

***Borrelia* Serology Test Interpretation**

Revised 5-26-2017

***B. burgdorferi* ELISA Serology Test Interpretation**

Negative: Patient's result is **less than** the internally established reference value. This result indicates that the sample tested was non-reactive with *Borrelia burgdorferi* whole cell sonicate and **does not meet** the threshold criteria for reflex testing by Western blot.

Equivocal: Patient's result is **equal to** the internally established reference range. This result indicates that the sample tested exhibits borderline reactivity with *Borrelia burgdorferi* whole cell sonicate and **does meet** the threshold criteria for reflex testing by Western blot.

Positive: Patient's result is **greater than** the internally established reference value. This result indicates that the sample tested exhibits reactivity with *Borrelia burgdorferi* whole cell sonicate and **does meet** the threshold criteria for reflex testing by Western blot.

Reference Values: derived from a panel of *B. burgdorferi*-negative, healthy donor sera.

***B. burgdorferi* IgM Western Blot Serology Test Interpretation**

Positive: At least 2 out of the 3 following diagnostic bands (23, 39, 41 kDa) are present at an intensity greater than or equal to band intensities present in validated control samples. Sample meets or exceeds the threshold for reactivity with the *Borrelia burgdorferi* whole-cell lysate.

Negative*: Less than 2 out of the 3 diagnostic bands are present at an intensity greater than or equal to band intensities present in validated control samples. Sample does not meet the threshold for reactivity with the *Borrelia burgdorferi* whole-cell lysate.

Indeterminate: Reactivity status cannot be definitively determined. It is recommended that a new sample be sent for re-testing.

***B. burgdorferi* IgG Western Blot Serology Test Interpretation**

Positive: At least 5 out of the 10 following diagnostic bands (18, 23, 28, 30, 39, 41, 45, 58, 66, 93 kDa) are present at an intensity greater than or equal to band intensities present in validated control samples. Sample does meet or exceeds the threshold for reactivity with the *Borrelia burgdorferi* whole-cell lysate.

Negative*: Less than 5 out of the 10 diagnostic bands are present at an intensity greater than or equal to band intensities present in validated control samples. Sample does not meet the threshold for reactivity with the *Borrelia burgdorferi* whole-cell lysate.

Indeterminate: Reactivity status cannot be definitively determined. It is recommended that a new sample be sent for re-testing.

***B. burgdorferi* Western Blot Notes**

Results for bands 31 and 34 kDa are available on a Research Use Only (RUO) basis. Please contact Galaxy Diagnostics.

***Borrelia burgdorferi* Western Blot Research Use Only (RUO) Serology Test Report**

Research Use Only Disclaimer

These results are for research use only. The clinical utility of the 31 kDa and 34 kDa bands has not been determined by Galaxy Diagnostics, Inc.

***B. burgdorferi* Two-Tier Test Interpretation¹**

Positive: BOTH the IgM ELISA and Western blot, or BOTH the IgG ELISA and Western blot are Positive (Positive/Positive), or the ELISA is Equivocal and the Western blot is Positive (Equivocal/Positive). The patient has been exposed to *Borrelia burgdorferi* and may have Lyme disease. The patient should consult with their physician to review test results and discuss treatment options.

Negative: Two-tier tests results for IgM ELISA/Western blot or IgG ELISA/Western blot are not Positive/Positive or Equivocal/Positive. The patient does not meet CDC guidelines for serodiagnosis of Lyme disease. However, laboratory tests are only one component utilized by physicians to diagnose and treat potential infections. The patient should consult with their physician to discuss test results and other options.

Potential Cross-reactivity: Serum samples from patients with *Bartonella* infections, Epstein-Barr viral infections (mononucleosis), rheumatoid arthritis, or that have had other spirochetal infections (e.g. periodontitis, syphilis) may exhibit cross-reactivity with *B. burgdorferi* ELISA and Western blot tests and produce false positive results.

Suspected duration of infection	ELISA Testing	Western Blot (WB) Testing	Two-tier (TT) Testing
0 - ≤ 30 days	<p><u>IgM and IgG ELISAs:</u> Positive (Pos.)/Equivocal (Eq) antibody (Ab) reactivity indicates early exposure to <i>B. burgdorferi</i> (Bb); reflex to Western blot testing</p> <p>Negative (Neg.): undetectable antibody reactivity to Bb; does not meet threshold criteria for reflex testing; antibody response not yet developed; re-test convalescent sample ≥ 4-6 weeks.</p>	<p><u>IgM and IgG WBs:</u> IgM Positive Ab reactivity with 2-3, or IgG Positive Ab reactivity with 5-10, diagnostic antigens indicates early exposure to Bb.</p> <p>Negative: IgM Ab reactivity with < 2, or IgG Ab reactivity with < 5, diagnostic antigens; does not meet threshold criteria for exposure to Bb; full antibody response not yet developed; re-test convalescent sample ≥ 4-6 weeks.</p>	<p><u>TT Positive for Lyme Exposure:</u> IgM ELISA Eq/Pos and WB Pos. and/or IgG ELISA Eq/Pos and WB Pos.; physician and patient discuss treatment options.</p> <p><u>TT Negative for Lyme Exposure:</u> IgM ELISA Eq/Pos and WB Neg. and/or IgG ELISA Eq/Pos and WB Neg; physician and patient discuss options.</p>

¹ CDC criteria are utilized for reporting Lyme Western Blot serology test results

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> 30 days - years	<p>IgG ELISA: Positive (Pos.)/Equivocal (Eq) antibody reactivity indicates exposure to <i>B. burgdorferi</i> (Bb); reflex to Western blot testing</p> <p>Negative (Neg.): undetectable antibody reactivity to Bb; does not meet threshold criteria for reflex testing</p>	<p>IgG WB: Positive antibody reactivity with 5-10 diagnostic antigens, indicates early exposure to Bb.</p> <p>Negative: antibody reactivity with < 5 diagnostic antigens; does not meet threshold criteria for exposure to Bb.</p>	<p>TT Positive for Lyme Exposure: IgG ELISA Eq/Pos and WB Pos.; physician and patient discuss treatment options.</p> <p>TT Negative for Lyme Exposure: IgM ELISA Eq/Pos and WB Neg. and/or IgG ELISA Eq/Pos and WB Neg; physician and patient discuss options.</p>
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Key References

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