March 27, 2026

IMMUNOLOGY

Anti-Phospholipid Profile

Date effective: April 13, 2026

Clinical Practice Change:

The Shared Health Immunology Laboratory at St Boniface Hospital will be changing its testing platform for Anti-Phospholipid Antibody testing.

Background Information:

The Anti-Phospholipid Profile includes β2-glycoprotein I antibodies (IgG/IgM) and cardiolipin antibodies (IgG/IgM) which are crucial for diagnosing antiphospholipid syndrome (APS). Diagnosis of APS requires a positive test result of either cardiolipin, β2-Glycoprotein or lupus anticoagulant on more than one occasion separated by at least 12 weeks, in addition to either thrombosis, fetal loss, or thrombocytopenia. Only IgG and IgM antibodies are tested as IgA antibodies lack specificity.

Antibody	Frequency in Normal / Healthy Individuals
β2-glycoprotein I IgG	**<1 – 3%**
Cardiolipin IgG	**~5 – 7%**
β2-glycoprotein I IgM	**~2.6% – 5%**
Cardiolipin IgM	**~6% – 9%**

Changes in Test Procedure:

Testing will change from an ELISA to a Chemiluminescent (CLIA) method.

References/Resources:

Test:	Anti-Phospholipid Profile Laboratory Information Manual - APHL		
Delphic Code:	APHL		
Delphic Labels:	CLIA		
Sample:	Serum 1.0 ml (All CLIA tests can be performed on single 1.0ml aliquot)		
Normal Range:	β2-glycoprotein I IgG	0.0 – 20.0	AU/ml
	β2-glycoprotein I IgM	0.0 – 9.9	AU/ml
	Cardiolipin IgG	0.0 – 20.0	GPL U/ml
	Cardiolipin IgM	0.0 – 9.9	MPL U/ml
Availability:	Weekdays (3-5day TAT)		
Requisition:	Immunology Autoimmune Laboratory Requisition		

Patient Impact:

- As no international reference serum exists for antibodies against β2-glycoprotein I or Cardiolipin, the calibration and reporting are in arbitrary units. There is no linear correlation between the CLIA and ELISA methods. Patients pending 12 week follow-up testing should be re-baselined as assay-to-assay variability may be observed for results near established cutoff values. Consistency of testing platform is recommended to mitigate inter-method discordance and support accurate longitudinal assessment.

System Improvements:

1. Improved TAT
2. CLIA often showing higher sensitivity but sometimes lower specificity for IgM

Contact Information:

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