Chapter 2
Testing for infection

> Scientific folk want evidence of causative agents to enable disease; patients want focus on their symptoms, their illness, while science works on the details. Both groups make equally valid points, but lives are at risk and people are suffering.[1]

2.1 The question of pathology testing is perhaps the most contentious issue to emerge from this inquiry, and is at the root of the frequently-posed and incessantly debated question: can Lyme disease be contracted in Australia? The committee explored this issue at length in its interim report but found that conclusive answers were elusive. In this, its final report, the committee aims to identify a few areas where some progress may be made.

2.2 Evidence presented to the committee over the course of this inquiry suggests three principal points of contention:

1. A lack of an agreed definition and understanding of what constitutes Lyme-like illness and how, if at all, it differs from Lyme disease.
2. Disagreement over laboratory testing protocols and results when looking for the pathogens responsible for Lyme disease.
3. The lack of conclusive, accepted scientific evidence linking tick bites in Australia to Lyme-like illness.

2.3 This chapter will examine all three.

Lyme, or Lyme-like?

2.4 The illnesses discussed throughout this inquiry are Lyme disease, chronic Lyme disease and Lyme-like illness. The terms are often used interchangeably, and generate considerable disagreement.

Classical Lyme disease

2.5 In its interim report, the committee outlined known epidemiological facts about Lyme disease in detail.[2] Classical Lyme disease, or Lyme borreliosis, is a tick-borne disease caused by a number of closely related species of *Borrelia* bacteria. Lyme disease is recognised as one of the most common tick-borne diseases in

---

1 Ms Elaine Kelly, Secretary, Sarcoidosis Lyme Australia, *Committee Hansard*, 14 April 2016, p. 9.

2 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3.

humans, and is known to be present in parts of the United States of America (US), Europe and Asia. Lyme disease is named after the town of Lyme in Connecticut where it was first recognised in the early 1970s.[3]

2.6 There are a number of common species of *Borrelia* known to cause Lyme disease. In the US, the most common of these is *Borrelia burgdorferi*. Different species of *Borrelia* have been identified as Lyme pathogens in Europe and Northern Asia, such as *Borrelia afzelii* and *Borrelia garinii*. Although different, these species are related and referred to as the '*Borrelia burgdorferi* sensu lato complex'.[4]

Chronic Lyme disease

2.7 If classical Lyme disease is understood to be an acute infection, one that is treated with readily available antibiotics,[5] the concept of chronic Lyme disease, on the other hand, is a controversial one. This is in part because the symptoms some patients experience after an acute Lyme infection are not easily defined. As put by the Department of Health (department):

> In some patients, a post-treatment late Lyme disease syndrome occurs, with patients experiencing non-specific symptoms like headache, fatigue, and muscle and joint pain. These symptoms are generally not regarded as persistence of active infection but more as post infectious problems.[6]

2.8 There is much debate about whether post-infection symptoms constitute chronic Lyme disease, whether such a disease even exists. This debate, as set out in the committee's interim report, is not unique to Australia. Disagreement revolves around whether an ongoing *Borrelia* infection can manifest as chronic, debilitating illness once the acute state of infection has subsided:

> The department is aware of the controversy in endemic areas overseas about the diagnosis of chronic Lyme disease. That controversy which focuses on persistent infection rather than post infectious sequelæ as the cause of ongoing symptoms is relevant to the Australian context because the Australian advocacy groups for a Lyme disease-like illness support the concept of persistent infection.[7]

---

3 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3. Department of Health, *Submission 495*, p. 2.

4 See Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 3. The committee notes that there are other, known *Borrelia* species which cause different illnesses in humans and animals, but not Lyme disease.

5 Department of Health, *Submission 495*, p. 3.

6 Department of Health, *Submission 495*, p. 2.

7 Department of Health, *Submission 495*, p. 2.

2.9 Australian medical authorities do not support the use of the term 'chronic Lyme disease', nor do they accept that its associated symptoms are the result of ongoing *Borrelia* infection:

> The issue of chronic Lyme disease assumes that there is persistent, active infection. That is what is so contentious. The mainstream conventional position is that the sequelae that we see after an infection is post-infectious and not active infection … So, in Australia, like in many other countries that we would be like-minded with in terms of medicine, the experts in microbiology and infectious disease will not readily accept that there is chronic Lyme disease or chronic persistent active infection. So, for that reason, and because of the association between what is happening in Australia with chronic Lyme disease, most of the medical profession expert in this field do not accept that it is Lyme disease.[8]

2.10 This view was, however, challenged by submitters such as Dr Mualla McManus, a scientist with credentials and expertise in immunology, pharmacology, pharmacy, neuroscience and molecular biology:

> The significance of *Borrelia* infection is that once you are infected with it, you have to be treated early so that it does not disseminate. Once disseminated, it becomes chronic. It is very hard to eradicate…after 20 years of antibiotic treatment on a patient, they took the samples from the synovium, the knee joint, and they could actually identify the *Borrelia burgdorferi*—after 20 years of treatment. So you are looking at a unique pathogen that is emerging, but the problem with this pathogen is that it is emerging very slowly.[9]

2.11 The notion of chronic Lyme disease is also important to understanding the debate around laboratory testing results, to be discussed later in this chapter.

