

## Chapter 3

### Diagnostic testing for Lyme-like illness

3.1 As noted in Chapter 1, patients diagnosed with Lyme-like illness often have their clinical diagnoses confirmed by laboratory tests conducted in overseas laboratories or non-accredited laboratories in Australia. These conflicting diagnoses cause concern and frustration to sufferers of chronic debilitating symptoms.

3.2 This chapter examines the diagnostic process by which patients come to be diagnosed with Lyme-like illness. It explores the discordant results for Lyme disease testing between accredited laboratories in Australia and laboratories overseas and non-accredited laboratories in Australia.

#### Diagnostic testing for Lyme disease

3.3 In 2015, the Department of Health (department) released Australian guidelines on the diagnosis of overseas acquired Lyme disease. The department emphasised that these guidelines are for the diagnosis of classical Lyme disease only, and do not apply to Lyme-like illness acquired in Australia.<sup>1</sup>

3.4 The diagnostic protocols in the department's guidelines are consistent with the 2014 position statement prepared by the Royal College of Pathologists of Australasia (RCPA), *Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*.<sup>2</sup> Submissions to the inquiry from medical authorities and state and territory governments supported the RCPA's position statement and highlighted that the diagnostic protocol it outlines should be followed for diagnosing Lyme disease or any similar syndromes.<sup>3</sup>

3.5 Figure 3.1 outlines the proposed protocol for diagnosing cases of suspected Lyme disease in Australia recommended by the RCPA's 2014 position statement on the treatment of Lyme disease and related syndromes.

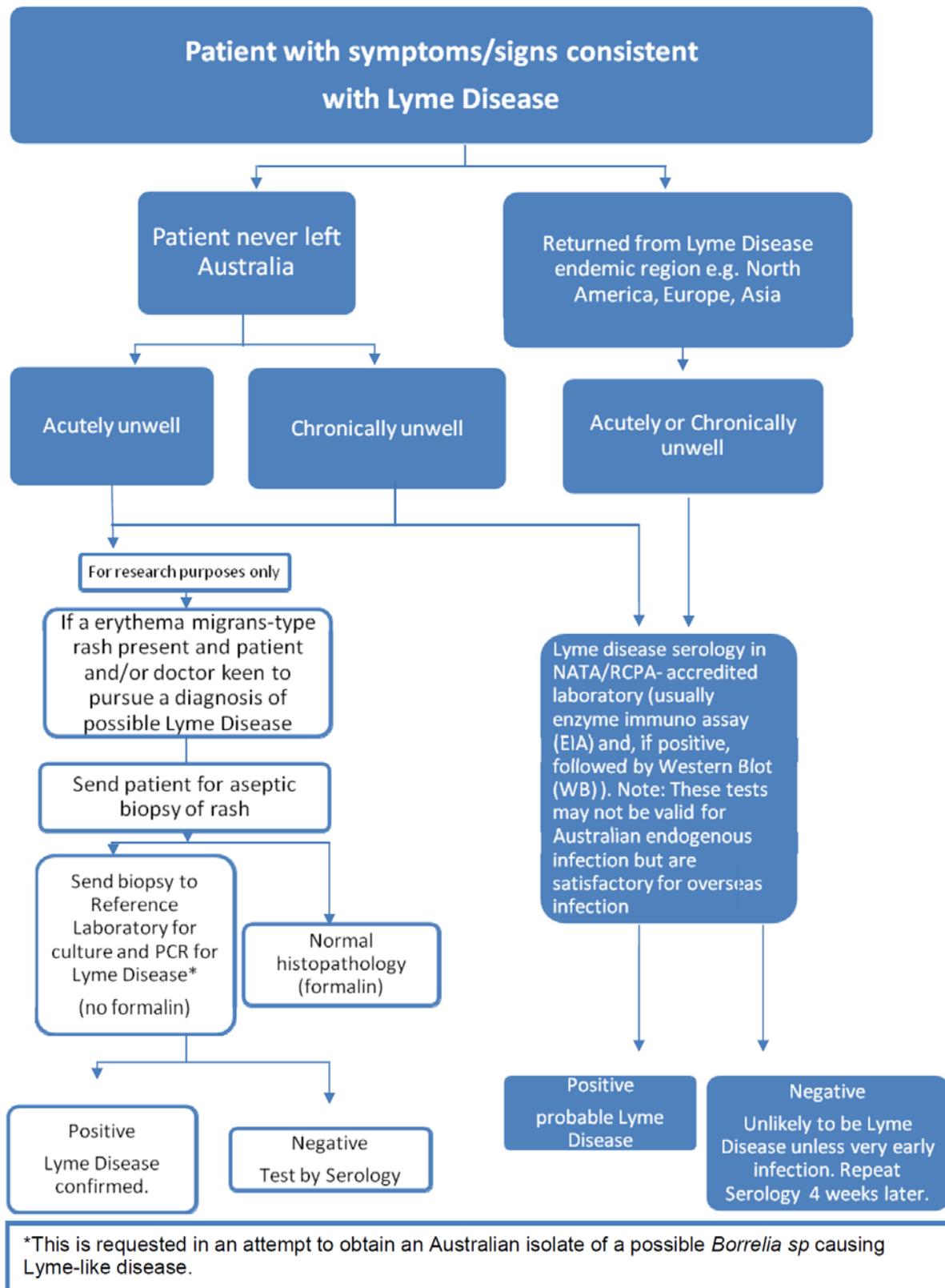
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1 Department of Health, *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, August 2015, <http://www.health.gov.au/lyme-disease> (accessed 1 December 2015).

