

FDA approves Sofia Lyme FIA, 12/17

December 2017—Quidel received 510(k) clearance from the FDA to market its Sofia Lyme FIA 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. The test is intended for use with the Sofia analyzer to aid in the diagnosis of Lyme disease.

The Sofia analyzer and Sofia Lyme FIA combine immunofluorescence chemistry, advanced lateral flow technology, and failure alert and fail-safe systems designed to ensure reliable, objective, diagnostic results within 10 minutes of application of the patient's specimen.

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