Fingerstick Sofia 2 Lyme FIA gets FDA clearance, CLIA waiver

Sept. 6, 2018—Quidel has received 510(k) clearance and Clinical Laboratory Improvement Amendments waiver from the FDA to market its Sofia 2 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 fingerstick whole blood specimens from patients suspected of *B. burgdorferi* infection. The test is intended for use with the Sofia 2 analyzer to aid in the diagnosis of Lyme disease.

The Sofia 2 Lyme FIA uses a bi-directional test strip format to detect both IgM and IgG antibodies to *B. burgdorferi* from a single fingerstick whole blood sample—one side of the test strip detects IgM antibodies to *B. burgdorferi* and the other side detects IgG antibodies to *B. burgdorferi*.

"The Sofia 2 Lyme FIA's 510(k) clearance and CLIA waiver for use on the Sofia 2 instrument will allow health care workers to generate a result in a single office visit, accelerating the time to 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 results," Douglas Bryant, president and chief executive officer of Quidel, said in a press release.

Sofia 2 utilizes the original Sofia's fluorescent chemistry design while improving on the graphical user interface and optics system to provide an accurate, objective, and automated result in as few as three minutes. The next-generation system comes connected to Virena, Quidel's data management system, which provides aggregated, de-identified testing data in near real time.