Diagnosis of Lyme disease is currently based on a 2-tiered serologic testing algorithm, as recommended by the Centers for Disease Control and Prevention (CDC). It involves an initial screening assay using an enzyme-linked immunoassay (EIA) for the detection of antibodies to the Borrelia species. Samples that screen positive or equivocal are subsequently reflexed for supplemental assessment using a Borrelia burgdorferi Western blot for detection of IgM and IgG class antibodies specific to B. burgdorferi antigens.

A negative EIA result does not exclude the possibility of infection with B. burgdorferi. Patients in the early stages of Lyme disease and those who have been treated with antibiotics may not exhibit detectable antibody titers. Patients with clinical history, signs, or symptoms suggestive of Lyme disease should be retested in 2 to 4 weeks in the event that the initial test result is negative.

A positive result is not definitive evidence of infection with B burgdorferi. It is possible that other disease conditions will produce a false positive. All equivocal or positive results are reflexed to a Western blot in accordance with the CDC recommendations. Results are only considered positive if the EIA and the Western blot are both positive. The CDC does not recommend skipping the EIA and just performing the Western blot, doing so will increase the frequency of false positive results and could lead to misdiagnosis and improper treatment. False positive IgM Western Blot results in patients that have had signs and symptoms for more than 30 days may occur and should be interpreted with caution.

In an effort to provide a clearer testing protocol, effective September 26, 2018 ProMedica Laboratories will change the appending result comments to fully explain the proper testing protocol for Lyme disease. Below are the updated appending comments.

**Positive or Equivocal test results:**
- Not diagnostic. Specimen sent to reference lab for western blot in accordance with Centers for Disease Control & Prevention (CDC).

**Negative test results:**
- No evidence of antibodies to B. burgdorferi detected. False-negative results may occur in recently infected patients (< or = 2 weeks) due to low or undetectable antibody levels to B. burgdorferi. If recent exposure is suspected, a second sample should be collected and tested in 2 to 4 weeks.
Lyme Disease Testing Algorithm

1. Signs or symptoms of Lyme disease
2. Serological EIA testing LYME panel
   - Positive OR Equivocal Result
   - Negative Result
   - If patient with signs/symptoms consistent with Lyme disease, consider retesting in
3. IgM & IgG Western Blot
   - Only positive if EIA & Western Blot are positive