



MEMORANDUM

To: OSF System Lab Clients and Partners:

From: James Siebert, M.D. – Laboratory Medical Director

Subject: **Anti- β 2-Glycoprotein I & Anticardiolipin / Antiphospholipid syndrome Ab panel**

Date: November 3, 2016

The antiphospholipid syndrome (APS) is an autoimmune disease defined by the co-occurrence of specific clinical and serological findings. Diagnosis of APS requires persistent positive antiphospholipid antibodies in the setting of clinical manifestations (*e.g.*, thrombosis, pregnancy loss, thrombocytopenia). The initial measurement of these autoantibodies is just the first step in the diagnosis of APS. According to the international consensus statement on classification criteria established in 1999 in Sapporo and updated in 2006 in Sydney, persistently elevated levels of specific antiphospholipid antibodies are required for the diagnosis of APS.

Beginning November 28, 2016 the OSF System Laboratory will change from enzyme linked immunosorbent assay (ELISA) for the detection of antiphospholipid antibodies to a comprehensive antiphospholipid antibody panel on the BioPlex® 2200 multiplex flow cytometry platform (Bio-Rad Laboratories, Hercules, CA, USA) to screen for APS in patients with a clinical occurrence such as thrombosis or pregnancy loss. The BioPlex® 2200 is a fully automated Luminex-based system developed for high-throughput simultaneous analysis of autoimmune analytes in a single tube. The advantages of the BioPlex include a shorter turnaround time, detection of multiple antibodies simultaneously, and less inter-observer variability, while minimizing phlebotomy for patients.

LAB4656 is a new test code for ordering the APS screening panel on the BioPlex® 2200. The new panel includes: anti- β 2-Glycoprotein I (β 2GPI), Anticardiolipin, and lupus anticoagulant. The new APS screening panel was created in accord with the 2006 revised laboratory classification criteria for the diagnosis of APS that strongly recommend anti- β 2-Glycoprotein I (β 2GPI) antibody testing be performed on all requests for APS screening (even if only antibodies are requested).¹ The consensus guidelines on APS testing also recommend that anti- β 2GPI IgG specifically be performed when the β 2GPI antibody isotype is not specified.¹ Unfortunately, the current menu of APS test options is both confusing and time consuming for physicians and healthcare providers to navigate. We have consolidated the menu to three simple APS test options (see Table 1 - on page 2) based on the consensus guidelines for APS testing.¹

The APS panel on the BioPlex® 2200 is an excellent screening test for APS, with a high level of diagnostic accuracy and more rapid and consistent results than ELISA based serologies.²

ANTIBODY	Test Code
APS screening panel (β 2GPI; Anticardiolipin; lupus anticoagulant)	LAB4656
Anti- β 2-Glycoprotein I IgA, IgG & IgM	LAB4643
Anticardiolipin IgA, IgG, & IgM	LAB722

Table 1. Antiphospholipid syndrome test options and corresponding LAB test codes

Any questions or concerns may be addressed to your OSF clinical client representative or to:

John Farrell, MD – Medical Director of Clinical Microbiology & Serology Labs
 OSF System Laboratory
 (309) 624-9127

1. Miyakis S, Lockshin MD, Atsumi T, Branch DW, Brey RL, Cervera R, et al. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). Journal of Thrombosis and Haemostasis. 2006;4(2): 295–306.
2. Tozzoli R, Villalta D. Autoantibody profiling of patients with antiphospholipid syndrome using an automated multiplexed immunoassay system. Autoimmun Rev. 2014 Jan;13(1):59-63.