MTTT: SUGGESTED RESULT REPORTING AND INTERPRETATION

Figure 2. MTTT Algorithm 1 - Two Total IgM/IgG Immunoassays

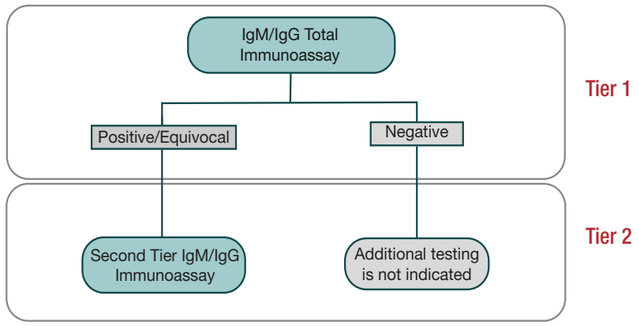

Table 3. Suggested Guidance for Reporting Results from the Modified Two-Tiered Lyme Disease Serologic Testing Algorithm Using Two *B. burgdorferi* IgM/IgG Immunoassays[a]

Test Sequence		Interpretation for Laboratories	Interpretation for Providers	Comments/Further Actions (may be included on the laboratory report)
Tier 1: IgM/IgG Total Immunoassay	Tier 2: IgM/IgG Total Immunoassay			
Negative	Not Indicated or If performed, results should not be considered for clinical care.	Negative for antibodies to *B. burgdorferi* (Lyme disease).	No laboratory evidence of infection with *B. burgdorferi* (Lyme disease).	Negative results may occur in patients recently infected (≤14 days) with *B. burgdorferi*. If recent infection is suspected, repeat testing on a new sample collected in 7–14 days is recommended.
Positive/ Equivocal	Negative	Antibodies to *B. burgdorferi* (Lyme disease) not confirmed.	No laboratory evidence of infection with *B. burgdorferi* (Lyme disease).	Negative results may occur in patients recently infected (≤14 days) with *B. burgdorferi*. If recent infection is suspected, repeat testing on a new sample collected in 7–14 days may be considered to confirm infection.
Positive/ Equivocal	Positive/Equivocal[b]	IgM- and/or IgG-class antibodies to *B. burgdorferi* (Lyme disease) detected. Specific antibody class detected cannot be determined.	Results are consistent with *B. burgdorferi* infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection.	Timing of infection (acute/recent vs. past) cannot be determined by these assays. Clinical correlation is required. Results should not be used to monitor or establish adequate response to therapy. Response to therapy is confirmed through resolution of clinical symptoms; additional laboratory testing should not be performed. If both tiers are equivocal consider repeat testing in 7–14 days if clinically warranted.

a Testing must be performed using assays that have been FDA-cleared together for this purpose.

b Equivocal results from the Tier 2 Immunoassay should be reported as positive per the package insert and interpreted as supportive evidence for the presence of IgM/IgG antibodies and exposure to B. burgdorferi.

Figure 3: MTTT Algorithm 2 – Separate IgM and IgG Second Tier Immunoassays

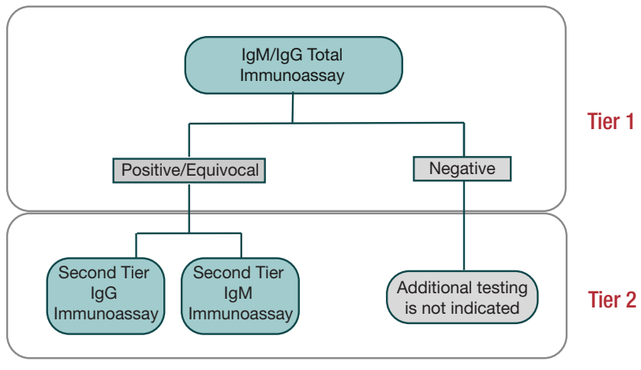

Table 4. Suggested Guidance for Reporting Results from the Modified Two-Tiered Lyme Disease Serologic Testing Algorithm Using Separate B. burgdorferi IgM and IgG Second Tier Immunoassays[a]

Test Sequence			Interpretation for Laboratories	Interpretation for Providers	Comments/Further Actions (may be included on the laboratory report)
Tier 1: IgM/IgG Total Immunoassay	Tier 2a: IgM Immunoassay	Tier 2b: IgG Immunoassay			
Negative	Not Indicated or If performed, results should not be considered for clinical care.	Testing Not Indicated/ Negative	Negative for antibodies to *B. burgdorferi* (Lyme disease).	No laboratory evidence of infection with *B. burgdorferi* (Lyme disease).	Negative results may occur in patients recently infected (≤14 days) with *B. burgdorferi*. If recent infection is suspected, repeat testing on a new sample collected in 7–14 days is recommended.
Positive/Equivocal	Negative	Negative	Antibodies to *B. burgdorferi* (Lyme disease) not confirmed.	No laboratory evidence of infection with *B. burgdorferi* (Lyme disease).	Negative results may occur in patients recently infected (≤14 days) with *B. burgdorferi*. If recent infection is suspected, repeat testing on a new sample collected in 7–14 days to demonstrate seroconversion may be considered to confirm infection.
Positive/Equivocal	Positive/ Equivocal[b]	Negative	IgM-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with acute or recent infection with *B. burgdorferi* (Lyme disease).	In untreated patients who have been sick for more than 30 days, positive IgM results should be interpreted with caution if IgG results are negative. Consider testing a new specimen collected in 7–14 days to demonstrate seroconversion.
Positive/Equivocal	Negative	Positive/Equivocal[b]	IgG-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with *B. burgdorferi* infection (Lyme disease) in the recent or remote past. IgG-class antibodies may remain detectable for months to years following resolution of infection.	Results should not be used to monitor or establish adequate response to therapy. Response to therapy is confirmed through resolution of clinical symptoms; additional laboratory testing should not be performed.
Positive/Equivocal	Positive/Equivocal[b]	Positive/Equivocal[b]	IgM and IgG-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with *B. burgdorferi* infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection.	Results should not be used to monitor or establish adequate response to therapy. Response to therapy is confirmed through resolution of clinical symptoms; additional laboratory testing should not be performed.

a. Testing must be performed using assays that have been FDA-cleared together for this purpose.

b. Equivocal results from the Tier 2 Immunoassay should be reported as positive per the package insert and interpreted as supportive evidence for the presence of IgM and/or IgG antibodies and exposure to B. burgdorferi