B. burgdorferi IgG/IgM ELISA assay cleared

October 2018—Gold Standard Diagnostics announced FDA clearance of its *Borrelia burgdorferi* IgG/IgM ELISA assay. The test is intended as an initial screening assay in the CDC-recommended two-step testing for evidence of antibodies against the Lyme disease bacteria. Both steps can be performed using the same blood sample. The highly sensitive EIA Lyme screen contains *B. burgdorferi* strains B31 and 2591, as well as VIsE, an immunogenic lipoprotein included for optimal performance. The kit includes ready-to-use controls and features a 15-15-15-minute incubation protocol.

Gold Standard Diagnostics, 855-268-6940