Lab Dept:	**Serology**
Test Name:	**LYME DISEASE SEROLOGY EVALUATION REFLEX, SERUM**

General Information

Lab Order Codes:	LYMS, LYCON
Synonyms:	Borrelia burgdorferi screen
CPT Codes:	86618 – Antibody; Borrelia burgdorferi screen, EIA 86617 x2 – Antibody; Borrelia burgdorferi, confirmatory, Western blot (If appropriate)
Test Includes:	If the Lyme screen is positive, a western blot confirmation will be performed at an additional charge (confirmation testing is referred to Mayo Medical Laboratories).

Logistics

Test Indications:	Useful for identifying specimens with positive or equivocal Lyme serology and eliminating any false-positive results by a Lyme Western blot confirmatory assay including both IgG and IgM levels.
Lab Testing Sections:	Chemistry (performed on the St. Paul campus)
Referred To:	Mayo Medical Laboratories (Test# LYWB), Western Blot/Immunoblot confirmation test
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	2 – 10 hours, testing is performed daily
Special Instructions:	Specimens retained in St. Paul Chemistry for 2 weeks.

Specimen

Specimen Type:	Blood
Container:	SST (Gold, marble or red)
Draw Volume:	3 mL (Minimum: 1.5 mL) blood

Processed Volume: 1 mL (Minimum: 0.5 mL) serum

Note: For positive tests sent to MML for confirmation, please send (0.75 mL, Minimum: 0.5 mL serum)

Collection: Routine venipuncture

Special Processing: Lab Staff: Centrifuge specimen and remove serum aliquot into a plastic screw-capped round bottom vial. Screening test performed internally, specimen to be referred to MML for positives. Store and ship at refrigerated temperatures. Forward promptly.

Patient Preparation: None

Sample Rejection: Specimens other than serum; hemolyzed specimens; mislabeled or unlabeled specimens; lipemia; particulate samples

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Interpretive

Reference Range:

CLIA Lymes Screen:	<0.9 Index Negative – no antibody to Borrelia burgdorferi detected 0.9 – 1.0 Index Equivocal – Confirmed by Western Blot > or = 1.1 Index Positive - Confirmed by Western Blot)

Interpretation:
Negative: A negative CLIA result does not exclude the possibility of *Borrelia burgdorferi* infection. Patients in early stages of infection may not produce detectable levels of antibody. Antibiotic therapy in early disease may prevent antibody production from reaching detectable levels. Patients with clinical history and/or symptoms suggestive of Lyme disease or where early Lyme disease is suspected, but with negative test results should be retested in 2 to 4 weeks.

Equivocal: The imprecision inherent in any method implies a lower degree of confidence in the interpretation of specimens with absorbance values very close to the calculated cutoff value. For this reason an equivocal category has been designated. Equivocal specimens will be tested by WB and IFA assays in accordance with Centers for Disease Control and Prevention (CDC)/Association of Public Health Laboratories (APHL) recommendations.

Positive: Antibody to *Borrelia burdorferi* detected. All positive results will be supplemented by retesting the serum by WB for the detection of IgG antibodies to *Borrelia burdorferi,* and an IFA assay for the detection of IgM antibodies in accordance with CDC/APHL recommendations.

Western Blot IgG:	IgG: Negative
Western Blot IgM:	IgM: Negative

Interpretation:
IgM: IgM assay is useful for confirming stage 1 (acute) Lyme disease. IgM antibodies to *Borrelia burgdorferi* may be detectable within 1-2 weeks following the tick bite. They usually peak during the third to sixth week after disease onset, and then demonstrate a gradual decline over a period of months. IgM antibody may persist for months even though antimicrobial agents are given. The IgM assay is more likely to be useful during early disease, and should only be tested during the first 4 to 6 weeks after disease onset.

Negative specimens typically demonstrate antibodies to less than 2 of the 3 significant *Borrelia burgdorferi* proteins. Additional specimens should be submitted in 2 to 3 weeks if *Borrelia burgdorferi* exposure has not been ruled out.

