SERVICE UPDATE

UnityPoint Health
Methodist | Proctor

CAMPUS AFFECTED: Methodist			
AFFECTS PATIENT CARE			
TEST NAME: **Lyme IgG and IgM**			**DATE OF CHANGE: New Test**
REPLACING: NA			
SPECIMEN TYPE:	Serum – Gold Top Tube		
ORDERING CODES:	**EPIC:**	LAB2293	NEW: LAB2293
	SQ:	LYMSER	NEW: LYMSER
OTHER USEFUL INFORMATION:	CPTS: 86618 X 2		

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

For Technical Information Contact:

June Bembenek, Technical Coordinator 309-672-4219 JSB 4/4/18

Kathy Turpin, MLS (ASCP), Laboratory, Asst. Manager 309-672-5549 KLT 4/4/18

Dana Spears, Director of Laboratories 309-672-4930 DSS 4/4/18

For Scientific and Clinical Information Contact:

Lori Racsa, DO, Clinical Pathologist 309-671-2181

Elizabeth Bauer-Marsh, MD, Medical Director 309-672-4972 EBM

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221 NE Glen Oak Ave.
Peoria, IL 61636

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.[1] However, CDC studies suggest that the number of people diagnosed with Lyme disease each year in the United States is closer to 300,000.[1] 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.[2]

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:
1. 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.
2. 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.