



Technical Reports



RECOMBINANT CHIMERIC ANTIGEN
CHIMLYME FOR *BORRELIA BURGDORFERI*



The aim of the research presented in this technical report is to show the sensitivity of the recombinant chimeric antigen ChimLyme for *Borrelia burgdorferi* in comparison with several other biomarkers for Lyme disease. This chimera has been design and produced in Rekom Biotech and in this report we show its purity, integrity and the increased sensitivity due to the presence of multiple antigenic determinants.

Lyme borreliosis is the most prevalent tick-borne disease in Europe, the United States and parts of Asia. It is a multisystem disease involving many organs, such as the skin, nervous system, joints and heart. This condition is the most frequent tick-borne disease in the northern hemisphere. As a result of the diversity of clinical symptoms, Lyme borreliosis is often considered as a differential diagnosis. Lyme disease is caused by a group of genetically diverse spirochetes collectively termed *Borrelia burgdorferi sensu lato*. This complex includes several genospecies, of which 5 are known to be pathogenic to humans. The North American pathogenic strains that have been identified are *B. burgdorferi sensu stricto*, in contrast, in Europe and China, all 3 genospecies are found, with *B. garinii* and *B. afzelii* being the most prevalent isolates. Examinations for antibodies against *Borrelia burgdorferi sensu lato* are thus in high demand, and are among the most frequently requested serological tests in microbiological laboratories. Microbiological diagnosis in european patients must consider the heterogeneity of the agents of Lyme borreliosis in Europe.

It is generally accepted that serological examination should follow the principles of a two-step approach: (1) a serological screening assay (ELISA); and (2) in the event of a positive or equivocal result, a confirmatory assay (immunoblot).

Regarding the geographical distribution of this disease, there are foci of Lyme borreliosis in forested areas of Asia, north-western, central and eastern Europe, and the USA (figure 1).

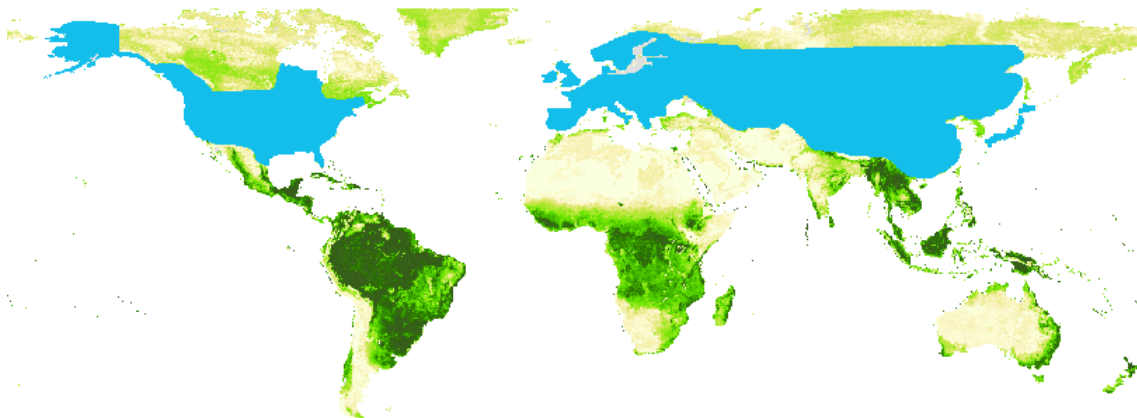


Figure 1. Geographical distribution of Lymedisease in the World.
Adapted from: <https://geo.arc.nasa.gov/sge/health/sensor/diseases/lyme.html>

In order to complete our several Lyme antigen references, Rekom Biotech has developed **ChimLyme**, a new recombinant multi-epitope chimera for detection of Lyme disease and with reference RAG0027.