2 Royal College of Pathologists Australasia (RCPA), *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, <http://www.rcpa.edu.au/Library/College-Policies/Position-Statements/Diagnostic-Laboratory-testing-for-Borreliosis-Lyme> (accessed 7 December 2015).

3 See, for example: Royal Australia College of Physicians, *Submission 754*; Australian Society for Microbiology, *Submission 781*; WA Department of Health, *Submission 529*; NSW Health, *Submission 457*; Victorian Department of Health and Human Services, *Submission 547*.

**Figure 3.1 – Recommended protocol for laboratory testing of patients with suspected Lyme disease in Australia**



Source: Royal College of Pathologists of Australasia, *Submission 532*, p. 8.

### *Diagnosis of overseas acquired classical Lyme disease*

3.6 According to the guidelines for the diagnosis of overseas acquired Lyme disease prepared by the department, a confirmed case of Lyme disease requires laboratory definitive evidence (culture, DNA or serological assays), clinical evidence and epidemiological evidence. The guidelines highlight the importance of epidemiological evidence in determining whether a patient has Lyme disease:

Epidemiological context is important. Determining a travel history and tick exposure prone activities are essential. The likelihood of Lyme disease increases as the probability of a tick bite increases in a geographically endemic area (particularly wooded, brushy, or grassy habitats).<sup>4</sup>

3.7 Laboratory definitive evidence for Lyme disease can be collected through culture, DNA or serological assays. The 'gold standard' for specificity of *Borrelia* infection is culture of spirochaetes from patient specimens. Molecular detection of *Borrelia* bacteria using a Polymerase Chain Reaction (PCR) test in patient specimens may also be used. However, these tests are not regarded as reliable as the bacteria are difficult to detect and appropriate samples are difficult to obtain.<sup>5</sup>

3.8 The more common way for diagnosing Lyme disease is through testing for antibodies to *Borrelia* bacteria through serological assays. The United States (US) Centers for Disease Control and Prevention (CDC) notes that serological test results need to be interpreted according to strict criteria, including whether Lyme disease is endemic to a particular area and whether the patient exhibits clinical symptoms.<sup>6</sup>

3.9 Most serological diagnostic protocols in the US and Europe use a two tier system. The first stage is most commonly an enzyme-linked immunosorbent assay (ELISA), followed by a Western blot. Western blots are interpreted using standardised criteria. These criteria differ between the US and Europe depending on the different genospecies of *B. burgdorferi* in different regions. The RCPA's position statement recommends the use of the two-tiered system and highlights that Western blot tests 'must be interpreted with caution, especially in the absence of an Australian *Borrelia* sp'.<sup>7</sup> Figure 3.2 outlines the two-tiered testing process recommended by the US CDC.

