UPSTATE
UNIVERSITY HOSPITAL
Clinical Pathology - Core Laboratory
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MEMORANDUM

TO: All Physicians

FROM: Katalin Banki, M.D., Director of Core Laboratory
Stephen Gwilt, MS, MT(ASCP) SH, SC

DATE: March 16, 2016

RE: Updated Lyme Disease Testing

Lyme disease testing will be updated on March 28, 2016 in the Clinical Laboratory at the Downtown Campus. Following the manufacturer's recommendation, the first step in the testing, the VIDAS ELISA assay, will change:

1. IgG and IgM antibodies will be measured and reported in separate assays. (Until now the assay detected them together and was positive if either or both IgG and IgM Lyme antibodies were present.)
   - This might provide more specific information about the disease stage, as IgM antibodies appear earlier.
2. Interpretation:
   - IgG assay reported as: Negative, Positive
   - IgM assay reported as: Negative, Equivocal, Positive
3. Both assays will have recombinant chimeric proteins instead of native antigens as their targets, and will include epitopes from all pathogenic strains (Borrelia burgdorferi sensu stricto, garinii, afzelii).
4. Confirmatory IgM and/or IgG immunoblot testing will be performed based upon the positive result.

Performance characteristics (VIDAS):

Sensitivity	Lyme IgG	Lyme IgM
Stage I (Early localized, single lesion) 1-30 days	49.60%	52.10%
Stage II (Early disseminated, multiple lesions) 1-30 days	83.90%	91.90%
Stage III (Late disseminated)	95.20%	76.20%
Specificity		
Endemic (n=100)	97.0%	88.0%
Non-endemic (n=100)	100.0%	86.0%