoimmune testing is often complicated to interpret both analytically and clinically, and performance of the assay is highly dependent on the antigen preparation used in the assay and on the patient.
- When comparing the previous and new results they follow the same trend, however the numerical values are quite different and should not be directly compared.

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    - It is important to remember that both the previous assay and the new assay are semi-quantitative in nature and some patients will react differently with each assay dependent on the specificity of their autoantibodies.
- Caution should always be used when comparing results from one method to another.
- In general, the higher the autoantibody results the greater the likelihood the result is clinically significant.
  - β2GP1 IgG & IgM antibodies are detected using purified human β2GP1 antigen
  - Analytical evaluation was performed using 60 IgM and 70 IgG specimens and the new assay showed comparable sensitivity and specificity for IgG antibodies, with reduced sensitivity for IgM antibodies. The reduced sensitivity for IgM may be due to false positive results with the previous assay.
  - IgG Anti-β2GP1 antibodies
    - Sensitivity = 88.9%
    - Specificity = 90.0%
  - IgM Anti-β2GP1 antibodies
    - Sensitivity = 37.8%
    - Specificity = 100%

If you have further questions, please contact Client Care at (416) 422-3000 Ext. 300 or info@ICLabs.ca

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