Lyme-like illness

2.12 Whereas Lyme disease is caused by known pathogens, and later stages of infection are sometimes referred to as chronic Lyme disease, the term 'Lyme-like illness' has been used to describe a constellation of symptoms thought to be caused by a variety of tick-borne pathogens. As these symptoms are closely connected to those exhibited by patients with classical Lyme disease, the terms 'Lyme disease', 'Lyme-like illness' and 'chronic Lyme disease' are often used interchangeably by patients and their advocates.

2.13 Public discourse on Lyme-like illness is problematic in part due to a lack of agreement or understanding around terminology:

> The department [Department of Health WA] notes that there is no widely published or accepted definition of Lyme-like illness. It is not possible, therefore, to determine the prevalence or geographical distribution of

8 Dr Gary Lum, Principal Medical Adviser, Office of Health Protection, Department of Health, *Committee Hansard*, Canberra, 20 April 2016, p. 10.

9 Dr Mualla McManus, Director, Karl McManus Foundation, University of Sydney, *Committee Hansard*, 15 April 2016, p. 28.

> Lyme-like illness in Australia or even to be certain that different groups discussing Lyme-like disease are referring to the same concept.[10]

2.14 Patient advocacy groups, such as the Lyme Disease Association of Australia, similarly recognise the lack of clear definition. From their perspective, however, the semantic debate is unhelpful:

> There is considerable contention around these two simple words 'Lyme' and 'disease'. On their own they do not offend, used together they invoke very powerful, often emotive shifts in the demeanour, language and behaviours of others. Depending on your perspective, we either have it in Australia or we don't – it's binary.
>
> It is impossible to find a precise and consistent definition of the term in Australia. It is used by the medical community to describe a very specific strain of a biological organism, or sometimes organisms; even they can't decide. It is used by the rest of the world to describe a suite of symptoms and infections caused by a number of organisms.
>
> …We don't know what people have. We do know that some people become seriously ill, sometimes after the bite of a tick, and that their symptoms closely resemble that of internationally defined Lyme disease.[11]

2.15 Given that the pathogens which cause Lyme disease overseas are known, Australian authorities are firm in the view that the term 'Lyme disease' is misused in the local context. This is because the pathogens responsible for Lyme disease overseas were identified some time ago, and have not been identified locally:

> The term is used to describe a variety of symptoms and clinical features ranging from well-defined illnesses to non-specific chronic symptoms. However, there is no evidence to indicate that infection with *Borrelia burgdorferi* sensu lato, resulting in Lyme disease, has been acquired within Australia. In addition, there is no convincing scientific evidence to date that tick bites from native Australian ticks result in Lyme-like disease.[12]

2.16 Critics of this position, however, challenge both the assertion that a) *Borrelia* known to cause Lyme disease have not been found in Australia, and b) only bacteria known to be part of the *Borrelia burgdorferi* sensu lato complex can cause Lyme disease.

---

10 Professor David Forbes, Office of the Chief Medical Officer, Department of Health Western Australia, *Committee Hansard*, Perth, 14 April 2016, p. 1.

11 Lyme Disease Association of Australia, *Submission 528*, p. 5.

12 Professor David Forbes, Office of the Chief Medical Officer, Department of Health Western Australia, *Committee Hansard*, Perth, 14 April 2016, p. 1.

Lack of consensus on the name or the cause

2.17 If symptoms of Lyme-like illness in Australia lack clear definition, its cause is similarly very poorly understood and in dispute. As put by Dr McManus, exclusive focus on *Borrelia burgdorferi* as a causative agent for Lyme-like disease may be counterproductive:

> We need to change our view. The government only thinks of Lyme disease, and follows the CDC [US Center for Disease Control] criteria. I have an explanation for *Borrelia*…There is *Borrelia burgdorferi* sensu lato group, and a subset of that is Lyme disease *Borrelia*. There is relapsing fever, which has over 20 genospecies known today. 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. Some of the relapsing fever genospecies can produce 80 per cent of their infections neurologically, but there is no research, because relapsing fever is a poor-country disease. It is endemic in Africa, Asia, India, Indonesia and Vietnam. All the focus is in Lyme disease; everyone makes such a fuss about it. Lyme disease, *Borrelia burgdorferi* sensu stricto, is much easier to treat that relapsing fever. This is something that has not been understood.[13]