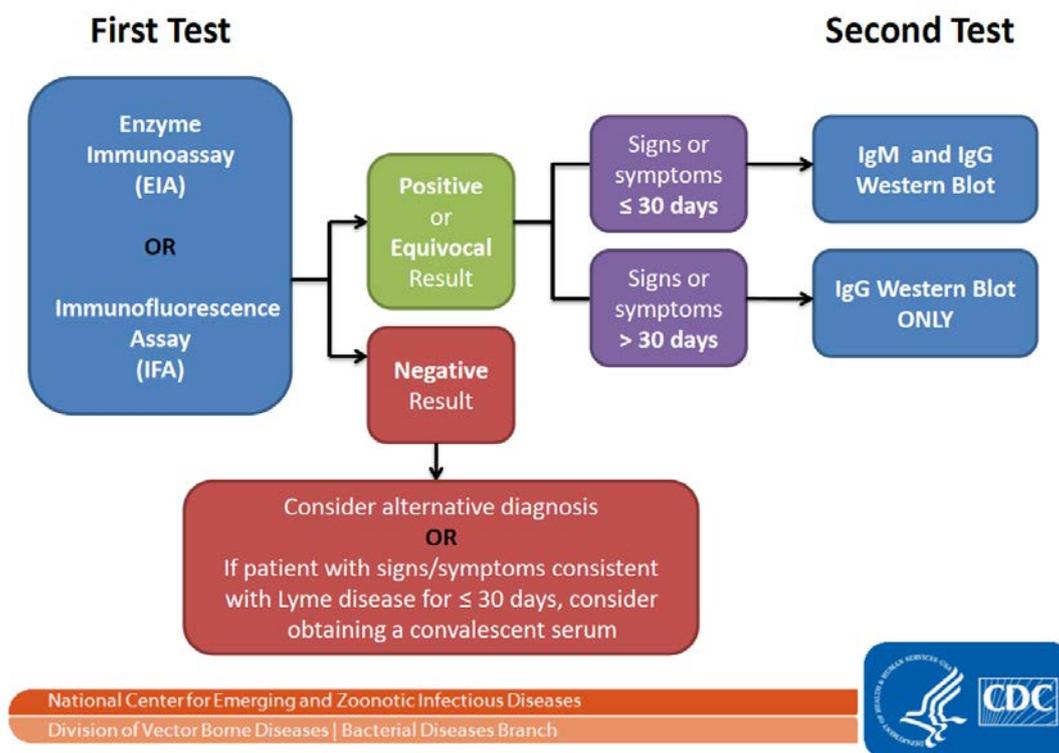
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4 Department of Health, *An Australian guideline on the diagnosis of overseas acquired Lyme Disease/Borreliosis*, August 2015, <http://www.health.gov.au/lyme-disease> (accessed 1 December 2015).

5 Professor John Mackenzie, *Scoping study to develop a research project(s) to investigate the presence or absence of Lyme disease in Australia*, 30 September 2013, p. 15.

6 Barbara Johnson, 'Laboratory diagnostic testing for *Borrelia burgdorferi* infection', in *Lyme Disease: An Evidence Based Approach*, John Halperin (ed.), CABI International, 2011, p. 73, [http://www.cdc.gov/lyme/resources/Halperin\\_2012\\_Chap4\\_JohnsonB.pdf](http://www.cdc.gov/lyme/resources/Halperin_2012_Chap4_JohnsonB.pdf) (accessed 9 December 2015).

7 RCPA, *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, p. 4.

**Figure 3.2 – Two-tiered testing for Lyme disease**

Source: US CDC, [http://www.cdc.gov/lyme/healthcare/clinician\\_twotier.html](http://www.cdc.gov/lyme/healthcare/clinician_twotier.html) (accessed 8 December 2015).

3.10 Australian laboratories are accredited for medical testing by the National Association of Testing Authorities Australia (NATA) in conjunction with the RCPA.<sup>8</sup> According to the department, NATA accredited laboratories can readily test for Lyme disease acquired overseas where patients have travelled to an endemic area. Dr Gary Lum told the Community Affairs Legislation Committee:

If a patient who is from Maine, Connecticut or another area in the north-east of the United States or from the Black Forest of Germany, who has been bitten by a tick and then travels to visit Australia and sees a general practitioner and has a blood test, we get a positive diagnosis. The same is true for Australians travelling to those areas and coming back with a rash and feeling unwell. Lyme disease is considered because they were in an endemic area, and a diagnosis is readily made in an Australian accredited medical testing laboratory.<sup>9</sup>

3.11 The Public Health Laboratory Network (PHLN) submitted that the interpretation of serology tests depend on three key factors:

8 National Association of Testing Authorities (NATA), 'Types of Accreditation', <http://www.nata.com.au/nata/accreditation-info/types-of-accreditation> (accessed 8 December 2015).

