

Product Name: *Borrelia burgdorferi* grade 2 Antigen

Catalogue Number: EL-24-02

Storage: Store this antigen preparation frozen at - 70 °C to - 100 °C. Repeated freezing and thawing should be avoided.

Hazards:

The product has been inactivated. No test method guarantees a product to be non-infectious. All products should be handled as if potentially infectious. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Strain: B31

Cultured In: BSK 11 medium.

Buffer: PBS with magnesium

Agent Description: A spirochete first identified in 1982. A tick borne zoonotic disease characterized by distinctive skin lesion (ECM), systemic symptoms, polyarthritis, neurological and cardiac involvement, malaise, fatigue, fever, headache, stiff neck, myalgia, migratory arthralgia or lymphadenopathy lasting several weeks and may precede lesions; neurological and cardiac abnormalities weeks to months after onset of ECM; chronic arthritis may develop

Preparation: Organisms are harvested from growth medium and washed in PBS using low speed centrifugation. The pellet is resuspended in PBS and gently sonicated.

Inactivation: *Borrelia burgdorferi* grade 2 antigen is inactivated using gamma radiation.

Recommendations for Use: This antigen preparation should be sonicated immediately prior to use to ensure that the preparation is uniform. This preparation may be used as is in a variety of immunoassay formats or may be further purified to meet the needs of a particular assay format. Grade 2 antigen is widely used for both IgG and IgM detection in assays which include EIA with polystyrene and latex solid phases.

Quality Control Information

Product Name: *Borrelia burgdorferi* grade 2 Antigen

Lot Number: 24XXXXX

Microbix performs quality control tests to ensure each batch meets in-house specifications. Test results are provided with each lot of antigen shipped. Antigen users require this information for a number of reasons:

- to maintain a record for good manufacturing purposes,
- to correlate user results with Microbix results and
- for use as a starting point for those just starting with either a new antigen or developing a new assay.

It is important that each user perform titrations of antigen using their own assay as each assay format and serum release panel makes different performance demands on the antigen. Often, use of an antigen may be optimized by making adjustments to concentrations of other assay reagents such as conjugate. Once this is complete the result is cost effective use of the antigen and optimal assay performance.

Tests:

Protein Concentration: Protein is determined using the BioRad dye binding assay in the micro assay format. The standard curve is generated with a known concentration of IgG.

Result: XXX mg/mL

Inactivation Assay: The effectiveness of inactivation is determined when no detection of growth in two blind passages under the original culture conditions is observed.

Result: No growth detected

Quality Assurance Signature:

Date:



Assistance: If you have any questions regarding the production, testing or use of this antigen, please send them by email to customer.service@microbix.com or fax 905-361-8911, with any relevant data, to Microbix Technical Services. Your complete satisfaction with the performance of this product is important to us.