2.18 Dr Richard Horowitz, who spoke to the committee in a private capacity, suggested that Lyme disease itself is far more complex than first imagined. The fact that Lyme disease is still poorly understood, Dr Horowitz believes, contributes in large part to the controversy over its diagnosis and treatment:

> I think some of the controversy is happening because we are not understanding the definition of what Lyme disease really is. The patients that I see with Lyme disease do not just have *Borrelia burgdorferi* sensu latu. What they end up having is many other species of bacteria, viruses and parasites because the ticks are now containing many of these different species and are rapidly spreading.[14]

2.19 The evidence supplied by Dr Horowitz is not easily dismissed. He is one of the founding members, as well as past president, of the International Lyme and Associated Diseases Society (ILADS), has published a large number of peer-reviewed articles on the subject and has engaged with a number of governments—including the US, Chinese, UK, French and Belgian—on the subject of Lyme and related diseases.[15]

2.20 On the basis of his own research and that of others cited in his submission, Dr Horowitz in fact advocates a move away from the term "Lyme disease", submitting that the Lyme diagnosis fails to capture the chronic symptoms and multiple infections exhibited by many patients:

> One of the first and most basic problems we face is in helping Australian patients is defining “chronic Lyme disease” or “Lyme-like illness”. Patients

---

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

14 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 1.

15 Dr Richard Horowitz, *Submission 936*, pp. 25–33.

> with chronic symptoms who see me, either before or after classical treatment for Lyme disease, have multifactorial causes for their illness. I call this syndrome Lyme-MSIDS. MSIDS stands for Multiple Systemic Infectious Disease Syndrome, and represents sixteen potential overlapping medical problems contributing to persistent symptoms in the Lyme patient.
>
> …
>
> The first point on the MSIDS map is infections. Ticks are now containing multiple bacterial, viral and parasitic infections which can be transmitted simultaneously with *Borrelia burgdorferi*, the agent of Lyme disease. Patients infected with Lyme disease and associated co-infections are much sicker and resistant to standard therapies.[16]

2.21 Dr McManus similarly pointed to multiple infections as an impediment to straightforward diagnosis and treatment:

> The scientific community is not in a state to understand the multiple infections. Over 100 years ago, Koch's postulates were formulated to say, 'You have one infection, one specific set of symptoms—we give you one antibiotic.' That was the treatment. But then you come to something with four or five infections—which one do you treat first? Which is the prominent one that produced the symptoms?
>
> Doctors do not know, we do not know. There are no clinical trials, no investigations into it, because most of the research community thinks that it is too hard to handle. Most of the research on Lyme disease or any species of *Borrelia* looks at acute disease because it is easier to follow. You have got one tick bit, you have got history and you can detect it because the immune system is competent and you can follow it through and treat it. But when it comes to chronic—I have talked to IDSA members; they do not know what to do. ILADS try to treat with long-term antibiotics.[17]

Where to from here?

2.22 Despite considerable disagreement around most aspects of tick-borne illness in Australia, this inquiry also highlighted important areas of agreement. The committee chose to focus on these, as they are a clear indication that progress on the issue is possible.

2.23 Importantly, the committee noted a promising level of interest in further research and examination of the issues from authorities, such as this statement from the department indicating its preparedness to work towards broadening and deepening understanding of tick-borne illness:

> We acknowledge that the cause of these tick-bite-associated, chronic debilitating symptoms may not be limited to a single bacterial species. Parasitic and viral causes as well as environmental toxins should also be investigated.

16 Dr Richard Horowitz, *Submission 936*, p. 2.

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

> As part of the department's work in communicable diseases in states and territories, we are developing an awareness of newer genomic technology that is using specimens from patients to look for bacterial and viral nucleic acid, in an attempt to find commonalities in patient specimens. It may reveal a common pathogen or pathogens which can be further considered.[18]

Committee view

2.24 The committee notes that the term 'Lyme-like illness' is in use to describe a constellation of symptoms and what may very well be a number of different illnesses. In the committee's view debate around what to call tick-borne illness in Australia has impeded progress on establishing its cause and optimising treatment. The scope of what scientists and clinicians are grappling with—tick-borne infections, co-infections and post-infection symptoms—is not yet well defined, but appears to be considerable. Australia's understanding of what is in our ticks, and how it might be making some people sick, is clearly at a very nascent stage.

2.25 The committee notes the department's commitment to exploring tick-borne illness and identifying the pathogens involved:

> Through regular communication and correspondence, the department has gained a deeper appreciation and real concern for those Australians experiencing these chronic debilitating symptoms, which they associate with a tick bite. The department remains engaged with the patient and medical community to continue to find, share and understand the evidence associated with this medical conundrum. The department hopes our work with diagnostic pathology and research communities will result in answers and relief for patients and their families.[19]

2.26 The committee is encouraged by this and calls on medical authorities to engage with the research presented during the course of this inquiry.