9 Dr Gary Lum, Principal Medical Adviser, *Estimates Hansard*, 21 October 2015, p. 14.

- the sensitivity of the test (the percentage of people with the disease who will have a positive test);
- the specificity of the test (the percentage of people without the disease who will have a negative test); and
- the pre-test likelihood of the person having the disease, based on the prevalence of the disease in the population being tested.<sup>10</sup>

3.12 As classical Lyme disease is considered to have a low prevalence in Australia, locally acquired cases are considered likely to return negative results for *Borrelia*. The PHLN notes that positive results for locally acquired Lyme disease are likely to be 'false positives' and are not uncommon in patients suffering other conditions:

... a positive result is more likely to be a false-positive if the test is performed on a person with a low pre-test likelihood of having the condition, such as testing for Lyme disease in Australia. There are two factors at play here – the first is that when less stringent interpretative criteria are used ... the results will be skewed to more patients with the disease. The other factor is that the assays were developed for classical Lyme disease, so for patients in a low prevalence population with nonspecific symptoms, the predictive value is low and reactive results are more likely to reflect absence of disease while nonreactive results likely reflect true absence of disease. False positive results for Lyme disease are not uncommon in patients suffering from other conditions.<sup>11</sup>

### ***Diagnostic testing for Lyme-like illness***

3.13 The diagnostic protocol for testing for classical Lyme disease acquired overseas outlined above is widely accepted by Australian medical authorities. However, due to the debate about the cause or causes of Lyme-like illness, the diagnostic protocol for Lyme-like illness is more disputed.

3.14 The RCPA position paper states that for patients presenting with 'syndromes resembling Lyme disease' with no history of travel to an endemic area:

... although [i]t is not entirely possible to rule in or rule out locally acquired Borreliosis on the basis of a series of negative results, it is important that patients are not diagnosed erroneously as having Lyme Disease, when they may well have some other, potentially treatable, conditions: examples include chronic pain syndromes including fibromyalgia; complex neurodegenerative disorders such as motor neurone disease; or psychiatric illness such as major depression with somatisation.<sup>12</sup>

3.15 As noted in Chapter 1, 'Lyme literate' practitioners assert that Lyme-like illness is caused by an ongoing *Borrelia* bacterial infection, together with other co-infections. Most other medical authorities assert that the *Borrelia* responsible for

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10 Public Health Laboratory Network (PHLN), *Submission 319*, p. 1.

11 PHLN, *Submission 319*, p. 2.

12 RCPA, *Position statement: Diagnostic Laboratory testing for Borreliosis ('Lyme Disease' or similar syndromes) in Australia and New Zealand*, February 2014, pp 2–3.

causing Lyme disease is not endemic to Australia and suggest that there may be multiple causes of Lyme-like illness that are yet to be identified.

3.16 Many submitters who have acquired their illness in Australia stated that when their blood samples have been sent to an accredited Australian laboratory to test for *Borrelia* bacteria, the results have come back negative.<sup>13</sup>

3.17 However, when these same submitters consulted a 'Lyme literate' practitioner, they have recommended sending their blood samples to either a non-accredited laboratory in Australia or laboratories in the US or Germany. As these tests are not covered under the Australian Medicare system, the costs for patients are significant (for example, \$800 for tests in Australia and \$2 000 for tests from overseas laboratories).<sup>14</sup>

3.18 Tests results from these laboratories have returned a positive result for *Borrelia*, often with a number of co-infections such as *Bartonella* and *Babesia*. These results have been used by 'Lyme literate' practitioners to confirm their clinical diagnosis. Dr Hugh Derham, a 'Lyme literate' practitioner in Western Australia, told the committee:

Almost all of my patients have a clinical diagnosis of Lyme disease and reasonable to excellent laboratory evidence as well, and at least half of them have some laboratory evidence from an accredited laboratory, either accredited by or recognised by NATA. I do not have hundreds of patients who believe they have Lyme disease; their belief is founded on good evidence.<sup>15</sup>

3.19 Evidence from submissions suggests that the differences between laboratory results can cause significant confusion and frustration for patients. Submitters expressed their deep concern that results from overseas laboratories are disregarded by Australian medical authorities, particularly infectious disease specialists:

Patients who attempt IDS [infectious disease specialist] consults are turned away with negative test results even though they may have gone to huge expense to be tested in accredited laboratories overseas and carry positive test results with them, they are still disregarded by the IDS.<sup>16</sup>

3.20 The issue of discordant results between accredited laboratories in Australia and non-accredited Australian and overseas laboratories needs further inquiry.

#### *Accreditation of Australian laboratories*

3.21 The committee heard that one non-accredited Australian laboratory, Australian Biologics, is used by a number of 'Lyme literate' practitioners to test for

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13 See, for example: Ms Michelle Wood, *Submission 129*; *Submission 282*; *Submission 307*; *Submission 508*.

14 See, for example: *Submission 67*; *Submission 119*; *Submission 123*; *Submission 156*; *Submission 303*; *Submission 403*; *Submission 616*; *Submission 853*.

15 Dr Hugh Derham, *Committee Hansard*, Perth, 14 April 2016, p. 41.

16 *Submission 101*, p. 2.

