SERVICE UPDATE



CAMPUS AFFECTED: Me	tnoaist			
	AF	FECTS PA	TIEN'	T CARE
TEST NAME: Lyme IgG and IgM				DATE OF CHANGE: New Tes
REPLACING: NA				
SPECIMEN TYPE:	Serum – Gold Top Tube			
ORDERING CODES:	EPIC:	LAB2293	NEW: LAB2293	
	SQ:	LYMSER	N	EW: LYMSER
OTHER USEFUL	CPTS: 86618 X 2			
INFORMATION:				

Effective April 17, 2018, UnityPoint Methodist will begin performing Lyme IgG and IgM qualitative testing. Testing will be orderable as a panel which includes both IgG and IgM. Results will be reported as negative, positive or equivocal. All specimens with the presumptive results of equivocal and or positive will be automatically referred out for immunoblot (Western Blot) testing, per CDC recommendation.

Specimen Requirement: 3 mL serum from a gold top tube (2 mL minimum)

Specimen Stability: Refrigerated 6 days; Frozen 6 months

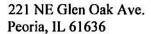
For further Information Refer to UnityPoint Methodist Laboratory User Manual

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Drs 4/4/18





Dear Valued Clinician:

Our clinical laboratory will implement the new Lyme disease tests, VIDAS® Lyme IgM and VIDAS® Lyme IgG on April 17, 2018. These 27-minute dissociated assays are beneficial in the following ways:

- 1) Increases sensitivity and specificity. Sensitivity and specificity of these assays are high and achieved with the addition of innovative recombinant chimeric proteins (VLsE, DbpA, and OspC). The design of the chimeric protein constructs, which include the VlsE invariant region (commonly known as C6 peptide), allows the VIDAS® Lyme IgG assay to provide high sensitivity and specificity and helps reduce cross reactivity and the potential for interaction with other spirochetes.
- 2) Distinguishes acute from later stage or historic exposure to Lyme disease. This decreases unnecessary and/or inappropriate treatment for previous infections. In addition, our dissociated test provides earlier information on the differential diagnosis within endemic areas.
- 3) Reduces the number of confirmatory tests and costs, since confirmatory testing is required only on a positive IgG or positive/equivocal IgM.
- 4) Reduces laboratory diagnosis time and patient anxiety.

Annually, approximately 30,000 cases of Lyme disease are reported to CDC by state health departments and the District of Columbia. However, CDC studies suggest that the number of people diagnosed with Lyme disease each year in the United States is closer to 300,000. In addition, the CDC suggests that Erythema Migrans (EM), which is the most frequent manifestation of Lyme borreliosis, occurs in only 70% to 80% of infected persons.

The laboratory has completed our internal validation of this assay and is ready to provide test results for clinical use. VIDAS® Lyme IgM and VIDAS® Lyme IgG results should be used in conjunction with the patient's clinical signs and symptoms. Interpretation of the VIDAS® Lyme IgM and VIDAS® Lyme IgG result should be in context of the patient's clinical situation.

References:

Lyme Disease Statistics, Centers for Disease Control and Prevention website.
http://www.cdc.gov/lyme/stats/humancases.html. Updated September 30, 2015. Accessed June 30, 2016.
Lyme Disease Signs and Symptoms, Centers for Disease Control and Prevention website.
http://www.cdc.gov/lyme/signs_symptoms/index.html. Updated August 17, 2015. Accessed June 30, 2016.