Diagnosing Lyme disease

2.27 Diagnostic testing of samples—usually blood—taken from patients suspected of having Lyme-like illness is perhaps the most controversial issue to emerge from this inquiry, and one that evidence returned to time and again.

2.28 Much—if not most—of the evidence presented was contradictory, and most of it was confidently articulated by qualified, experienced and respected professionals. It is therefore necessary to establish from the outset that the committee is not in a position to arbitrate a scientific debate. Instead, the committee's objective is to broadly define the parameters of the disagreement around laboratory testing, and identify how some progress can be made.

2.29 As outlined in the committee's interim report, a number of prominent and experienced doctors have questioned the reliability of laboratory tests used to

18 Department of Health, *Submission 495*, p. 2.

19 Department of Health, *Submission 495*, pp. 1–2.

diagnose or rule out Lyme-like illness—classical and chronic Lyme disease or other Lyme-like illnesses. Broadly, the question can be seen from two perspectives:

1. Classical Lyme disease, caused by *Borrelia* bacteria, cannot be contracted in Australia. This position is held by the Australian medical authorities and many experts in relevant fields, and supported by the fact that accredited Australian laboratories return negative results when testing for Lyme disease.
2. An illness with considerable similarities to Lyme disease can and has been contracted in Australia, and pathogens which cause Lyme disease do exist here. This position is held by some doctors and scientists, and supported by the fact that patients who have not travelled overseas have had positive laboratory test results when tested for Lyme disease by some Australian and overseas laboratories.

2.30 A key part of the matter is the issue of test quality—understanding which testing protocol is optimal and how test results are to be interpreted.

2.31 This section will build on evidence already explored by the committee's interim report. Evidence already examined by the interim report is only referred to again where necessary.

The two-tier testing protocol

2.32 As previously described, classical Lyme disease is caused by a number of known, closely related species of *Borrelia* bacteria. The *Borrelia* strains known to cause Lyme disease in Europe, for example, are different to the strains responsible for Lyme disease in the United States (US)—together the bacteria make up the *Borrelia burgdorferi* sensu lato complex. It is antibodies to these bacteria that most laboratories test for when doctors send patients for pathology tests, looking to diagnose or rule out Lyme disease.

2.33 The committee's interim report detailed the protocol used for testing and diagnosis.[20] In brief, most Australian laboratories accredited with the National Association of Testing Authorities (NATA)[21] use a two-tier serological diagnostic protocol, as is also the case with accredited US and European laboratories.

2.34 The first tier is most commonly an enzyme-linked immunosorbent assay (ELISA). If the ELISA test returns a positive result, laboratories will then conduct a Western blot test. The committee understands that laboratories can, but will rarely run a Western blot test in the absence of a positive ELISA result.

2.35 This testing protocol is considered to be world-class and reliable. Accredited laboratories using the protocol in Australia have only returned positive results for

20 For details, see Chapter 3 of Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016.

21 NATA Australia provides assessment, accreditation and training services to laboratories. Accreditation with NATA provides assurance of laboratory competence. See www.nata.com.au (accessed 16 November 2016).

Lyme disease acquired overseas, reinforcing the understanding that the pathogens responsible for Lyme disease are not endemic to Australia.[22]

2.36 Seeking to understand the logic behind the two-tier testing system, the committee questioned why the ELISA test was routinely performed first. Professor Stephen Graves, spokesman on Lyme disease for the Royal College of Pathologists Australasia, described how and why the two tiers of testing ensure accuracy:

> The Western Blot assay is more "reliable" than the ELISA in that it is more specific, at least when the IgG class of antibodies is being tested for. This means it is less likely to give a false-positive result. i.e. mis-call some other illness as Lyme Disease.
>
> The ELISA assay is more sensitive than the Western Blot and will detect almost all patients with antibodies to the Lyme bacteria, but it is less specific and some of the antibodies it detects are not the result of Lyme Disease. These are cross-reacting antibodies. The ELISA assay can therefore give false-positive results.
>
> By going straight to a Western Blot assay, there is a possibility that some Lyme cases could be missed, as it a less sensitive assay than the ELISA.
>
> The logic for this serological testing pattern is that the ELISA is a "screening" assay that will detect all cases of Lyme Disease [and some non-case also] and the Western Blot is a "specific" assay and will differentiate the true Lyme cases from the non-Lyme cases, as it is a more specific assay than the ELISA.
>
> In practice however, both assays can give false positive results and also false-negative results. By having the 2 assays the lab is more likely to obtain the correct result.
>
> If a lab went straight to the Western Blot assay they are likely to miss some genuine cases of Lyme Disease.[23]

2.37 However, a considerable number of submitters and witnesses questioned the reliability of the protocol. These ranged from patients and their advocates, to respected members of the medical and scientific community—each provided evidence in stark contrast to that presented by Professor Graves. Their positions can be broadly divided into two categories:

- those who hold that the ELISA test is not sensitive enough, can therefore only detect antibodies to Lyme disease in some patients, and cannot rule infection out; and

22 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, pp. 47–49.

