FDA clears POC Sofia Lyme FIA for Sofia 2

March 15, 2018—Quidel received 510(k) clearance from the FDA to market its Sofia Lyme FIA to be used with the Sofia 2 fluorescent immunoassay analyzer for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens from patients suspected of *B. burgdorferi* infection, which causes Lyme disease.

“The Sofia Lyme Assay’s 510(k) clearance for use on the Sofia 2 instrument will allow health care workers to generate a faster result, thereby accelerating the diagnosis and potential treatment of Lyme disease for the patient. This is another example of our ability to provide simple, cost-effective solutions for physician offices and hospitals that previously had to wait several days for send-out Lyme results,” Douglas Bryant, president and CEO of Quidel, said in a statement. “We expect that this new product introduction will increase the utilization of our Sofia 2 platform and could create incremental instrument placement opportunities in the near to medium term.”

Sofia 2, the next-generation version of the Sofia instrument, provides results in as few as three minutes. The Sofia Lyme Assay was previously 510(k) cleared for use on the Sofia instrument. It is the fourth 510(k) cleared Sofia test for use on the Sofia 2 system; the Sofia Influenza A+B Assay, RSV Assay, and Strep A+ Assay were 510(k) cleared and CLIA waived by the FDA last year.

More top news