# Lupus Anticoagulant Panel now includes Cardiolipin and β2-Glycoprotein-I Antibodies

Effective June 27, 2023, Laboratory Alliance of Central New York will offer in-house testing for β2-glycoprotein-I antibodies IgG, IgA and IgM. These tests may be ordered separately or as part of the Lupus Anticoagulant Panel, a comprehensive testing panel to aid in the diagnosis of antiphospholipid syndrome (APS or APLS).

**Clinical Significance:**
APS is a thrombophilic condition marked by the presence of autoantibodies that recognize phospholipid-binding proteins. Clinical manifestations of APS include vascular thrombosis and obstetrical complications, especially recurrent spontaneous miscarriages.

Per the summary of the 2006 Sydney Consensus Statement on Classification Critera for APS[1], APS may be diagnosed if at least one of the following clinical criteria and one laboratory criteria are met:

| Clinical Criteria | Laboratory Criteria |
|---|---|
| • Vascular thrombosis<br>• Pregnancy morbidity | • Lupus anticoagulant (LA) detected in plasma on 2 or more occasions at least 12 weeks apart<br>• Anti-cardiolipin antibody detected in serum or plasma, present at moderate or high levels on 2 or more occasions at least 12 weeks apart<br>• Anti-β2-glycoprotein-I antibodies detected in serum or plasma, present on two or more occasions at least 12 weeks apart. |

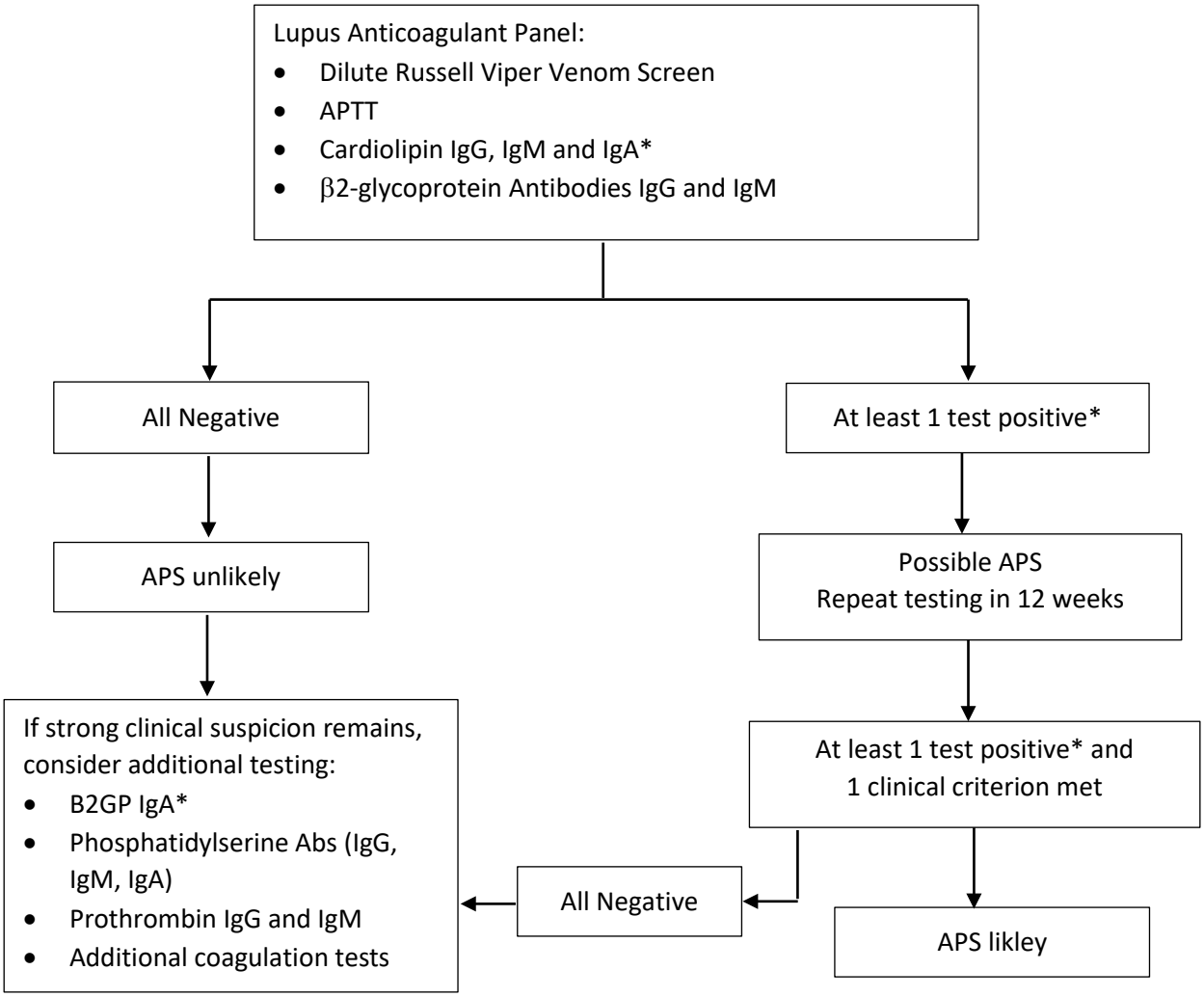
A single negative test cannot rule out APS; it is recommended that a panel of tests be performed to exclude the diagnosis. A positive LA appears to be more specific for APS than an elevated anticardiolipin antibody (aCL). Patients who test positive for all three of the major assays, positive LA, elevated aCL and elevated anti-β2GP, are at markedly increased risk for thrombosis and pregnancy complications.