23 Professor Stephen Graves, Spokesman on Lyme Disease, Royal College of Pathologists of Australasia, answer to question on notice, received 15 November 2016.

- those who hold that Lyme-like illness is in Australia caused by an as-yet unidentified pathogen, perhaps a species of *Borrelia* unique to Australia, and therefore testing for *Borrelia* which are endemic overseas is redundant.

2.38 A small sample of the evidence presented in support of a move away from ELISA-led testing is cited below.

ELISA sensitivity

2.39 Dr Peter Dobie, Secretary of the Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS), told the committee that Lyme disease and Lyme-like illness were underdiagnosed in Australia due to over-reliance on ELISA, which in his experience is not sensitive enough to detect the presence of infection:

> [M]ost 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. There is a large body of scientific opinion that this test should be abandoned because of the high rate of false negatives.[24]

2.40 Mr Christopher Walker, Acting Chief Executive Officer of the Karl McManus Foundation, was unequivocal in his assessment of the two-tier protocol:

> The complicated nature of Borrelia infections makes it highly possible for laboratory tests to miss an infection, for multiple reasons. One of the biggest flaws in the current Australian Borrelia or Lyme disease testing is the singularity presumption—that is, a presumption that a negative test result is a positive confirmation that one does not have a Borrelia infection. Permit me to repeat that: there is a presumption that a negative test result is a positive confirmation that one does not have a Borrelia infection.[25]

2.41 Dr Richard Horowitz similarly questioned the logic behind the protocol, concluding that ELISA lacks the necessary sensitivity to detect ongoing infection:

> According to these guidelines, an immunoblot is not to be performed if the ELISA is negative, despite the poor sensitivity of ELISA tests ranging from 34 to 70.5%.[26]
>
> The problem with that is if you look at the scientific literature carefully, the scientific literature is supporting that the ELISA test is not reliable…these organisms can persist. I think the literature is there.[27]

---

24 Dr Peter Dobie, Secretary, Australian Chronic Infectious and Inflammatory Disease Society (ACIIDS, formerly the Australian Chronic Infectious Disease Society, ACIDS), *Committee Hansard*, 15 April 2016, p. 19.

25 Mr Christopher Walker, Acting Chief Executive Officer, Karl McManus Foundation, *Committee Hansard*, 2 November 2016, p. 45.

The Karl McManus Foundation is a charity funding research into tick-borne diseases.

26 Dr Richard Horowitz, *Submission 936*, p. 10.

27 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 4.

2.42 Dr McManus concurred, describing *Borrelia* as complex and possessing a considerable capacity for mutation which makes testing difficult:

> The testing is problematic because the bacteria *Borrelia* has got very variable, hypervariable genomes. Basically, it can mutate inside you. If I had a rat injected in one leg with one genome species of *Borrelia* and I took blood from the other leg, I can get a different genospecies. That is not normal; you do not normally find that. If I inject a rat with a *staph. aureus*, or a golden staph, I get the golden staph, but a different strain, not a different genospecies. The reason for this is that this bacteria: (1) can mutate a lot; and (2) it as a lot of phages, or bacterial viruses. I can give you an example. Golden staph has got only one phage, and it is very difficult to eradicate from hospitals because of the way it develops a tolerance to all the treatment protocols. You have a *Borrelia*, the *burgdorferi* one in the US has 21 phages. That means it can dress itself in so many different ways that it can hide in your body—it can change from vector to vector; it can be in a tick; it can be in a deer; it can be in a human—because it has the capacity to change itself so enormously. I do not think that is really understood by the scientific community or by the clinicians.[28]

2.43 The committee put this to Professor Graves. He indicated that having hypervariable genomes was not particular to *Borrelia*, but instead could be said of all microbes. He reiterated that the accuracy of the two-tiered protocol in use by the majority of laboratories is not impeded by the hypervariable genomes:

> This problem doesn't apply to serological assays that detect antibodies, as a wide variety of antibodies of different specificities that are produced by a patient in response to an infectious agent.
>
> Those persons who believe that Lyme Disease occurs in Australia can always point to minor defects in certain assays that may result in the assay not detecting the occasional patient with Lyme Disease due to a rare variability in the patient or the bacterium. But this would not be the case for the majority of patients and the fact that no genuine patients have been detected, by a variety of laboratory assays, strongly points to the conclusion that this infection [Lyme Disease] does not occur naturally in Australia.
>
> The patients who claim to have Lyme Disease have something else wrong with them, whether an infection transmitted by tick bite or not remains to be seen. They clearly need help but giving them the wrong diagnosis does not help them![29]

2.44 The committee noted the contradictory evidence.

2.45 Dr Richard Schloeffel, Chairperson of ACIIDS, challenged the role which has been ascribed to laboratory testing, making the point that pathology should only be used to confirm a doctor's clinical assessment, not the other way around. The tests

---

28 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 28.

