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Clinical utility of the different Western blot antigen profiles in the context of disseminated Lyme disease

English Summary

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et en services sociaux (INESSS)

Québec

HISTORY OF CHANGES

Date	Changes made
June 2025	A standard two-tiered serology approach consisting of an ELISA and a Western blot was used by the Laboratoire de santé publique du Québec (LSPQ) until the beginning of 2025. Since then, a modified two-tiered serology approach combining two ELISA is performed. The standard two-tiered serology is still available following a case-by-case evaluation. The information presented in clinical tools concerning two-part serology has been adjusted accordingly and may differ from what is presented in this document published prior to 2025.

SUMMARY

Clinical utility of the different Western blot antigen profiles in the context of disseminated Lyme disease

Introduction

The diagnosis of Lyme disease is complex, and the information circulating about this disease on various websites and social media platforms is not always consistent with the scientific data. The medical community is fundamentally divided over the possibility that Lyme disease may cause persistent, general systemic symptoms. In addition, there are still many concerns and uncertainties regarding the reliability of laboratory tests and the efficacy of antibiotic treatments. Regardless of these uncertainties, the presence of such persistent and often significant symptoms is a reality for many people and result in a large number of medical visits and requests for laboratory tests or specialized examinations. Furthermore, some people struggling with such symptoms and looking for their cause step outside Québec's conventional healthcare system. They turn to clinicians who specialize in managing such patients, or they resort to tests performed by certain private laboratories and to different treatments, both pharmacological and nonpharmacological.

In May 2019, at the request of three branches of the Ministère de la Santé et des Services sociaux (MSSS), INESSS published clinical and implementation recommendations regarding the diagnosis, treatment and management of patients with localized or disseminated Lyme disease to equip health professionals, especially front-liners, given the increase in this illness. As a continuation of this work, MSSS asked INESSS to shed scientific light on the plausibility that Lyme disease can cause persistent, general systemic symptoms, on the contribution of laboratory approaches and tests to the diagnostic process, and on the benefits and risks of prolonged single and combined treatments and other treatment options, both pharmacological and nonpharmacological, that are suggested in such cases. These topics are dealt with in a separate publication. At the same time, INESSS was also asked to assess the clinical utility of the Western blot antigen profile and to identify the issues associated with the Laboratoire de santé publique du Québec providing this information to requesting clinicians, in order to support decision-makers in their decision-making. This aspect is the subject of this report.

Methodology

For the purposes of this part of the task, INESSS conducted a systematic review of the scientific literature and of publications containing positions, recommendations and guidelines on the subject. As well, contextual data and the perspectives of different stakeholders were gathered in order to document the issues important for patients, health professionals and the organization of services.

To gather the different perspectives, INESSS created an advisory committee consisting of clinicians, including medical specialists; experts in laboratory tests, acarological surveillance and public health; and patient partners with Lyme disease. In addition, eight clinicians with expertise in managing patients with persistent, general systemic symptoms attributed to Lyme disease were consulted through interviews or a survey to obtain the perspectives of clinicians with differing viewpoints. Further consultations were held with representatives from the Association québécoise de la maladie de Lyme and Enfance Lyme Québec.

To ensure that the recommendation intended for decision-makers will suit the context of Québec, several committees collaborated on its development. This report reflects this exhaustive consultative process.

Results

Two-tiered serology measures the immune response induced by bacteria belonging to the *B. burgdorferi s.l.* complex. It is usually based on an ELISA test and Western blot. According to U.S. Centers for Disease Control and Prevention recommendations, in order for the Western blot result to be considered positive, a minimum number of bacterial antigens must be detected by the patient's antibodies. These detected antigens appear to vary, among other things, according to the geographical location in North America where the infection was contracted and according to the year.

