UPSTATE
UNIVERSITY HOSPITAL
Clinical Pathology - Core Laboratory
Room 3702, University Hospital
750 E. Adams Street
Syracuse, NY 13210

MEMORANDUM

TO: All Physicians

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

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:

Analytical and clinical performance of a new, automated assay panel for the diagnosis of antiphospholipid syndrome. de Moerloose P, Reber G, Musial J, Arnout J. *J Thromb Haemost* 2010; 8:1540-6.

International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, Derksen RH, DE Groot PG, Koike T, Meroni PL, Reber G, Shoenfeld Y, Tincani A, Vlachoyiannopoulos PG, Krillis SA. *J Thromb Haemost* 2016;4(2):295.