CPAL
**C**entral **P**ennsylvania **A**lliance **L**aboratory

# Technical Bulletin

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## Lyme Testing Algorithm

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**Affected Tests:**

| | | |
|---|---|---|
| **Mnemonics:** | Lyme PG | Lyme Blot |
| **Test Name**: | Lyme IgG/IgM Screen—Progressive (Includes reflex to Lyme Blot) | Lyme Blot Group (Includes IgG and IgM) |
| **Test Number:** | 3003082 | 1757060 |
| **Specimen:** | 1 mL serum, 2-8$^0$C up to 7 days, -20$^0$C or colder up to 6 months | |

**Notice:**

In January 2014, CPAL published a technical bulletin announcing that Western Blot testing for Lyme Disease would be performed in our laboratory. The following statements were included in the "Limitations" section of that bulletin:

1. *The MarDx B. burgdorferi (IgG) Marblot Strip Test System should only be used to test human serum samples which have been found positive or equivocal using an EIA or IFA test procedure. Western blot should not be performed as a screening procedure.*
2. *Individuals with POSITIVE Western blot for antibodies to B. burgdorferi should be referred for medical evaluation which may include additional testing. The diagnosis of Lyme Disease must include careful clinical evaluation and should not be based only on detection of antibodies to B. burgdorferi.*

In an article in the April 18, 2014 edition of Morbidity and Mortality Weekly Report (MMWR) concerning the use of a non-FDA approved test for Lyme Disease, the Centers for Disease Control (CDC) reinforced a 2005 caution concerning the testing algorithm for Lyme Disease. This report warns against utilization of screening tests that are not FDA approved and/or tests that are not intended as screening tests. Further, they state:

> *When laboratory testing is indicated, CDC recommends two-tier serologic testing for the diagnosis of Lyme disease. Two-tier testing consists of an FDA-cleared enzyme immunoassay (EIA) that, if positive or equivocal, is followed by an FDA-cleared immunoblot test, commonly known as a "Western blot" test. Results are considered positive only when both the EIA and Western blot are positive.*

Please note that the testing algorithm used at CPAL follows these guidelines. While the Western Blot is an orderable test, this should not be used as a stand-alone screen. Western Blot should only be used when there has been a positive or equivocal result on the screening test, as stated in the CPAL technical bulletin 121. Comments with each result will be further updated as follows to stress this CDC recommendation.

> Effective 02/01/2014, method changed to Western blot.
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> Western Blot should not be used as a screening procedure.
>
> The CDC recommends a two tier serologic testing for the diagnosis of Lyme disease. Two tier testing consists of an FDA cleared enzyme immunoassay (EIA) that, if positive or equivocal, is followed by an FDA cleared immunoblot test, most commonly known as a Western blot test. Results are considered positive only when both the EIA and Western blot are positive.
>
> The diagnosis of Lyme Disease must include careful clinical evaluation and should not be based solely on detection of antibodies to B. burgdorferi. Individuals with other pathologenic spirochetal diseases or connective tissue autoimmune diseases may exhibit false positive results. Individuals with other bacterial and viral infections may also have antibodies which cross react with B. burgdorferi and yield false positive results. A negative Western blot does not exclude the possibility of infection with B. burgdorferi.
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> Band Interpretation Notes:
> Although considered negative, if there is IgG reactivity to fewer specific B. burgdorferi proteins or IgM reactivity to only 1 protein this may indicate recent B. burgdorferi infection and warrant testing of a later sample.
>
> A positive IgM but negative IgG result obtained more than a month after onset of symptoms likely represents a false IgM result rather than acute Lyme disease.
>
> Studies have demonstrated that antibiotic therapy may or may not affect the seroconversion from IgM to IgG during the course of the disease.
> (4/24/2014)


1. CDC Notice to readers: caution regarding testing for Lyme disease. MMWR 2005;54:125.
2. CDC Concerns Regarding a New Culture Method for *Borrelia burgdorferi* Not Approved for the Diagnosis of Lyme Disease. MMWR 2014:63(15);333-333
3. CPAL Technical Bulletin 121. Lyme Blot, IgG and IgM—Now Performed at CPAL. Jan 2014.