

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Supplementary Budget Estimates 2015 - 2016, 21 October 2015**

**Ref No:** SQ15-000755

**OUTCOME:** 9 - Biosecurity and Emergency Response

**Topic:** Lyme Disease

**Type of Question:** Written Question on Notice

**Senator:** Madigan, John

**Question:**

Global best practise dictates that Lyme and Lyme-like disease is primarily a clinical diagnosis largely attributable to the difficulties with blood testing for Lyme and Lyme-like illness. What has the Department of Health done to educate doctors in the fact that a negative Lyme disease test does not necessarily mean a patient is free of that particular infection?

**Answer:**

The Department of Health will soon make available on its Lyme disease webpage answers to commonly asked questions. The Department will provide an explanation on the limitations of laboratory tests including the sensitivity and specificity of the diagnostic test and that the likelihood of disease is dependent on the prevalence of the disease as well as the interpretive criteria being used. In the case of Lyme disease, in Australia, because the assays being used have high specificity and because the prevalence is low, a nonreactive (i.e. negative) serological result is highly predictive of no disease being present.

This answer was provided at the Budget Estimates hearing on 21 October 2015.

“One of the things we often have difficulty in appreciating, outside of pathology circles, is that each test has its own sensitivity and specificity but the predictive value of the diagnostic test is really determined on two things. One is the prevalence of the disease in its truer state and also in the interpretation. What we know about Lyme disease testing—classical Lyme disease testing, in Australia—is that the prevalence of true classical Lyme disease in Australia, is low. In fact, it is probably zero. The prevalence in those areas where it is endemic is high. Based on that, if you have a test with a high specificity, a negative test here is highly likely to predict true negativity—whereas a positive test is likely to be a false positive. The other important factor is interpretation. I have seen the results from patients who have submitted their specimens overseas to America, to Germany and to other places and, when I look at the results that come back and the interpretation of the results, those interpretations are often at odds with the standardised criteria that are established by large agencies, like the Centers for Disease Control and Prevention, in the United States, as well as

other centres in Europe for communicable diseases. The criteria that are used need to be stringent, because they are criteria used not only for surveillance but also they assist with diagnosis.

The disharmony or discordance we see in testing is not necessarily unexpected. It is unfortunate and it is difficult for a lot of patients. Without wanting to sound prejudiced against my medical colleagues, outside of pathology it is fairly difficult for people to understand the nuances of diagnostic tests and their value, and that demonstrates the importance of having pathologists in the Australian medical system.”