UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

To: Penn Medicine Physicians and Staff

Date: 4/17/2020

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

Re: New assay methods for Toxoplasmosis IgG, Rubella IgG and Lyme IgG/IgM

Beginning on April 21, 2020, Penn Medicine Pathology and Laboratory Medicine will change these current antibody assay methods: Toxoplasmosis IgG, Rubella IgG and Lyme IgG/IgM. These assays will now be performed on the DiaSorin Liaison XL chemiluminescent analyzer. Validation studies showed excellent correlation between the current and new methods.

Toxoplasmosis IgG antibody assay

The reference range and units of measure have changed from a positive cutoff of >= 1:64 result for the old assay, to >= 1.00 IV for the new assay.

Interpretive information for the new assay will be as follows:

Negative: <7.2 IU/ml

Equivocal: >=7.2 IU/mL to <8.8 IU/ml

Positive:>= 8.8 IU/mL

Assay performance characteristics have not been established for neonatal specimens or infants.

Rubella IgG antibody assay

The reference range and units of measure have changed from a negative or positive result for the old assay, to >= 1.00 IV for the new assay.

Interpretive information for the new assay will be as follows:

Negative: <0.90 IV

Equivocal: >=0.90 to <1.00 IV

Positive:>=1.00 IV

Lyme IgG/IgM antibody assay

The reference range and units of measure have changed from a positive cutoff of >1.19 ISR for the old assay, to >= 1.10 IV for the new assay.

Interpretive information for the new assay will be as follows:

Negative: < 0.9 IV

Indeterminate: >=0.90 IV to < 1.10 IV

Positive:>= 1.10 IV

All indeterminate and positive samples for Lyme will be sent out to a reference laboratory for confirmatory Enzyme immunoassay and IgG Western Blot.

The order codes and tube type (SST) will not change.

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.