To: Penn Medicine Physicians and Staff

Date: August 10, 2020

From: Eline T. Luning Prak, MD, PhD
Joyce Gonzalez, BS, M(ASCP)
Malek Kamoun, MD, PhD

Re: Revisions to Confirmatory Testing for the Diagnosis of Lyme Disease

Beginning on August 17, 2020, Penn Medicine Pathology and Laboratory Medicine will change its procedures for confirmatory testing for Lyme disease. This is an interim change until new assay kits are available for in-house testing. The order codes for the screening assay and tube type will not change. However, the analytical methods and some of the test reporting will be different for the confirmatory assays (please see **Figure**).

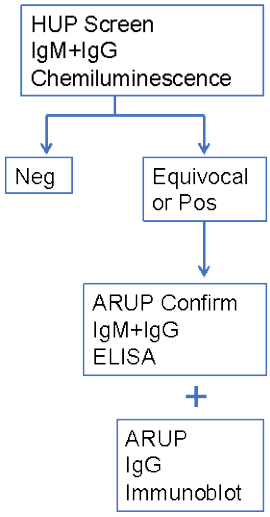
Interim Method

HUP Screen
(IgG +IgM,
Chemiluminescence)

ARUP Confirm
(IgM+IgG, ELISA)

ARUP Confirm
(IgG, Immunoblot)

Interim Serum Testing Algorithm



Interim Serum Results Interpretation

HUP Screen	ARUP ELISA	ARUP IB	Assay Interpretation
Neg	NA	NA	Negative
Eq/Pos	Neg	Neg	Negative
Eq/Pos	Pos	Neg	Positive (Early)
Eq/Pos	Pos	Pos	Positive
Eq/Pos	Neg	Pos	Positive

Eq/Positive = equivocal or positive
NA = not applicable (not performed)
IB = immunoblot

As before, the serum screening assay will be performed at HUP on the DiaSorin LIAISON XL chemiluminescent analyzer and detects IgM and IgG antibodies to the Lyme VlsE (variable major protein-like sequence, expressed) antigen, derived from *B. burgdorferi* and *B. garinii*. The lab will now refer all presumptive positive and equivocal results for additional confirmatory testing to ARUP instead of to Quest, because Quest is discontinuing the immunoblot. The two confirmatory assays are: (1) an ELISA that detects IgM and IgG antibodies that bind to bacterial lysate and (2) an immunoblot for IgG antibody. There will no longer be separate antibody isotyping (IgM, IgG, IgA). As before, testing for antibodies to *B. burgdorferi* in CSF will require a positive serum assay result.

For clinical questions related to this change, please contact the Immunology Resident at 215-980-9871. For operational questions related to this change, please contact Joyce Gonzalez at Joyce.Gonzalez@pennmedicine.upenn.edu or 215-662-6023.