

# Sofia<sup>®</sup> 2 Lyme FIA and CDC-Recommended Two-Tiered Testing for Lyme Disease



If you've adopted Quidel's Sofia 2 Lyme FIA or are thinking about it, congratulations! You've just taken a big step toward providing more timely diagnosis and care for your patients suspected of having Lyme disease.



If you're used to ordering a Lyme test and waiting for the results to arrive, it's important to fully understand the CDC's recommendations for Lyme testing and where Sofia 2 Lyme FIA fits in.

## Who you test matters

According to the CDC, diagnosis of Lyme disease should take into account:



History of possible exposure to ticks in areas where Lyme disease is known to occur



Signs and symptoms of the illness



The results of blood tests used to detect whether the patient has antibodies to Lyme disease bacteria<sup>1</sup>

***Laboratory tests are not recommended for patients who do not have symptoms typical of Lyme disease.<sup>2</sup>***

While it may be tempting for you or others in your office to test yourself for Lyme using Sofia 2 Lyme FIA's simple, CLIA-waived workflow, such an action would go against the CDC's recommendations and the intended use of the Sofia 2 Lyme FIA. If you suspect you may have Lyme disease, talk to your doctor.

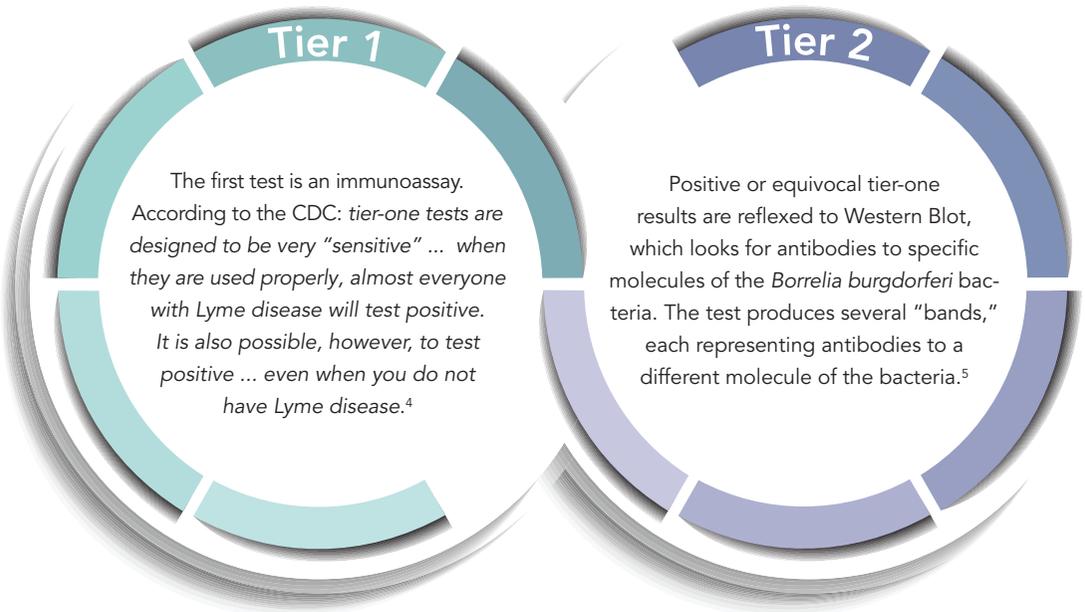
**Why does the CDC recommend testing only symptomatic patients with possible exposure to infected ticks? The answer lies in how Lyme testing is done.**

<sup>1</sup> <https://www.cdc.gov/lyme/resources/brochure/lymediseasebrochure.pdf>, accessed 10 December, 2018.

<sup>2</sup> <https://www.cdc.gov/lyme/diagnosistesting/index.html>, accessed 10 December, 2018

# How you test matters

The CDC recommends a two-tiered testing algorithm for testing for Lyme disease.<sup>3</sup>



Besides Lyme, positive EIA results can be caused by other medical conditions such as Syphilis, Mono and others.<sup>4</sup> *Western Blot can help distinguish patients who have Lyme disease from those with other conditions.*<sup>4</sup>

The CDC explains how to interpret a Western Blot: *the combination of multiple, specific lines ... identifies the infection as being due to Borrelia burgdorferi ... The criterion that requires at least 5 IgG bands reflects the fact that people with Lyme disease have at least 5 antigens (specific molecules) detectable.*<sup>5</sup>

**The two steps of Lyme disease testing are designed to be done together.<sup>3</sup>**

According to CDC researcher Alison Hinckley and her counterparts, EIAs performed individually deliver positivity rates of 11.4% while the two-tiered tests had a positivity rate of 5.8%.<sup>6</sup> This would suggest that about 50% of positive tier one Lyme results – one in two – will be determined negative by Western Blot.

<sup>3</sup> <https://www.cdc.gov/lyme/diagnosistesting/labtest/twostep/index.html>, accessed 10 December, 2018

<sup>4</sup> <https://www.cdc.gov/lyme/diagnosistesting/labtest/twostep/eia/index.html>, accessed 10 December, 2018

<sup>5</sup> <https://www.cdc.gov/lyme/diagnosistesting/labtest/twostep/westernblot/index.html>, accessed 10 December, 2018

<sup>6</sup> Hinckley, A. et al.; Lyme Disease Testing by Large Commercial Laboratories in the United States, *Clinical Infectious Diseases*, Volume 59, Issue 5, 1 September 2014, Pages 676–681, <https://doi.org/10.1093/cid/ciu397>

# Sofia 2 Lyme FIA is a tier one Lyme test

If you are currently sending your Lyme testing out today, your lab is most likely adhering to the CDC two-tiered testing guidelines, performing an EIA first and reflexing positive or equivocal results to Western Blot for confirmation. By implementing Sofia 2 Lyme FIA, **you are now performing the tier one test right in your office.** As such, it is important to keep two things in mind:

**1** The CDC guidelines to determine history of exposure and symptoms of the illness prior to running a blood test for Lyme disease apply to Sofia 2 Lyme FIA. It is also important to adhere to Sofia 2 Lyme FIA's intended use, which says in part:

The Sofia 2 Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from finger-stick whole blood specimens from patients suspected of *B. burgdorferi* infection of at least 2 weeks' duration ... Professional guidelines should be consulted regarding testing and treatment for Lyme disease when acute *B. burgdorferi* infection is suspected.<sup>7</sup>

**2** You may need to change how you order a Lyme test when you send a positive Sofia 2 Lyme FIA result for Western Blot confirmation.

To avoid accidentally ordering duplicative tier-one Lyme tests, you want to ensure you order only Western Blot confirmation of your positive tier-one Sofia 2 Lyme FIA results.

The CPT codes\* for tier one Lyme EIA and tier two Lyme Western Blot are:  
CPT for tier 1 EIA: 86618, 86618-59 (add QW modifier for Medicare CLIA-waived)  
CPT for tier 2 Western Blot: 86617, 86617-59

By adhering to the CDC's guidelines and recommendations for two-tiered Lyme testing, understanding how the two-tiered testing algorithm works, and knowing how Sofia 2 Lyme FIA fits into that algorithm, you are better positioned for both clinical and operational success with Sofia 2 Lyme FIA.



\*Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims.

For state by state Medicare Clinical Laboratory Fee Schedule, go to [www.cms.hhs.gov](http://www.cms.hhs.gov).