STTT: SUGGESTED RESULT REPORTING AND INTERPRETATION

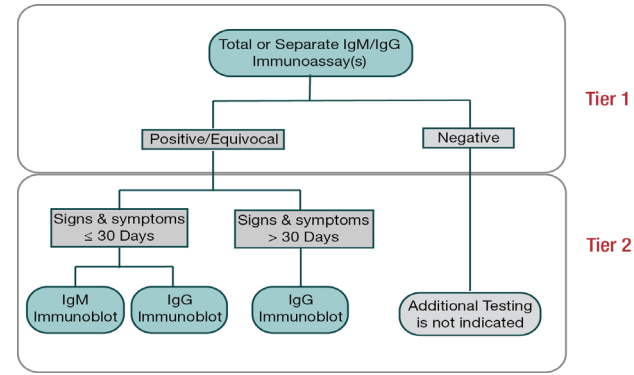**Figure 1.** Standard Two-Tiered Testing

Table 1a. Suggested Guidance for Reporting Results from the Standard Two-Tiered Lyme Disease Serologic Testing Using a Total Ig Immunoassay as a First Tier Assay

Test Sequence			Interpretation for Laboratories	Interpretation for Providers	Comments/Further Actions (may be included on the laboratory report)
Tier 1: Total Ig Immunoassay	Tier 2a: IgM Immunoblot[a,b]	Tier 2b: IgG Immunoblot[c]			
Negative	Testing Not Indicated[d]	Testing Not Indicated[d]	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[e]	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 is recommended.
Positive/ Equivocal	Positive[e]	Negative[e]	IgM-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with acute or recent infection with *B. burgdorferi* (Lyme disease).	IgM immunoblot results should only be considered as indicative of recent infection in patients presenting within 30 days of symptom onset. Consideration of IgM immunoblot results in patients with symptoms lasting >30 days is discouraged due to the risk of false positive IgM immunoblot results or prolonged IgM seropositivity following disease resolution. Testing of a new specimen collected in 7-14 days to demonstrate IgG seroconversion may be considered to confirm infection.
Positive/ Equivocal	Negative	Positive[e]	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[e]	Positive[e]	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 Immunoblots for IgM antibodies to *B. burgdorferi* are interpreted as "negative" if <2 *B. burgdorferi*-specific proteins are detected. Conversely, if ≥2 out of a possible 3 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgM-class antibodies to *B. burgdorferi*. The *B. burgdorferi*-specific proteins that may be detected include: p23, p39, p41.

b Testing for IgM antibodies to *B. burgdorferi* is not indicated in patients presenting >30 days post-symptom onset.

c Immunoblots for IgG antibodies to *B. burgdorferi* are interpreted as "negative" if <5 B. burgdorferi-specific proteins are detected. Conversely, if ≥ 5 out of a possible 10 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgG-class antibodies to *B. burgdorferi*. The *B. burgdorferi*-specific proteins that may be detected include: p18, p23, p28, p30, p39, p41, p45, p58, p66, p93.

d In accordance with the current standard two-tiered testing algorithm, testing by the IgM and IgG blots is not indicated due to negative initial screening immunoassay.

e Laboratories may choose to report individual bands when the overall test is positive and individual IgG bands when the overall test result is negative. Reporting of individual IgM bands when the overall test is negative is not recommended.

Table 1b. Suggested Guidance for Reporting Results from the Standard Two-Tiered Lyme Disease Serologic Testing Algorithm Using Separated IgM and IgG Immunoassays as First Tier Assays

Test Sequence			Interpretation for Laboratories	Interpretation for Providers	Comments/Further Actions (may be included on the laboratory report)
Tier 1: Separate IgM and IgG Immunoassays	Tier 2a: IgM Immunoblot[a,b]	Tier 2b: IgG Immunoblot[c]			
Concordant *Tier 1 IgM and IgG Immunoassay results*					
Negative	Testing Not Indicated[d]	Testing not indicated[d]	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 by both assays	Negative	Negative[e]	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 is recommended.
Positive/Equivocal by both assays	Positive[e]	Negative[e]	IgM-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with acute or recent infection with *B. burgdorferi* (Lyme disease).	IgM immunoblot results should only be considered as indicative of recent infection in patients presenting within 30 days of symptom onset. Consideration of IgM immunoblot results in patients with symptoms lasting >30 days is discouraged due to the risk of false positive IgM immunoblot results or prolonged IgM seropositivity following disease resolution. Testing of a new specimen collected in 7-14 days to demonstrate IgG seroconversion may be considered to confirm infection.
Positive/Equivocal by both assays	Negative	Positive[e]	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 by both assays	Positive[e]	Positive[e]	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.
Discordant *Tier 1 IgM and IgG Immunoassay results*					
IgM Positive/ Equivocal IgG Negative	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.
IgM Positive/Equivocal IgG Negative	Positive[e]	Not indicated or if performed, results should not be considered for clinical care.	IgM-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Results are consistent with acute or recent infection with *B. burgdorferi* (Lyme disease).	IgM immunoblot results should only be considered as indicative of recent infection in patients presenting within 30 days of symptom onset. Consideration of IgM immunoblot results in patients with symptoms lasting >30 days is discouraged due to the risk of false positive IgM immunoblot results or prolonged IgM seropositivity following disease resolution. Testing of a new specimen collected in 7–14 days to demonstrate IgG seroconversion may be considered to confirm infection.
IgM Negative/Not performed IgG Positive/Equivocal	Not indicated or if performed, results should not be considered for clinical care.	Negative[d]	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.
IgM Negative/Not performed IgG Positive/Equivocal	Not indicated or if performed, results should not be considered for clinical care.	Positive	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.
Discordant *Tier 1 & 2 IgM and IgG Immunoassay results*					
IgM Positive/Equivocal IgG Negative	Negative	Positive[d]	Inconclusive	Repeat testing using a new sample. If results remain inconclusive, consider testing using a different algorithm.	Consider further testing or alternate diagnosis.
IgM Negative/Not performed IgG Positive/ Equivocal	Positive[d]	Negative[d]	Inconclusive	Repeat testing using a new sample. If results remain inconclusive, consider testing using a different algorithm.	Consider further testing or alternate diagnosis.

