

FDA clears GSD's *B. burgdorferi* VlsE-OspC IgG/IgM assay

May 14, 2021—[Gold Standard Diagnostics](#) announced the availability of its FDA-cleared *B. burgdorferi* VlsE-OspC IgG/IgM recombinant ELISA screen. The OspC antigen is highly specific for the detection of IgM antibodies and, when used in combination with the recombinant VlsE, produces a superior first-tier screen. True Lyme-negative samples are eliminated prior to second-tier testing.

The assay has a specificity of 98 percent and has demonstrated a nearly 20 percent increase in early Lyme disease detection compared with the standard two-tier testing algorithm, the company says.

The test is optimized for use with second-tier immunoblots and the modified two-tier test algorithm and can be automated on any open EIA processor.