

Diagnostic Testing for Lyme Disease

Diagnosis of Lyme borreliosis infections by indirect methods, i.e. looking for certain antibodies in patients' blood, has been proved to be unreliable by many studies published over the past 3 decades. The criteria necessary for providing accurate clinical decision-making and for the safe stewardship of maintaining Public Health have not been met.

A recently published meta-analysis by Leeflang et al., (1), reviews all testing methods to date and shows that this problem is evident:

"We found no evidence that ELISAs have a higher or lower accuracy than immunoblots; neither did we find evidence that two-tiered approaches have a better performance than single tests.

"However, the data in this review do not provide sufficient evidence to make inferences about the value of the tests for clinical practice. Valid estimates of sensitivity and specificity for the tests as used in practice require well-designed cross-sectional studies, done in the relevant clinical patient populations.

"Furthermore, information is needed about the prevalence of Lyme borreliosis among those tested for it and the clinical consequences of a negative or positive test result. The latter depend on the place of the test in the clinical pathway and the clinical decisions that are driven by the test results or not. Future research should primarily focus on more targeted clinical validations of these tests and research into appropriate use of these tests."

It should be realised that all of the validity data sets for test kits, as published by their manufacturers, have been determined in patients with known or highly probable borreliosis infection, as seen from their symptoms, such as EM rash, or frank symptoms such as facial palsy or Bannwarth's syndrome. Rarely have any antibody tests been matched against true microbiological evidence, which would have had to have been done by checking each patient with a culture test.

The test kits have not been validated in patients who have less obvious presentations of Lyme borreliosis. The only true validation would be to test each patient with manufacturer's kits and then to assess each patient by means of culture and/or DNA detection of the bacteria.

It is of the utmost clinical importance that the true state of the infection in each patient should be accurately assessed, This should be done in microbiological terms by looking for evidence of the bacteria themselves, instead of looking for the immune response. There are many reasons why the immune response is variable and often suppressed in patients with Lyme borreliosis. (2)

Microscopic visualization of live *Borrelia* spirochetes offers the strongest of all proofs that an infection is present. *Borrelia burgdorferi* can be visualized directly in infected vectors, reservoir hosts, laboratory animals and clinical specimens from patients with Lyme borreliosis using dark-field or phase-contrast microscopy. The spirochetes may also be microscopically visualized after Giemsa, Gram, immunological or silver staining of specimens

The BIA have dismissed microscopy and culture investigations of patients. They cite the long time period necessary for the borrelia spirochetes to grow, and the cost of technical manpower. However, if we are on the brink of a public health hazard, liable to affect future generations - because of the high probability of congenital transfer of the infection, and possible contamination of the nation's blood supply - then the cost has to be met. In fact, costs will not be as high as expected, since advanced culture methods have recently been patented which enable identification of borrelia species in patient sera within 1 week, in many cases:

This advanced culture method has been in operation as a successful commercial enterprise in Pennsylvania, at Advanced Laboratory Services, for the last 3 years, and has been published in the peer-reviewed literature (3, 4) and patented (5).

The method is endorsed by Philip M. Tierno, Jr., PhD Frm Director of Clinical Microbiology and Immunology, New York University School of Medicine
Dr Tierno refutes accusations by some CDC scientists that there might have been contamination during the method. (6).

Criticism of the method by UK scientists has been quashed with research by Dr Sheila Woods and her team at Advanced labs. PHE have claimed that the spirochaetes seen in the microscope were artefacts, or pieces of collagen or fibrin. Sheila Wood used a special Rhodium-based stain which has the property of only attaching to collagen and fibrin, and it was conclusively shown that, in the very small percentage of cases where the obvious shape of Borrelia spirochaetes was not so distinct (about 2% of samples), the Rhodium stain did not attach to what were suspected to be Borrelia spirochaetes. The Rhodium stain did attach to bits of the background extra-cellular matrix, as it is designed to do, but absolutely did not stain the Borrelia. (7).

The Abstract states : "In order to distinctly differentiate the organisms from the collagen of this matrix that could be observed as background in the staining process, we developed an immunostaining procedure using polyclonal and monoclonal antibodies in combination with rhodamine fibronectin. The culture samples from both control organisms and patient samples were tested using the new immunostaining protocol. Results showed clear delineation of organisms compared to the collagen pieces gathered in the harvesting process. This new immunostaining process, used with in vitro cultivation, provides for precise identification of cultured organisms."

Given that the true prevalence of borreliosis in the UK has not been fully monitored, and that it will be bound to increase in the British Isles, as it has been seen to do so across the Northern hemisphere , we can expect tens of thousands of cases each year (8,9).

The Health and Safety of the UK over the next 10 to 15 years will depend on how the NICE committee decides to tackle the problem of not just Lyme disease, but also other arthropod-borne infections. It is imperative that our health service chooses the best diagnostic techniques .

References

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