Lyme-like illness. In her evidence to the committee, the Director of Australian Biologics, Ms Jennie Burke stated that through their testing process, Australian Biologics has identified evidence of *Borrelia* in Australian paralysis ticks.<sup>17</sup>

3.22 Unlike other Australian accredited laboratories, Australian Biologics uses Polymerase Chain Reaction (PCR) assays to test for the presence of *Borrelia* DNA in human samples. Australian Biologics also uses different serological tests for *Borrelia* imported from Germany (the Mikrogen *recom*Line and AID EliSpot Lymphocyte Transformation Test). In their submission, Australian Biologics asserts that the serological tests used by other Australian laboratories are not effective for patients with a chronic infection of *Borrelia* and that PCR and the German serological tests are more effective.<sup>18</sup> A large number of submitters who have been diagnosed with Lyme-like illness have noted that they have had positive tests for *Borrelia* from Australian Biologics.<sup>19</sup>

3.23 A number of submissions have expressed concerns about the reliability of the tests provided by Australian Biologics. For example, one infectious disease specialist suggested that the false positive rate for the tests used by laboratories such as Australian Biologics 'appears to be extremely high'.<sup>20</sup>

3.24 Australian medical authorities noted that results from laboratories that are not accredited by NATA and the RCPA, such as Australian Biologics, should be interpreted with caution. The RCPA submitted:

If a laboratory is not NATA/RCPA accredited this means that the laboratory may not have testing protocols and quality assurance processes in place that would be considered satisfactory compared to the standards. Such laboratories may be more likely to obtain an incorrect result for a particular laboratory investigation.<sup>21</sup>

3.25 However, Ms Burke expressed concerns about the process by which laboratories are accredited by NATA. Australian Biologics applied for accreditation in 2014 for its PCR testing. Ms Burke stated that NATA does not acknowledge the accuracy of their testing protocols for *Borrelia* or their quality assurance programs, and that it breached its charter in assessing their accreditation application by disclosing confidential intellectual property information to a rival laboratory.<sup>22</sup>

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17 Ms Jennie Burke, *Committee Hansard*, Brisbane, 15 April 2016, p. 56.

18 *Submission 545*, pp 1–2.

19 See, for example: *Submission 103*; *Submission 104*; *Submission 112*; *Submission 122*.

20 See: *Submission 362*.

21 RCPA, *Submission 532*, p. 9.

22 At its hearing in Brisbane, Ms Burke alleged that the CEO of NATA told her during a meeting that "We do not believe that you are detecting *Borrelia*". See: Ms Jennie Burke, *Committee Hansard*, Brisbane, 15 April 2016, p. 57.

3.26 In evidence to the committee, representatives from NATA highlighted that in the accreditation process for innovative laboratory processes, such as PCR testing for *Borrelia*, the threshold for evidence is higher than for usual accreditation:

For new and innovative methods for which the availability of appropriate validation is limited or where standard methods have been modified or, indeed, used outside their design parameters, the threshold of evidence for acceptance naturally becomes higher. The soundness of evidence provided is judged by relevant experts and professional bodies, not by employees of NATA. NATA must seek the best advice from expert sources, peers of the laboratory, before it commits to a precedent that will impact on the health and safety of the Australian population.<sup>23</sup>

#### *Recognition of overseas laboratories*

3.27 The committee heard arguments from 'Lyme literate' practitioners that the tests for *Borrelia* conducted by accredited Australian laboratories are not appropriate, and the criteria by which they are interpreted are inadequate. These practitioners assert that the two-tier process recommended by the RCPA and the US CDC does not adequately detect *Borrelia* and other co-infections acquired in Australia.<sup>24</sup>

3.28 For example, Dr Peter Dobie from the Australian Chronic Infectious and Inflammatory Disease Society told the committee that the ELISA test – the first tier in the two tier process – is not sensitive enough to detect Lyme-like illness and should be 'abandoned':

...most Australian pathology laboratories are doing the wrong blood test for Lyme disease. This is one reason why Lyme disease and Lyme-like illness are underdiagnosed in Australia. Most laboratories are using a test called the ELISA test. This test is not sensitive enough to detect most cases of this illness ... Pathology laboratories should be doing western blot and PCR as the frontline tests for Lyme disease, not the ELISA test.<sup>25</sup>

3.29 These practitioners insist that overseas laboratories (specifically IGeneX in California and Arminlabs or Infectolab in Germany) are better placed to accurately test for *Borrelia*. Dr Dobie told the committee that the main reason that 'Lyme-literate' practitioners use overseas laboratories is that these laboratories will do the Western blot test if requested, whereas Australian laboratories will only do so if the ELISA test is positive:

One of the reasons that doctors are using these overseas laboratories is that these laboratories will do the western blot on request. Doctors treating this illness are not interested in the result of the ELISA test. If Australian

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23 Mr John Mitchell, *Committee Hansard*, Canberra, 20 April 2016, p. 19.