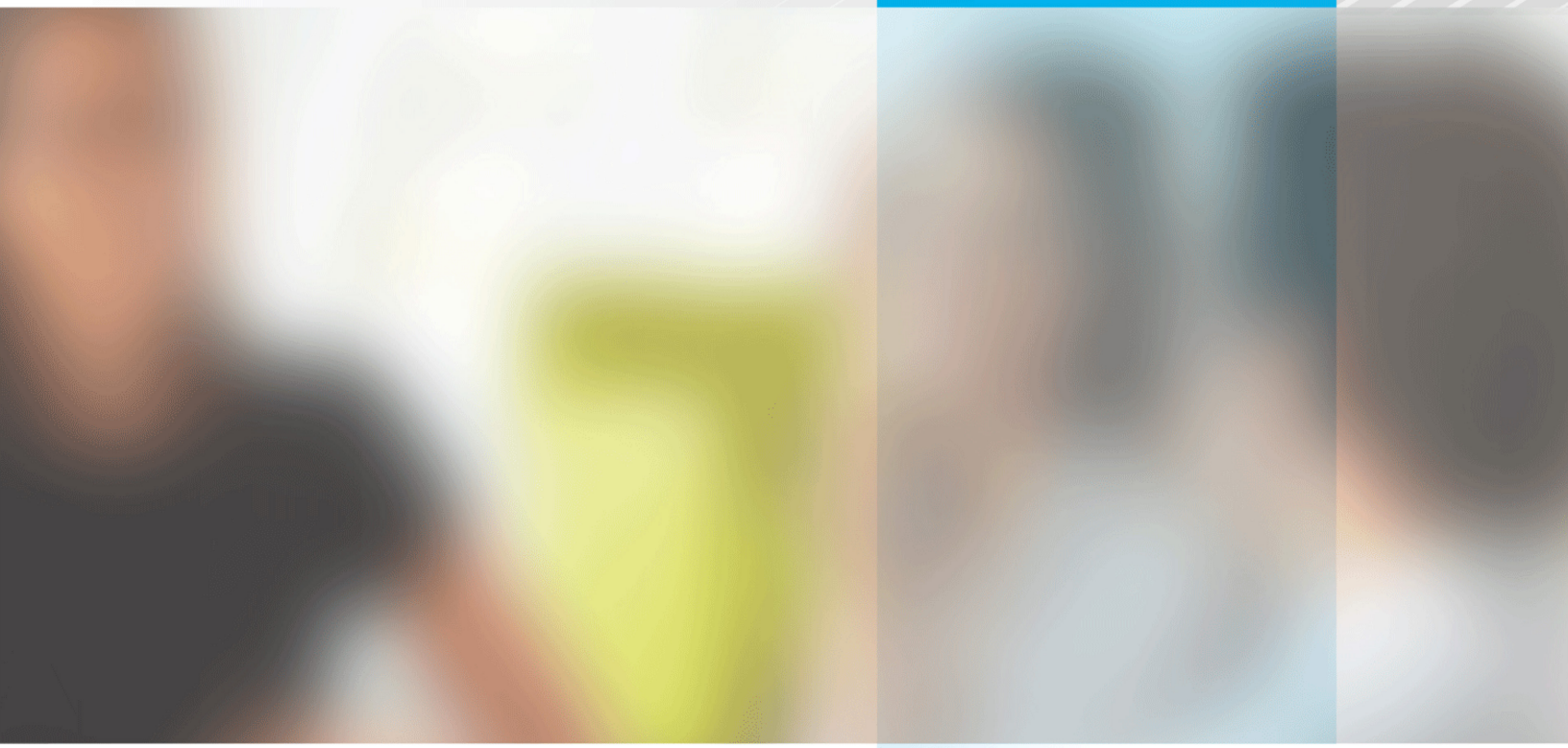
Although some clinicians ascribe a certain clinical utility to the Western blot antigen profile, this utility could not be assessed because no studies on this subject were found in the scientific literature. Furthermore, the organizations that publish recommendations have not taken a position on this subject. In general, it seems that clinicians are satisfied with knowing whether the Western blot result is positive or negative and do not inquire about the profile of the detected antigens in order to guide their clinical decisions. While clinicians are divided on the usefulness of knowing what this profile is in the overall approach to care, all the patient partners and patient association representatives are convinced of it. The transmission of the Western blot antigen profile is not addressed in the scientific literature or by organizations that publish recommendations. Although it is in accordance with current provincial legislation, providing this profile to the requesting clinician could pose certain problems, notably in terms of the feasibility for public health laboratories, depending on the number of requests and the interpretation of the information given to the requesting clinicians.

Conclusion

The clinical utility of the Western blot antigen profile in the context of disseminated Lyme disease cannot be assessed from the currently available scientific data. Research will therefore be necessary in order to be able to rule on this matter. In the meantime, although some of the stakeholders consulted see the usefulness of knowing what this profile is in the general approach to care, the overall assessment and consultation process indicates that it is too early and even potentially risky to make this information available for the purpose of guiding clinical management. Therefore, this work supports the use of the Western blot antigen profile for research and documentation purposes only.

Recommendation

Because of the potential for non-standard interpretation and its unproven clinical utility, the Western blot antigen profile should not be used to guide the clinical management of patients with suspected Lyme disease. The Laboratoire de santé publique du Québec should make this profile available to requesting clinicians primarily for research and documentation purposes.



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