Lyme ImmunoBlot
IgM and IgG

Now Approved by New York State
Department of Health

PURPOSE

Although IGeneX Lyme Western blot prepared from *Borrelia burgdorferi* (BB) strains B31 and 297 is one of the most sensitive test to detect *B. burgdorferi* specific antibodies in human serum, it does not detect antibodies to all the BB antigens. To develop all inclusive Western blots would be very expensive and impractical. Therefore, we have developed a Lyme ImmunoBlot that is very specific and inclusive of most species of BB for clinical use. For diagnostic purposes, Immunoblot test results should be used in conjunction with the patient's clinical symptoms, history and other information available to the physician.

PRINCIPLE

The Lyme ImmunoBlot Test is a qualitative assay that detects *B. burgdorferi* specific IgM and IgG antibodies in human serum. Recombinant *B. burgdorferi* species antigens are sprayed at specific positions onto a nitrocellulose membrane and cut into strips. These strips are used to detect *B. burgdorferi* specific antibodies in patient serum.

PERFORMANCE CHARACTERISTICS

Based on a study performed on 174 well-characterized clinical samples, the sensitivity of the Lyme ImmunoBlot is 90.9% and the specificity is 98.0% for IgM and 98.7% for IgG.

ADVANTAGES

• The specificity of the ImmunoBlot is higher than the traditional Western Blot. In a Western Blot, proteins are separated by size. Therefore, more than one protein can be present at any one position (e.g. at 31kDa, Osp A and non-specific antigen are present.) Whereas on an ImmunoBlot, pure proteins are sprayed at specific positions on the blot.
• The 31kDa Epitope confirmation test will not be required on patient samples tested by Lyme ImmunoBlots.
• Immunoblot has better sensitivity than the current Western Blot, since the Immunoblot is designed to detect antibodies to *B. burgdorferi* variants.

SAMPLE REQUIREMENT: 0.5 ml serum
TEST NUMBER: 325 Lyme ImmunoBlot IgM
                                  335 Lyme ImmunoBlot IgG
CPT CODE: 041U, 042U