a Immunoblots for IgM antibodies to *B. burgdorferi* are interpreted as "negative" if <2 *B. burgdorferi*-specific proteins are detected. Conversely, if ≥ 2 out of a possible 3 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgM-class antibodies to *B. burgdorferi*. The *B. burgdorferi*-specific proteins that may be detected include: p23, p39, p41.
b Testing for IgM antibodies to *B. burgdorferi* is not indicated in patients presenting >30 days post-symptom onset.
c Immunoblots for IgG antibodies to *B. burgdorferi* are interpreted as "negative" if <5 *B. burgdorferi*-specific proteins are detected. Conversely, if ≥ 5 out of a possible 10 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgG-class antibodies to *B. burgdorferi*. The *B. burgdorferi*-specific proteins that may be detected include: p18, p23, p28, p30, p39, p41, p45, p58, p66, p93.
d. Laboratories may choose to report individual bands when the overall test is positive, and individual IgG bands when the overall test result is negative. Reporting of individual IgM bands when the overall test is negative is not recommended.

Table 2. Suggested Guidance For Reporting Tier 2 Results in the STTT When Results of Tier 1 Results are Unknown or Assumed Positive/Equivocal

Test Sequence			Algorithm Interpretations	Interpretation for Laboratory Report	Comments/Further Actions (may be included on the laboratory report)
Tier 1: Total Ig Immunoassay	Tier 2a: IgM Immunoblot[a,b]	Tier 2b: IgG Immunoblot[c]			
Unknown or Assumed 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 of a new sample collected in 7-14 days is recommended using the two-tiered testing algorithm.
Unknown or Assumed Positive/Equivocal	Positive[d]	Negative	IgM-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Interpretation of these results is only accurate if an initial *B. burgdorferi* immunoassay was positive or equivocal. If so, results are consistent with acute or recent infection with *B. burgdorferi* (Lyme disease).	IgM immunoblot results should only be considered as indicative of recent infection in patients within 30 days of symptom onset. Consideration of IgM immunoblot results in patients with >30 days of symptoms is discouraged due to the risk of false positive IgM immunoblot results or prolonged IgM seropositivity following disease resolution. Testing of a new specimen collected in 7–14 days to demonstrate IgG seroconversion may be considered to confirm infection.
Unknown or Assumed Positive/Equivocal	Negative	Positive	IgG-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Interpretation of these results is only accurate if an initial *B. burgdorferi* immunoassay was positive or equivocal. 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.
Unknown or Assumed Positive/Equivocal	Positive[d]	Positive	IgM- and IgG-class antibodies to *B. burgdorferi* (Lyme disease) detected.	Interpretation of these results is only accurate if an initial *B. burgdorferi* immunoassay was positive or equivocal. 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 Immunoblots for IgM antibodies to *B. burgdorferi* are interpreted as "negative" if <2 *B. burgdorferi*-specific proteins are detected. Conversely, if ≥2 out of a possible 3 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgM-class antibodies to *B. burgdorferii*. The *B. burgdorferi*-specific proteins that may be detected include: p23, p39, p41.

b Testing for IgM antibodies to *B. burgdorferi* is not indicated in patients presenting >30 days post-symptom onset.

c Immunoblots for IgG antibodies to *B. burgdorferi* are interpreted as "negative" if <5 *B. burgdorferi*-specific proteins are detected. Conversely, if ≥ 5 out of a possible 10 *B. burgdorferi*-specific proteins are detected, the immunoblot is interpreted as "positive" for IgG-class antibodies to *B. burgdorferi*. The *B. burgdorferi*-specific proteins that may be detected include: p18, p23, p28, p30, p39, p41, p45, p58, p66, p93.

d Laboratories may choose to report individual bands when the overall test is positive, and individual IgG bands when the overall test result is negative. Reporting of individual IgM bands when the overall test is negative is not recommended.