DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K183446

Device Name

BioPlex 2200 Lyme Total

Indications for Use *(Describe)*

The BioPlex 2200 Lyme Total kit is a multiplex flow immunoassay intended for the qualitative detection of total (IgM/IgG) antibodies to *Borrelia burgdorferi* in human serum and plasma (EDTA, heparin). This assay should be used to test patients with history and/or symptoms of infection with *B. burgdorferi*. The BioPlex 2200 Lyme Total assay is intended for use with the Bio-Rad BioPlex 2200 System. All reactive and equivocal specimens should be tested with a second tier test such as Lyme IgM and IgG Western blot assays. Positive second tier results are supportive evidence of infection with *B. burgdorferi*. Diagnosis of Lyme borreliosis should be made based on the presence of *B. burgdorferi* antibodies, history, symptoms, and other laboratory data. Non-reactive first tier or negative second tier results should not be used to exclude borreliosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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