24 See: Dr Hugh Derham and Dr Adam Nuttall, *Committee Hansard*, Perth, 14 April 2016, pp 40–46; Dr Peter Dobie and Dr Richard Schloeffel, *Committee Hansard*, Brisbane, 15 April 2016, pp 19–27.

25 Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 19.

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laboratories would do the western blot on request, there would be less need for us to use overseas laboratories.<sup>26</sup>

3.30 The committee also heard that the US CDC criteria used to interpret serological tests in accredited Australian laboratories focus too narrowly on *Borrelia burgdorferi*. Dr Mualla McManus told the committee that the CDC criteria are not appropriate for identifying other possible Australian species of *Borrelia*:

The government only thinks of Lyme disease, and follows the CDC criteria ... We have *Borrelia burgdorferi*, and a subset of that is Lyme disease. We have relapsing fever, and it has over 20 genospecies already. We have reptilian borrelia, but the infection has not yet been found in humans. So if we concentrate on Lyme disease we are missing out on 80 per cent of other borrelia infections, and that is really dangerous. We are being short-sighted ... We could have a unique class of borrelia.<sup>27</sup>

3.31 Some submitters suggested that results from overseas laboratories should be interpreted with caution, as each test has its own sensitivity and specificity based on the composition of the causative agent. According to these submitters, in the absence of a known causative agent in Australia, a positive test result is likely to indicate a false positive due to cross reactions from other bacteria.<sup>28</sup> The RCPA submitted:

If caused by a tick-born microbe, the causative microbe has not yet been identified and thus its antigenic make-up is unknown. Without knowing its antigenic make-up, it is impossible to design a proper serological test with measurable sensitivity and specificity. Cross-reactivity between patient antibodies and *Borrelia* antigens from overseas *Borrelia* used in vitro in Australian diagnostic assays are hard to predict.

There are many species of spirochetes (including *Borrelia spp.*) present in the normal human gastrointestinal tract (including the oral cavity) and some of these may potentially cause cross-reacting antibodies to be produced by the patient.<sup>29</sup>

3.32 Some submitters also suggested that tests conducted in non-NATA accredited laboratories in Australia and laboratories overseas may produce different results to accredited Australian laboratories because they may not interpret their results

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26 Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 19.

27 Dr Mualla McManus, *Committee Hansard*, Brisbane, 15 April 2016, p. 29.

28 Mackenzie, *Scoping study*, p. 15.

29 RCPA, *Submission 532*, p. 7.

according to the criteria set by the US CDC and the European Society of Clinical Microbiology and Infectious Diseases.<sup>30</sup> Dr Lum told the committee:

... when these tests are performed overseas, and also in some specialist laboratories in Australia, the interpretive criteria are different. What I mean by that is that they place less serological stringency on the test interpretation, so it makes it easier to diagnose a reactive [positive] result.<sup>31</sup>

3.33 The RCPA cautioned that it is difficult to assess the accuracy of results from serological tests conducted in overseas laboratories that are not accredited to Australian standards:

Overseas laboratories are by definition, not accredited to Australian standards so their use by Australian doctors and patients is on the basis of unknown quality of testing. While some may be excellent laboratories, accredited to international and their own country's standards and producing accurate and precise results, others may not be so. Australian authorities are not in a position to regulate or monitor these overseas laboratories and it is very difficult for Australian clinicians and patients sending specimens overseas to assess what veracity to place on the results and reports that they receive.<sup>32</sup>

3.34 The RCPA also warned that the overseas laboratories favoured by 'Lyme literate' practitioners are not used by 'mainstream' practitioners in their own countries and are likely to return false positive results. Professor Stephen Graves from the RCPA told the committee:

The laboratories in Germany and the United States that you are talking about, and that we are talking about now, are a minority. They are an exception. The mainstream doctors in those countries do not use those laboratories. They do not use them because they give them the wrong result. They give them false positive results. So it is not just us. The doctors in those countries say, 'Don't send your stuff to such and such a laboratory; you can't trust the result.' People here who are not getting results from mainstream laboratories are sending them to very off-the-mainstream types of laboratories in other countries. They are not the mainstream laboratories that are doing the routine testing all the time.<sup>33</sup>

3.35 'Lyme literate' practitioners suggested that NATA, the body responsible for accrediting Australian laboratories, should recognise the overseas accreditation of

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30 See: Dr Gary Lum, *Estimates Hansard*, 21 October 2015, p. 12; RCPA, *Position Statement*, February 2014. Dr Lum has previously told the Community Affairs Legislation Committee that 'when serologically less stringent interpretive criteria are employed along with poor predictive value associated with testing a low prevalence population with nonspecific symptoms, reactive serological results should be viewed cautiously'. See: Community Affairs Legislation Committee, *Additional Estimates 2015-16*, Response to question on notice SQ16-000221, received 4 April 2016.

