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Poster Presentation
Improved Diagnostics for Lyme Borreliosis Using a New Stripe Immunoblot Test System
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Introduction: Lyme Borreliosis, caused by the spirochete Borrelia burgdorferi, is the most commonly reported vector-borne infection in the United States. In the United States, the CDC prescribes a two-tier testing algorithm for determining if a patient is infected1. The primary step is a highly sensitive screen assay, using either an IFA (Indirect fluorescence assay) or an ELISA/EIA derived from Borrelia lysate or highly immunogenic C6 peptide. Patient samples that are positive or equivocal on screen assay are further confirmed using a highly specific immunoblot assay. Traditionally this was performed using western blots (WB) derivedfrom B. burgdorferi lysate. Although this is a highly sensitive and effective test system, the interpretation of results is complicated by immunoreaction of samples to non-specific portions of the B. burgdorferi proteome and variation in the CDC characterized immunogenic band locations. Line immunoblot technology, in which highly purified Borrelia antigens expressed using recombinant systems are striped on predefined locations on membranes, has simplified several

procedural and interpretation challenges associated with WB 2. Moreover, the line blots are well suited for automated execution and result interpretation of the assays.

Study objective: This study compares the performance of a new line immunoblot assay to that of the traditional WB test used for serological confirmation of Lyme infection and highlights the advantages of the new format for the clinical labs.

Methods: Patient Population: Between 7/20/2016 and 8/29/2016, 274 patient samples testing equivocal or positive on a first-tier screen test (Device ref# VIDAS?) (clinical immunology laboratory at Sharon Hospital (Sharon, CT) were confirmed by MarBlot IgG test system (Trinity Biotech Plc). The same sera were further evaluated on a new LIA test system (B. burgdorferi MarStripe IgG test system, Trinity Biotech Plc).

Results: MarBlot test system provided an overall sensitivity of 47.8% . Overall agreement between the MarBlot (WB) device and the new MarStripe (LIA) was 95.6% (262/274). Positive agreement between the MarBlot (WB) device and the new MarStripe (LIA) was 94.7% (124/131) and negative agreement between the two devices was 96.5% (138/143).

Conclusions:
•Western blot is the gold standard confirmatory device for Lyme borreliosisby feature of presenting the complete B. burgdorferi proteome.
•The MarStripe IgG test preserves the superior diagnostic performance of a western blot, and substantially improves the accuracy and ease of interpreting immunoblot reactions.
•The MarStripe IgG kit uses a next generation reagent set that is upgraded for superior performance and stability.

References:
1. Engstrom, S. M., E. Shoop, and R. C. Johnson. 1995. Immunoblot interpretation criteria for serodiagnosisof early Lyme disease. Journal of clinical microbiology 33: 419-427.

2. Louis A. Magnarelli, S.J.P. ErolFikrigand A. R. A. F. John F. Anderson. 1996. Use of Recombinant Antigens of Borreliaburgdorferiin Serologic Tests for Diagnosis of Lyme Borreliosis. Journal of clinical microbiology: 237–224.