29 Professor Stephen Graves, answer to question on notice, received 15 November 2016.

most commonly used, Dr Schloeffel, stated, were of little use in patients who are immunosuppressed:

> The tests are not good enough. The bugs are varied. There are viruses, parasites and bacteria. Pathology is very secondary. Sure, do no harm, but do not lie to your patient that they are not sick because the test was negative.[30]

2.46 This was supported by Ms Jennie Burke, Director of Australian Biologics, who clarified how the devastating effect *Borrelia* has on patients' immune system makes detection through ELISA, which looks for an immune response, uncertain:

> With tests that rely on an immune response, again Borrelia is difficult, as it has a devastating effect on the patient's immune system, which may lead to abhorrent effects in tests. With other infections you would expect the patient to produce IgM antibodies in the initial stage and, three to six months later, the antibodies to seroconvert to IgG antibodies. With Borrelia, however, patients may show no antibodies at all. They may not seroconvert and can remain IgM positive for greater lengths of time than usual.[31]

2.47 Australian Biologics does not use the two-tier protocol to detect *Borrelia* infection. This is explored below.

Other testing protocols

2.48 There are a number of laboratories which do not use the two-tier testing protocol, and which have reported positive results for Australian patients who have never travelled to known Lyme-endemic areas overseas. The laboratories most 'Lyme-literate'[32] doctors prefer to use are:

- Australian Biologics Testing Services, a Sydney-based laboratory which is not yet accredited with NATA;[33]
- ArminLabs, a German laboratory with a focus on Lyme disease which is in the process of accreditation with the German accreditation body, Deutsche Akkreditierungsstelle (DAkkS);[34]

---

30 Dr Richard Schloeffel, Chairperson, ACIIDS, *Committee Hansard*, 2 November 2016, p. 55.

31 Ms Jennie Burke, Director, Australian Biologics, *Committee Hansard*, 2 November 2016, p. 12.

32 The term 'Lyme-literate' is used by some clinicians, patients and advocacy groups to denote doctors who have expertise in Lyme disease and Lyme-like illness beyond that of the mainstream medical establishment. For more see Chapter 2 of the committee's interim report.

33 It is important to note that discussion of laboratory competence should not be linked to discussion of NATA accreditation. NATA has stated that it makes no judgement about the competence of non-accredited laboratories. The committee understands that Australian Biologics is aiming to secure NATA accreditation in the near future. See Mrs Nicole Bailey, Assistant Stakeholder Relations Manager, NATA, *Committee Hansard*, 2 November 2016, p. 10; Dr Hugh Derham, *Submission 453*, p. 2; Dr Adam Nuttall, *Submission 601*, p. 2.

34 http://www.arminlabs.com/en. See Dr Hugh Derham, *Submission 453*, p. 2; Dr Adam Nuttall, *Submission 601*, p. 2.

- Infectolab in Germany, which is accredited by DAkkS;[35] and
- IGeneX, a US-based laboratory which specialises in Lyme Disease and associated tick-borne diseases.[36]

2.49 Australian Biologics offers three types of testing for *Borrelia*—DNA testing, or Polymerase Chain Reaction (PCR), an immunoblot test imported from Germany, and EliSpot testing, also from Germany. Australian Biologics uses these tests because of a perceived lack of sensitivity of ELISA testing:

> Earlier ELISA testing was known to have poor sensitivity whereas the newer ImmunoBlot assays using recombinant antigens have a much higher level of sensitivity. The EliSpot Lymphocyte Transformation Test is useful to show if an infection is active.[37]

2.50 A submission from Australian Biologics explains that the PCR test is the gold standard for the detection of bacterial infection:

> PCR is one of the most sensitive methods utilised to detect microbial pathogens in clinical specimens. This is particularly necessary when specific pathogens, difficult to culture in vitro or are known to be of low level in blood, tissue and other samples, are to be detected. The diagnostic value of PCR is known to be significant.[38]

False positives vs false negatives

2.51 The committee held an additional public hearing partly with the aim of clarifying the apparent discordance in test results obtained from different laboratories, however this failed to provide conclusive answers.[39] In short, evidence on the presence of *Borrelia* in Australia was once again contradictory. However, two laboratories testing for the same infection but getting different results cannot both be right—it is an issue of false positives versus false negatives.[40]

2.52 When asked about the rate of false negatives of ELISA, Professor Graves assured the committee the tests have a high degree of sensitivity and are not likely to miss infections. On the contrary, it appears ELISA is more likely to return a false positive than false negative:

---

35 See Dr Hugh Derham, *Submission 453, Attachment 1*, p. 11; Dr Adam Nuttall, *Submission 601*, p. 2.

36 www.igenex.com. See Dr Richard Schloeffel, *Submission 2, Attachment 1*, p. 7.

