NEW/REPLACEMENT TEST
NOTIFICATION DATE: 08/29/2022
EFFECTIVE DATE: 09/13/2022

Affected Test: Lyme Antibody Panel with Reflex (LAB304369)

EXPLANATION:
The Ruby Laboratory will offer a two-tiered algorithmic approach to Lyme disease testing beginning on September 13, 2022. This "New Approach" begins with a screening immunoassay for Lyme "Total" antibodies (both IgG and IgM isotypes). Confirmatory testing for separate Lyme IgG and IgM antibodies by immunoassay is performed reflexively when the screening test is equivocal or positive. This algorithm has been evaluated by multiple research groups noted in the references below. Advantages as compared to the "Obsolete Approach" include earlier detection relative to the standard two-tier testing used for many decades as well as improved turn-around time because it is unnecessary to send a sample to a reference laboratory for immunoblotting.

There will be a short transition period from September 1-12 when this testing will be routed to Quest Laboratories, after which all testing will be performed in-house.

The updated testing approach will replace the current one, using the SAME Epic/catalog number – **LAB123298**

NEW APPROACH: Lyme Antibody Screen with Reflex – all specimens undergo screening by Lyme Total (IgG/IgM). If the result is equivocal or positive, reflex testing for separate Lyme IgG and Lyme IgM occurs automatically and is reported separately. If the screening result is negative, no further testing is performed.

OBSOLETE APPROACH: Lyme Antibody Panel with Reflex – Standard Two-Tier Testing approach that used separate Lyme IgG & Lyme IgM screening assays, which reflexed to Quest Immunoblot if either IgG or IgM result was equivocal or positive.

OTHER TESTS:
- Lyme Disease (Borrelia spp.) DNA, Qualitative PCR, Synovial Fluid (**LAB15219**) – may be useful for spirochete detection in cases of Lyme arthritis.
- Lyme Disease IgG/IgM Immunoblot (**LAB304396**) – This testing will remain independently orderable but is NOT necessary for confirmation of seropositivity.
- Borrelia burgdorferi (Lyme Disease) Reflexive Panel (CSF) (**LAB1237105**) – CSF antibody screen + confirmatory immunoblot. This testing will remain independently orderable but is NEITHER necessary for diagnosis of neuroborreliosis NOR recognized by CDC as a valid testing strategy.

REFERENCES:

1. Sfeir MM, et al. J Clinical Microbiology 2022;60(5):1-11.
2. Molins CR, et al. J Clinical Microbiology 2016;54(11):2726-2734.
3. Pradelli L, et al. ClinicoEconomics and Outcomes Research 2021;13:437-451.

QUESTIONS ABOUT THIS TESTING

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OUTREACH QUESTIONS
Contact WVUH Laboratories 304-598-4241 or UML Representatives 304-285-7201

ADDITIONAL INORMATION AVAILABLE ONLINE: WVU Medicine Online Test Catalog