

FDA Clears New Lyme Test



The Lyme Disease Association announces that the Food and Drug Administration (FDA) yesterday cleared for marketing four previously cleared tests for the diagnosis of Lyme disease. Called the modified two-tier, enzyme immune assay, (EIA), the new tests are able to be run at the same time or sequentially. The current two-tier testing has an EIA test (ELISA) run which is then followed by a Western Blot (WB).

The FDA reviewed data from clinical studies of the ZEUS ELISA *Borrelia VlsE1/pepC10* IgG/IgM Test System, ZEUS ELISA *Borrelia burgdorferi* IgG/IgM Test System, ZEUS ELISA *Borrelia burgdorferi* IgM Test System, and the ZEUS ELISA *Borrelia burgdorferi* IgG Test System. The FDA claims this alternative approach is as accurate as current methods for detecting antibodies for assessing exposure to *Borrelia burgdorferi*, the bacteria causing Lyme disease.

The tests were reviewed through FDA's premarket notification (510(k)) pathway— the device to be marketed is at least as safe and effective to a legally marketed device, i.e., substantially equivalent.

According to LDA President Pat Smith, "It appears the new two-tier system is being offered as an alternative to the existing two-tier. Whether it will prove out to be as accurate as the current system remains to be seen. Since the current two tier

system is considered to be about 50% accurate by many, and many treating physicians feel the Western Blot is perhaps the most significant portion of that system, it is hard to say what impact this new system without the WB will have on diagnosis. The fact that the tests can be run concurrently could mean less delay in testing to diagnosis/treatment time for some individuals. However, at this point, we do not know enough about the tests to make any further assessments, although it is not the new technology many have hoped for in a new testing paradigm.”

Click here for PR Newswire – *FDA clears new indications for existing Lyme disease tests that may help streamline diagnoses*