

MSIDS Inc. response in relation to:

Question: 1

Hansard page reference: 16

Hansard extract:

Senator WANG: Thank you, Chair. Ms Daniels, to your knowledge, what caused the laboratories to raise the bar?

This question is probably better directed to the Royal College of Pathologists (RCPA), as policy decisions regarding testing for 'classical' Lyme disease (*Borrelia burgdorferi* s) have been made by this company, which represents the interests of its members, or 'fellows', and their laboratories.

MSIDS Inc can only speculate on what 'caused' the RCPA to adopt these policies, based on limited information that is available in the public domain and via our own data collection exercises.

The 'short answer' to the question is that it appears the RCPA applies interpretive criteria to test results that are inconsistent with test kit guidelines and diagnostic guidelines applied in overseas labs. This has been justified on the basis that *Borrelia burgdorferi* s) has not been definitively identified in Australian ticks. The subsequent deductive formula applied is that the human population will, therefore, have a low prevalence of the bacteria.

the children's hospital at Westmead

Predictive Values

- Predictive values are of importance when a positive result does not automatically mean the presence of disease.
- Unlike sensitivity and specificity, predictive value varies with the prevalence of the disease within the population.
- Even with a highly specific test, if the disease is uncommon among those tested, a large proportion of the positive results will be false positives and the positive predictive value will be low.



Even where all other factors are the same (for example, following commercial test kit guidelines), an additional criterion is applied by RCPA-NATA labs requiring that the patient must have recently returned from a 'Lyme-endemic' country.

Hence, the vast majority of human serology tests that would be assessed as 'positive' in overseas countries (where endemicity of the northern hemisphere strains of the bacteria has been established in local tick species) are deemed to be 'false positives' in the RCPA-NATA accredited labs.

Completing the more comprehensive and detailed response to this question requires mental and physical resources currently unavailable to the MSIDS Inc. team members, who are compromised by illness. In the coming months we will endeavour to finalise our full submission, which presents evidence that challenges this position and may shed further light on this topic.