37 Australian Biologics Testing Services, *Submission 545*, p. 1.

38 Australian Biologics, *Submission 545*, p. 2.

39 A detailed discussion of alternative testing protocols, including arguments presented for and against their use, is contained in the committee's interim report and is not repeated here.

40 A 'false positive' is a test result that indicates that a person has an illness when they do not; a 'false negative' is a test result that indicates that a person does not have a particular disease when they in fact do.

> Probably close to zero as it is a very sensitive assay and won't miss many cases. However, many of the "positive" results will not be genuine Lyme Disease as the assay has poor specificity.
>
> In my lab, the Australian Rickettsial Reference Laboratory, the genuine cases of Lyme Disease that we have diagnosed [all in travellers returning from overseas and infected in endemic countries] the ELISA assay has always been positive.[41]

2.53 Professor Graves suggested that Australian Biologics must be getting false positive results:

> I would never refer a specimen to a nonaccredited laboratory so I never refer specimens to Jenny because I do not think that her laboratory is doing the tests properly. I think she is getting a lot of false positives. That is where the difference is. I hear everybody laughing but that is the bottom line. I think that she is putting out a lot of false positives for Lyme disease, mycoplasma and whatever so I do not have confidence in her testing; therefore, I would not refer to her.[42]

2.54 However, the committee noted that there is no concrete evidence to support the conclusion that Australian Biologics is returning false positives.[43]

2.55 The committee sought to clarify, through a question taken on notice, whether testing protocols used by Australian Biologics were peer reviewed:

> Yes, we have swapped samples (both positives and negatives) with the Reference Laboratory for Borreliosis in the Czech Republic. We detected all the samples they sent us and they detected all the samples we sent them. The six research papers on Borrelia to which we contributed used our PCR testing and the same samples were also tested by Prof Eva Sapi at New Haven University. Prof. Sapi is well known for her work on Borrelia. We have also had correlations in PCR testing with Professor Vett Lloyd at Mt. Alison University and since 2012 we have participated in a Quality Assurance Programme offered by QCMD (Quality Control Molecular Diagnostics), based at Glasgow University. We now have 5 years of results showing 100% correct detection of Borrelia through QCMD. Dr. Peter Mayn published "Clinical Determinants of Lyme Borreliosis, babesiosis, bartonellosis, anaplasmosis, and ehrlichiosis in an Australian cohort" in 2014 (paper is attached) which compared our testing to that of Igenex. Our positivity rate for Borrelia was given as 59% and Igenex as 58%. This is very good confirmation of both laboratories' testing.[44]

2.56 Professor Graves suggested that his laboratory and Ms Burke's might do well to compare the assays they use in order to ascertain why they are getting different results:

---

41 Professor Stephen Graves, answer to question on notice, received 15 November 2016.

42 Professor Stephen Graves, *Committee Hansard*, 2 November 2016, p. 16.

43 *Committee Hansard*, 2 November 2016, pp. 16–17.

44 Australian Biologics, answer to question on notice, received 17 November 2016, pp. 2–3.

> What usually happens in a situation like this is that different labs will compare their assays so we would take a common QAP, quality assurance process, sample. They would go to different laboratories and be tested to see whether or not they are getting the same results. That is how we normally do it. There may be, say, just for argument's sake, six or seven different assays for detecting antibodies for Lyme disease used in Australian laboratories. They will all have slightly different sensitivities and specificities but on the whole most of them will give the same answer—positive if it is truly positive or negative if it is truly negative. That is how we do it. Strictly speaking, what we should do is Jennie [Ms Burke, Director, Australian Biologics] and I should exchange specimens and methodologies and see why we are not getting the same results.[45]

2.57 Representatives of the Karl McManus Foundation suggested that some of the confusion could be alleviated if laboratories stated the parameters and limitations of their results when these are provided.[46]

2.58 Clarity around these issues may be within reach, however. As noted in the committee's interim report, the department has contracted the National Serology Reference Laboratory (NSRL) to conduct a review of serological assays used to diagnose Lyme disease. The review is looking at assays used in Australia and overseas.[47]