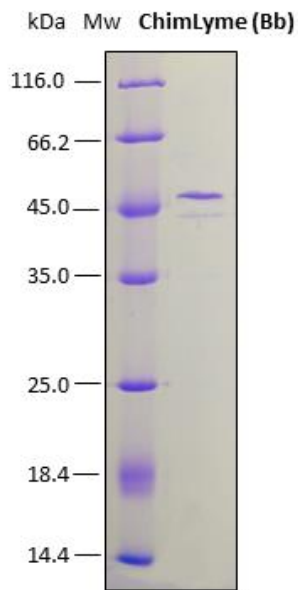


Figure 2. SDS-PAGE analysis (12.5%) of 5 μ l of recombinant ChimLyme. Purity is approx. 95% as determined by gel electrophoresis.

This ChimLyme has been evaluated in a preliminar way and compared in its antigenic performance with other Lyme antigens. An Immuno Dot assay is shown in the following figure (figure 3):

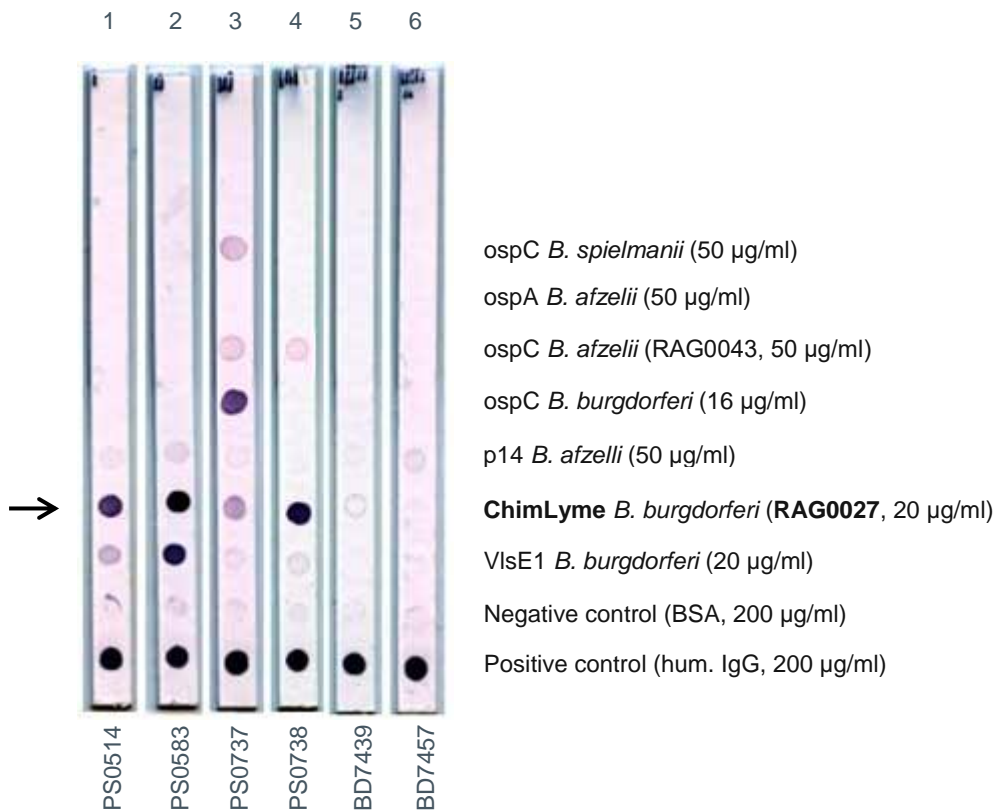


Figure 3. Comparative study by Immuno Dot assays of different biomarkers of *Borrelia burgdorferi sensu lato*. Immuno Dot performed with positive specimen sera for Lyme disease. Positive (human IgG) and negative (BSA) control in a concentration of 200 µg/ml is used by default for all immuno dots: (1) borreliosis positive sera, (2) borreliosis positive sera, (3) borreliosis positive sera, (4) borreliosis positive sera, (5) blood donor, randomly picked from our blood donor database and (6) blood donor, randomly picked from our blood donor database.

CONCLUSION

ChimLyme is a highly antigenic biomarker thanks to the multi-epitope presence in the molecule. In the light of preliminary studies, it seems to be better than other recombinant biomarkers used for this bacteria. We suggest a potential use of this chimera in the IVD diagnostics of Lyme disease, in both USA and especially in Europe, where the heterogeneity of the immunodominant epitopes must be considered.