Asymptomatic general medical or obstetrical populations should not be screened for APS. Testing should be restricted to patients with clinical criteria for APS and to patients with systemic lupus erythematosus.

The Lupus Anticoagulant Panel consists of coagulation-based assays in combination with immunoassays for aCL (IgG, IgM and IgA) and anti-β2GP (IgG and IgM). The recommended testing algorithm for suspected APS is as follows:

**Antiphospholipid Syndrome (APS) Testing**

Clinical Criteria present including vascular thrombosis or unexplained pregnancy loss.




* Cardiolipin IgA and β2-glycoprotein I IgA are non-criteria tests for APS. Positive values should be followed up with hematologist consultation. Treatment decisions should not be made on the basis of positive antiphospholipid IgA values alone.

**Assay Details:**

| Assay | Description | Order Code | CPT Code(s) |
|---|---|---|---|
| Lupus Anticoagulant Panel | Package:<br>• Dilute Russel Viper Venom Screen<br>• APTT<br>• Cardiolipin IgG, IgA, IgM<br>• B2 Glycoprotein IgG, IgM | LUPAN | <br>85613<br>85730<br>86147x3<br>86147x2 |

In addition, APS-associated immunoassays may be ordered separately from the Lupus Anticoagulant Panel, either individually or as panels.

| Assay | Description | Order Code | CPT Code(s) |
|---|---|---|---|
| Cardiolipin IgG, IgA, IgM | Battery | CLABS | 86147x3 |
| Cardioliipin IgG | Test | CLIGG | 86147 |
| Cardiolipin IgA | Test | CLIGA | 86147 |
| Cardiolipin IgM | Test | CLIGM | 86147 |
| B2 Glycoprotein IgG, IgA, IgM | Battery | B2GGAM | 86147x3 |
| B2 Glycoprotein IgG and IgM | Battery | B2GP | 86147x2 |
| B2 Glycoprotein IgG | Test | B2GPG | 86147 |
| B2 Glycoprotein IgA | Test | B2GPA | 86147 |
| B2 Glycoprotein IgM | Test | B2GPM | 86147 |

Assay and specimen details listed in the table below are applicable for any combination of the APS-associated immunoassays.

| | |
|---|---|
| **Method** | Multiplex Bead Immunoassay |
| **Reference ranges** | <20 U/mL is considered negative for each of the APS-associated immunoassays. |
| **Specimen requirements** | One 5mL gold (SST) top tube (preferred)<br>Transport 1 mL serum at 2 - 8°C (minimum 0.5 mL)<br>Lithium heparin or citrate plasma is also acceptable. |
| **Specimen stability** | Refrigerated: 7 days when tightly capped and stored at 2–8°C. |
| **Schedule of testing** | Monday - Friday |

See separate specimen requirements and schedule of testing for APS-associated coagulation testing.

**Reference:** Miyakis S, et al. *J thromb Haemost*. 2006;4:295-306

Questions regarding this test may be directed to Cheryl Haskins, MS, MT(ASCP)SC, Chemistry Special Projects Coordinator at 315-410-7014 or cherylhaskins@lacny.com.

cmh, 5/30/2023