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 Laboratorias | Interpretation for Dravidara | | |
|---------------------------------|---|---------------------------------------|---|--|---|--|
| Tier 1: Total Ig Immunoassay | Tier 2a: IgM Immunoblot ^{a,b} | Tier 2b: lgG Immunoblot⁰ | | | Comments/Further Actions (| |
| Negative | Testing Not Indicated ^d | Testing Not Indicated ^d | Negative for antibodies to <i>B. burgdorferi</i> (Lyme disease). | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative results may occur in patients recently infect repeat testing on a new sample collected in 7-14 day | |
| Positive/ Equivocal | Negative | Negative ^e | Antibodies to <i>B. burgdorferi</i> (Lyme disease) not confirmed. | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative results may occur in patients recently infect repeat testing on a new sample collected in 7-14 day | |
| Positive/ Equivocal | Positive ^e | Negative ^e | IgM-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with acute or recent infection with <i>B. burgdorferi</i> (Lyme disease). | IgM immunoblot results should only be considered as of symptom onset. Consideration of IgM immunoblot due to the risk of false positive IgM immunoblot resu | |
| | | | | | Testing of a new specimen collected in 7-14 days to infection. | |
| Positive/ Equivocal | Negative | Positive ^e | IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> 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 ac through resolution of clinical symptoms; additional la | |
| Positive/ Equivocal | Positive ^e | Positive ^e | IgM- and IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> 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 ac through resolution of clinical symptoms; additional la | |

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 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.

(may be included on the laboratory report)

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demonstrate IgG seroconversion may be considered to confirm

dequate response to therapy. Response to therapy is confirmed aboratory testing should not be performed.

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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 | | | | | |
|---|---|--|--|--|---|
| Tier 1: Separate IgM and IgG Immunoassays | | Tier 2b: IgG Immunoblot° | Interpretation for Laboratories | Interpretation for Providers | |
| Concordant Tier 1 IgM and I | gG Immunoassay results | | | | |
| Negative | Testing Not Indicated ^d | Testing not indicated ^d | Negative for antibodies to <i>B. burgdorferi</i> (Lyme disease). | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative If recent recomme |
| Positive/Equivocal by both assays | Negative | Negative ^e | Antibodies to <i>B. burgdorferi</i> (Lyme disease) not confirmed. | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative If recent recomme |
| Positive/Equivocal by both assays | Positive ^e | Negative ^e | IgM-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with acute or recent infection with <i>B. burgdorferi</i> (Lyme disease). | IgM immu patients p results in positive I Testing o |
| Positive/Equivocal by both assays | Negative | Positive ^e | IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. IgG-class antibodies may remain detectable for months to years following resolution of infection. | Results s to therap |
| Positive/Equivocal by both assays | Positive ^e | Positive ^e | IgM- and IgG-class antibodies to B. burgdorferi (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection. | Results s to therap should n |
| Discordant Tier 1 lgM and lg | G 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 <i>B. burgdorferi</i> (Lyme disease). | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative recent in recomme |
| IgM Positive/Equivocal IgG Negative | Positive | Not indicated or if performed, results should not be considered for clinical care. | IgM-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with acute or recent infection with <i>B. burgdorferi</i> (Lyme disease). | IgM imm patients results in positive I Testing o considere |
| 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 <i>B. burgdorferi</i> (Lyme disease). | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative If recent recomme |
| 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 <i>B. burgdorferi</i> (Lyme disease) detected. | Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. IgG-class antibodies may remain detectable for months to years following resolution of infection. | Results s to therap should n |
| Discordant Tier 1 & 2 lgM al | nd 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 |
| 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 |

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 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*-specific proteins are detected include: p18, p23, p28, p30, p39, p41, p45, p58, p66, p93.

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

nments/Further Actions (may be included on the laboratory report)

e results may occur in patients recently infected (\leq 14 days) with *B. burgdorferi*. infection is suspected, repeat testing on a new sample collected in 7-14 days is ended.

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of a new specimen collected in 7-14 days to demonstrate IgG seroconversion may be red to confirm infection.

should not be used to monitor or establish adequate response to therapy. Response by is confirmed through resolution of clinical symptoms; additional laboratory testing not be performed.

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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 Poport | Comment |
|--|--|----------|---|--|---|
| Tier 1: Total Ig Immunoassay | Tier 2a: IgM Tier 2b: IgG Immunoblot ^{a,b} Immunoblot ^c | | | | Commenta |
| Unknown or Assumed Positive/Equivocal | Negative | Negative | Antibodies to <i>B. burgdorferi</i> (Lyme disease) not confirmed. | No laboratory evidence of infection with <i>B. burgdorferi</i> (Lyme disease). | Negative rest burgdorferi. I collected in 7 |
| Unknown or Assumed Positive/Equivocal | Positive ^d | Negative | IgM-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Interpretation of these results is only accurate if an initial <i>B. burgdorferi</i> immunoassay was positive or equivocal. If so, results are consistent with acute or recent infection with <i>B. burgdorferi</i> (Lyme disease). | IgM immunol infection in p immunoblot due to the ris seropositivity in 7–14 days infection. |
| Unknown or Assumed Positive/Equivocal | Negative | Positive | IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Interpretation of these results is only accurate if an initial <i>B. burgdorferi</i> immunoassay was positive or equivocal. Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. IgG-class antibodies may remain detectable for months to years following resolution of infection. | Results shou therapy. Resp symptoms; a |
| Unknown or Assumed Positive/Equivocal | Positive ^d | Positive | IgM- and IgG-class antibodies to <i>B. burgdorferi</i> (Lyme disease) detected. | Interpretation of these results is only accurate if an initial <i>B. burgdorferi</i> immunoassay was positive or equivocal. Results are consistent with <i>B. burgdorferi</i> infection (Lyme disease) in the recent or remote past. Antibodies may remain detectable for months to years following resolution of infection. | Results shou therapy. Resp symptoms; a |

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 as "positive" for IgG-class antibodies to *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.

s/Further Actions (may be included on the laboratory report)

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