MEMORANDUM

TO: All Physicians

FROM: Katalin Banki, M.D., Director of Core Laboratory

DATE: June 2, 2016

RE: Antiphospholipid Antibody Assays

Four antiphospholipid antibody tests will be performed in-house, in the Special Hematology Laboratory at the Downtown Campus, starting June 7, 2016. IgA tests remain send-out tests for now and have to be ordered separately.

**B2 Glycoprotein IgG and IgM Ab**: can be ordered together as a battery or separately.

**Cardiolipin IgG and IgM Ab**: can be ordered together as a battery or separately.

**Method**: Fully automated, chemiluminescent immunoassay using antigen-coated magnetic particles (HemosIL AcuStar by Instrumentation Laboratory).

- Cut-off values: 20 U/mL
  - 99th percentile of reference population
  - Harmonized for the four tests
  - Correspond roughly to 40 Units in ELISA assays
- There will no longer be an intermediate or low-positive range reported (corresponding to 14-40 Units in ELISA kits, or 95-99th percentiles of normals).
- Results from different manufacturers and different methods may vary significantly and should not be compared. The agreement between the AcuStar method and an ELISA method (REAADS) was between 76.6-89.3% for the four tests.
- This method has increased sensitivity, wider linear range and faster results when compared to ELISA.

**Analytical Ranges:**
- Cardiolipin IgG Ab: 2.6-2024 U/mL
- Cardiolipin IgM Ab: 1.0-774 U/mL
- B2 Glycoprotein IgG Ab: 6.4-6100 U/mL
- B2 Glycoprotein IgM Ab: 1.1-841 U/mL

Performed: Monday through Friday, 7 a.m. - 3 p.m.
Antiphospholipid Antibody Assays

Reporting:  

<20 U/mL (Normal)  
Negative results do not rule out Antiphospholipid Syndrome. Other APL testing should be considered.

≥20 U/mL (Abnormal)  
The persistent presence of ≥20 U/mL antiphospholipid antibody (>99th percentile of the normal range) is a laboratory criterion for the diagnosis of Antiphospholipid Syndrome. Repeat testing at least 12 weeks apart is recommended to establish the persistence presence.

References:  