Individuals who have recently seroconverted due to infection with *Borrelia burdorferi* may display incomplete banding patterns, but may develop increased reactivity (both in band intensity and number) when followed for a period of 4 to 6 months.

IgG: The IgG assay is useful for confirming stage 2 and stage 3 Lyme disease. Serum IgG is detected as early as 2 weeks after onset of disease. Significant concentrations of antibody and Western blot banding patterns for Borrelia burgdorferi can be found years after onset.

For persons who have received recombinant OspA vaccine and who are not infected with *Borrelia burgdorferi*, an intense band representing antibody to the OspA protein (band 30) should be visible on the Western blot.

Critical Values: N/A

Limitations: A negative result does not exclude the possibility of infection with *Borrelia burgdorferi*.

A positive result is not definitive evidence of infection with *Borrelia burgdorferi*. It is possible that other disease conditions, including syphylis, periodontal disease, rheumatoid arthritis, systemic lupus erythematosis, and other autoimmune diseases, may produce artifactual reactivity in the assay.

This test should not be used to screen the general population. The predictive value of the assay is a function of the pretest probability of Lyme disease in the population tested. Hence, only patients with clinical symptoms of Lyme disease or suspected exposure to *Borrelia burgdorferi* should be tested.

The DiaSorin LIASON® *Borrelia burgdorferi* assay contains antigens from *Borrelia burgdorferi* and *Borrelia ganinii,* known to infect populations in Europe and other parts of the world, but not generally detected in US patients. Results from the second-step Western Blot that only detects *B. burgdorferi* specific antigens should be interpreted with caution. Treatment of these patients for Lyme disease should be based on clinical manifestations present and patient history, including travel outside of the US.

Potential assay interference due to circulating antibodies against Human Erlichiosis (HE) and Tick Borne Relapsing Fever (TBRF) has been found. Interpret results from these patients with caution.

This assay has been tested with samples from individuals vaccinated with a licensed OspA vaccine (LYMErixa – manufactured by GlaxoSmithKline Biologicals). The performance has not been determined on serum samples from recipients of other Lyme vaccines.

Western blot is not useful as a screening assay. WB may be negative in specimens that are weakly-positive by EIA or in patients with early Lyme Disease. Test results should be used in conjunction with clinical evaluation and information related to tick exposure.

A negative test result does not necessarily rule out current or recent infection. The specimen may have been drawn before demonstrable antibody developed. Patients with early stage disease often have serum antibody titers below the diagnostic threshold for several weeks after onset of disease.

Test results from immunosuppressed patients and pregnant women may be difficult to interpret.

Positive test results may not be valid in persons who have received blood or blood product transfusions with the past several months.

Antibiotic therapy early in the first-stage disease may blunt antibody response to the point that diagnostic threshold levels are never attained, making disease difficult to detect through serology.

False-positive reactions may occur with patients with other spirochetal diseases (syphilis, yaws, pinta, relapsing fever, and leptospirosis), influenza, auto-immune disorders, MS and ALS.

Methodology:

Chemiluminescent Immunoassay (CLIA)
Western Blot Assay

Contraindications:

The continued presence or absence of antibodies cannot be used to determine success or failure of therapy.

References:

LIASON® *Borrelia Burgdorferi* (310870) Directions for Use, DiaSorin, Inc, Stillwater, MN 55802, September 2008

Jacobs and DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th ed, 2001

Mayo Clinic Laboratories September 2014

Updates:

7/29/2004: Mayo now uses Western Blot methodology for both IgG and IgM confirmations. Mayo previously used IFA for the IgM portion effective 7/1/2004. Draw volume changed from 3.0 mL to 1.5 mL.

6/19/2008: Mayo no longer reports the number of bands present on Western blot testing confirmations.

1/10/2012: Moved inhouse at Children's as CLIA screening test with reflex WB to Mayo. Screening previously performed at Mayo as EIA. Draw volume changed to 3 mLs.

6/26/2017: Tube changed from Red to Red NO Gel.
8/13/2019: Updated containers and TAT.