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**Lab Dept:** Serology

**Test Name:** CARDIOLIPIN (IGG, IGM) ANTIBODIES

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***General Information***

**Lab Order Codes:** CARL

**Synonyms:** Phospholipid Antibodies (Cardiolipin Antibodies) IgG and IgM, Serum; Anti-Phospholipid Antibodies; Anticardiolipin Antibodies; Phospholipid Ab (Cardiolipin) IgG and IgM, Serum

**CPT Codes:** 86147 x2 – Cardiolipin (phospholipid) antibody, each Ig class

**Test Includes:** Antibodies to IgM and IgG reported in MPL (IgM Phospholipid Units, Note: 1 MPL unit is 1 microgram of IgM antibody) or GPL (IgG Phospholipid Units, Note: 1 GPL unit is 1 microgram of IgG antibody)

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***Logistics***

**Test Indications:** Useful for evaluation the following clinical situations:

- Unexplained arterial or venous thrombosis
- A history of pregnancy morbidity defined as 1 or more unexplained deaths of a morphologically normal fetus beyond the 10<sup>th</sup> week of gestation, 1 or more premature births before 34 weeks of gestation caused by severe preeclampsia or placental insufficiency, or 3 or more unexplained, consecutive spontaneous abortions before the 10<sup>th</sup> week of gestation with no identifiable maternal hormone or anatomic, of maternal or paternal chromosomal causes
- Presence of unexplained cutaneous circulatory disturbance, eg, livido reticulans or pyoderma gangrenosum
- Presence of a systemic rheumatic disease especially lupus erythematosus
- Unexplained thrombocytopenia or hemolytic anemia
- Possible nonbacterial, thrombotic endocarditis

**Lab Testing Sections:** Serology - Sendouts

**Referred to:** Mayo Medical Laboratories (MML Test: CLPMG)

**Phone Numbers:** MIN Lab: 612-813-6280

STP Lab: 651-220-6550

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 1 - 3 days

**Special Instructions:** N/A

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***Specimen***

<b>Specimen Type:</b>	Blood
<b>Container:</b>	SST (Gold, marble or red)
<b>Draw Volume:</b>	1.5 mL (Minimum: 1.2 mL) blood
<b>Processed Volume:</b>	0.5 mL (Minimum: 0.4 mL) serum
<b>Collection:</b>	Routine venipuncture
<b>Special Processing:</b>	Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial. Store and ship at refrigerated temperatures. Forward promptly.
<b>Patient Preparation:</b>	None
<b>Sample Rejection:</b>	Mislabeled or unlabeled specimens

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***Interpretive*****Reference Range:**

<b>IgG Phospolipid (Cardiolipin) Ab, Serum for All Ages</b>
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<15.0 GPL	Negative
15.0 – 39.9 GPL	Weakly positive
40.0 – 79.9 GPL	Positive
≥80.0 GPL	Strongly positive
<b>IgM Phospholipid (Cardiolipin) Ab, Serum for All Ages</b>	
<15.0 GPL	Negative
15.0 – 39.9 GPL	Weakly positive
40.0 – 79.9 GPL	Positive
≥80.0 GPL	Strongly positive
<p><b>Interpretation:</b> Positive and strongly positive results for phospholipid antibodies (&gt; or =40 GPL and/or MPL) are a diagnostic criterion for antiphospholipid syndrome (APS). Lesser levels of phospholipid antibodies and antibodies of the IgA isotype may occur in patients with clinical signs of APS but the results are not considered diagnostic. Detection of phospholipid antibodies is not affected by anticoagulant treatment.</p> <p><b>Units info:</b>  1 GPL unit is 1 microgram of IgG antibody.  1 MPL unit is 1 microgram of IgM antibody.</p>	

**Critical Values:** N/A

**Limitations:** The immunoassay for phospholipid antibodies does not distinguish between autoantibodies and antibodies produced in response to infectious agents or as epiphenomena following thrombosis. For this reason, a single positive test result is not sufficient to meet accepted serologic criteria for the diagnosis of antiphospholipid syndrome.

Comparative studies and interlaboratory proficiency surveys indicate that results of phospholipid antibody tests can be highly variable and results obtained with different commercial immunoassays may yield substantially different results.

**Methodology:** Enzyme –Linked Immunosorbent Assay (ELISA)

**References:** [Mayo Medical Laboratory Web Page](#) March 2017

**Updates:**

8/9/2005: Change in reference ranges reflecting consensus recommendations for defining results as Positive ( $\geq 40.0$  PL U/mL). Ranges previously defined as for IgM as  $\leq 10$  MPL (Negative), 10.1-29.9 MPL (Weakly positive), 30.0-79.9 MPL (Positive),  $\geq 80.0$  MPL (Strongly positive) and for IgG as  $\leq 15.0$  GPL (Negative), 15.1-29.9 GPL (Weakly positive), 30.0-79.9 GPL (Positive),  $\geq 80.0$  (Strongly positive).

5/7/2012: Mayo test down, temporarily moved to ARUP by Mayo. Note changes in reference ranges.

6/19/2012: Mayo resumed testing in Rochester. Specimens no longer forwarded to ARUP. Note changes in reference range and method. Ref range previously listed as: IgG: 0-14 (Negative), 15-19 (Indeterminate), 20-80 (Low to Medium Positive), 81 or higher (High Positive), IgM: 0-12 (Negative), 13-19 (Indeterminate), 20-80 (Low to Medium Positive), 81 or higher (High Positive)

3/3/2017: Updated reference range with new testing kit.