31 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 6.

32 RCPA, *Submission 532*, p. 9.

33 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 51.

these specific laboratories overseas, through such measures as the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (MRA).<sup>34</sup> Some advocacy groups also suggested that NATA should acknowledge that the overseas laboratories in question are accredited to the international standards for medical testing (ISO 15189) and should therefore recognise results from these laboratories. For example, Ms Rebecca Vary from the Lyme Disease Association of Australia (LDAA) suggested to the committee that NATA should recognise results from a German laboratory, Infectolab:

Infectolab were accredited with ISO 15189, and they have been accredited to that standard for quite a while. What happened in January was that NATA became a member of that accreditation as well, so NATA now has the right to recognise the other labs in ISO 15189, so it can therefore recognise the Infectolab results.<sup>35</sup>

3.36 In evidence to the committee, representatives from NATA confirmed it had achieved international recognition for medical testing (ISO 15189) in January 2016 under the MRA. However, NATA emphasised that the effect of MRA recognition is of equivalence of overseas testing methods; it does not expect or require laboratories or medical authorities in Australia to recognise another country's specific requirements or context:

Our role under the MRA is to promote recognition of equivalence. It is the end user, however, who is actually the individual making the final decision on the recognition.<sup>36</sup>

#### *Limits on diagnostic testing under Medicare*

3.37 The committee also heard that under the current Medicare Benefits Schedule, laboratories are only able to test for what the referring doctor requests. The Australian Rickettsial Reference Laboratory suggested that these limits mean that when a patient sample is referred for a Lyme disease test, laboratories are not be able to test for other known pathogens:

Diagnostic tests on patient specimens are generally bulk-billed and the income from this [85% of the Medical Benefit Schedule recommended fee] only covers the cost of undertaking the test requested by the referring doctor. Thus if the doctor asks for investigations for Lyme Disease, the laboratory is unable to also test for other potentially tick-transmitted diseases, despite the possibility that the patient may have acquired one of these, eg a rickettsial infection, which the referring doctor did not include on his/her list of differential diagnoses.<sup>37</sup>

3.38 Professor Stephen Graves from the RCPA and also Director of the Australian Rickettsial Reference Laboratory, suggested that the Medicare rules around laboratory

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34 See: Dr Peter Dobie, *Committee Hansard*, Brisbane, 15 April 2016, p. 20.

35 Ms Rebecca Vary, *Committee Hansard*, Perth, 14 April 2016, p. 19.

36 Mr John Mitchell, *Committee Hansard*, Canberra, 20 April 2016, p. 19.

37 Australian Rickettsial Reference Laboratory, *Submission 459*, p. 4.

testing should be changed to allow laboratories to explore other possible diagnoses when a test is referred for Lyme disease:

...what I am proposing ... is somehow make it possible for diagnostic laboratories—the sort of laboratory that is part of the Public Health Laboratory Network, like my laboratory, the Australian Rickettsial Reference Laboratory. If we get a serum specimen in from a patient who has query Lyme disease—endemic Australian Lyme disease—we can currently only test for Lyme disease. That is all I am allowed to do. If I do any other testing, it is basically called overservicing and, as a pathologist, I can get into big trouble over it. So I just have to do what is requested. So I do the Lyme disease testing. It is negative—end of story. But if I could also test for *Coxiella*, *Rickettsia*, *Anaplasma*, *Ehrlichia*, *Neoehrlichia*—although we do not have an assay for that yet—*Bartonella* or *Babesia*, that would make a big difference. We could possibly find out what is affecting these people. But not only cannot we do it; we are not allowed to do it.<sup>38</sup>

3.39 The department confirmed that there are 'coning' rules in place that only allow laboratories to seek remuneration for up to three tests under the current Medicare rules:

...under the current way that pathology testing is remunerated, that there not be any sense of overservicing, but if there is a legitimate request then there will not be overservicing. The important thing to remember, though, is that the pathology profession is subject to various rules under the Medicare Benefits Schedule and, when referrals are made by general practitioners, there are rules in place which make it difficult compared to when, say, another specialist medical practitioner makes a referral, such that the ability to make a claim on those tests is different. That needs to be understood. For example, if a general practitioner requests more than three tests, there is a coning rule in place, and the pathology practice will only receive remuneration for the most expensive three tests, rather than all of the tests.<sup>39</sup>

#### *Measures to address discordant results*

3.40 To address the discordant results between overseas laboratories and accredited laboratories in Australia, Professor John Mackenzie, author of the 2013 scoping study, suggested that the department coordinate a quality assurance/quality control (QA/QC) assessment of overseas testing procedures:

... the use of an international panel of specimens should be used for QA/QC is an essential step, and any putative positives should then be investigated fully in collaboration with the laboratory which has made the positive claim, and in parallel and together with an accredited public health reference laboratory to substantiate the claim ... The DOH [Department of Health] should indeed urgently liaise with overseas laboratories which claim to find positive results to ensure they participate in a QA/QC

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38 Professor Stephen Graves, *Committee Hansard*, Brisbane, 15 April 2016, p. 48.

39 Dr Gary Lum, *Committee Hansard*, Canberra, 20 April 2016, p. 8.

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assessment, and to ensure this is carried out properly, an international accredited and unaligned laboratory such as the UK Institute for Biological Standards and Control should be engaged to oversee the conduct and interpretation of the QA/QC results.<sup>40</sup>

3.41 The committee heard that the department is currently investigating the different approaches to the laboratory diagnosis of Lyme disease worldwide. The department has contracted the National Serology Reference Laboratory<sup>41</sup> to:

... evaluate the serological assays used to diagnose Lyme disease in specialist laboratories in Australia and overseas as well as accredited pathology laboratories in Australia. The specimens being tested are from individuals in Australia and overseas both with and without symptoms. The results will be used to examine the performance characteristics of these laboratory tests and hopefully resolve the conundrum of discordant results in laboratories in Australia and overseas.<sup>42</sup>

3.42 The committee notes that the department has previously advised the Senate Community Affairs Legislation Committee that ten laboratories have been approached and invited to participate in this evaluation, which is due to report in early 2017.<sup>43</sup>

3.43 The department suggested that it would welcome a review of current laboratory testing processes and treatments by the Medicare Services Advisory Committee and the Pharmaceutical Benefits Advisory Committee. The department submitted:

Both committees are in the best position to review the current data for the available diagnosis and treatment. Should the committees advise that supportive evidence of effectiveness and cost-effectiveness does exist, steps can be taken to update the Medicare Benefits Schedule and the Pharmaceutical Benefits Schedule.<sup>44</sup>

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40 Professor John Mackenzie, Response to Question on Notice, received 21 April 2016.

41 The National Serology Reference Laboratory (NRL) is a not-for-profit scientific organisation that was established in 1985 as part of the Australian Government's HIV/AIDS Strategy, to evaluate HIV tests and adjudicate on the interpretation of HIV test results. The NRL's overall goal is 'to support laboratories, in Australia and internationally, that perform testing for the diagnosis and management of human infectious disease'. See: <http://www.nrl.gov.au/About+Us> (accessed 26 April 2016).

42 *Submission 495*, p. 3. The department advised that a progress report on the status of this project is due on 31 July 2016, with the final report due on 31 January 2017.

43 The ten laboratories approached and invited to participate include: Australian Red Cross Blood Service; the Australian Rickettsial Reference Laboratory; the Institute for Clinical Pathology and Medical Research; Sullivan Nicolaides Pathology; Australian Biologics; Pacific Laboratory Medicine Service; IGeneX (USA); Infectolab (Germany); Arminlab (Germany); and Rare and Imported Pathogens Laboratory. See: Community Affairs Legislation Committee, *Additional Estimates 2015-16*, Response to question on notice SQ16-000219, received 4 April 2016.

44 *Submission 495*, p. 3.

***Committee view***

3.44 The committee is aware that discordant laboratory results between accredited laboratories in Australia and non-accredited Australian and overseas laboratories cause confusion and frustration for patients.

3.45 The committee supports the department's work with the National Serology Reference Laboratory to conduct an evidence-based assessment of laboratory testing in Australia and overseas, with a focus on tests for Lyme-like illness.

3.46 The committee notes that the following issues need further inquiry:

- progress of the National Serology Reference Laboratory's assessment of Australian and overseas laboratory testing for Lyme-like illness;
- the process of laboratory recognition and accreditation to assist patients in understanding why there are discordant results; and
- options for changing the Medicare rules to allow accredited Australian laboratories to explore possible alternate pathogens.