2.59 The NSRL provided an update on the status of the review:

- We have received approximately 650 specimens from the collaborators in UK, Germany, US and Australia, along with the results the collaborators obtained for those specimens.
- We have collected 308 specimens prospectively from Australian blood donors who have not travelled outside Australia.
- The collaborators have informed us of the serology assays they use to test for Lyme Disease.
- NRL has purchased sufficient of each of these assays to test all collaborator and blood donor specimens on all assays.
- We are in the process of testing the specimens now.
- The specimens are being tested in a blind manner. By that I mean that the specimens are labelled with an NRL identifier, not the identifier from the collaborator. Therefore we do not know the origin of the specimens or the results obtained by the collaborators

45 Professor Stephen Graves, *Committee Hansard*, 2 November 2016, p. 17.

46 Mr Christopher Walker, *Committee Hansard*, 2 November 2016, p. 45.

47 Senate Community Affairs References Committee, *Growing evidence of an emerging tick-borne disease that causes a Lyme-like illness for many Australian patients*, Interim report, May 2016, p. 57.

> as we are testing them. Therefore we cannot say anything at the moment about what the results are showing.[48]

Committee view

2.60 This inquiry has highlighted what is now decades-old disagreement on whether classical Lyme disease can be contracted in Australia. The committee acknowledges evidence provided by Australian medical authorities indicating that accredited laboratories—following established best-practice testing processes—have not found classical Lyme disease in Australian patients, with the exception of those who most likely contracted the disease overseas. This is what leads many in the medical profession to the conclusion that classical Lyme disease is not endemic to Australia.

2.61 However, while ever the issue of test quality remains contentious, the committee warns against ruling out the possibility that these bacteria are endemic to Australia. The committee is not satisfied that enough has been done to examine testing processes used by laboratories such as Australian Biologics. In the absence of such examination, the committee does not support an *a priori* conclusion that those test results are false positives.

2.62 Furthermore, the very fact that the reliability of the two-tiered testing protocol for Lyme disease is being questioned by respected doctors and scientists is, in the committee's view, reason enough for authorities to give careful consideration to these doctors' concerns. This notwithstanding, acknowledging the controversy does not in itself constitute proof of the inadequacy of the two-tiered testing protocol. The committee notes that work on developing new tests for Lyme disease is underway overseas and urges Australian medical authorities to remain appraised of the development of these tests.

2.63 The committee notes the NSRL review currently underway with interest. It is the committee's hope that this review will be conducted in a transparent manner and its findings published as anticipated. The committee expects that this review will provide some much-needed, conclusive answers, and enable the discourse on testing protocols to progress beyond the current impasse.

What is in our ticks?

2.64 Ticks in Australia, like ticks elsewhere, harbour a microcosm of bacteria, viruses and other pathogens. To reiterate, the department states that bacteria responsible for Lyme disease have not been identified in Australian ticks, and discovering such a bacterium is necessary before an evidence-based conclusion about the existence of Lyme disease in Australia—or a related illness—can be made:

> The conclusive finding of a bacterium that could cause Lyme disease or a Lyme disease-like illness in Australia has yet to be made. Such a finding

48 National Serology Reference Laboratory, answer to question on notice, received 18 November 2016, p. 1.

> would put beyond doubt the existence of Lyme disease, or a Lyme disease-like illness in Australia.[49]

2.65 Many submitters and witnesses concurred with this position, and suggested an alternative explanation: that another, as yet unidentified pathogen, may be the likely cause of tick-borne illness in Australia.

2.66 Others however challenged the assertion that bacteria causing Lyme disease were not present in Australian ticks, providing evidence to support their views.

2.67 Both positions are explored below.

Is Lyme Borreliosis endemic in Australia?

2.68 The committee was provided with excerpts from doctoral research dating back to the early 1990s which alludes to the likely presence in Australian ticks of *Borrelia* associated with Lyme disease. The objectives of the research were as follows:

> 1. To determine whether Australian ticks carry and transmit spirochaetes related to *Borrelia burgdorferi*.
> 2. To develop a specific and sensitive sero-diagnostic test to assess whether or not there is a correlation between clinical illness and the presence of *Borrelia burgdorferi* specific antibodies in likely Australian LB [Lyme Borreliosis] candidates.
> 3. To access the distribution of LB along the East Coast of Australia.[50]

2.69 The research project was initiated in 1989 and concluded in 1994. It began with a focus on the Manning Valley in New South Wales (NSW), but expanded to include the Sydney and Hunter Valley regions of NSW as well.

2.70 The paper concluded that Lyme Borreliosis does exist indigenously in Australia, because patients who had never left Australia tested positive for *Borrelia* antigens and displayed corresponding clinical symptoms.[51] Based on these findings, Dr Wills called for further research into:

> 1. Development of suitable cultural conditions for the growth and maintenance of Australian *B. burgdorferi*.
> 2. The molecular characteristics of Australian strains of *B. burgdorferi* so that a taxonomical comparison with existing genospecies can be obtained.
> 3. A more exact definition of the clinical manifestations of Australian Lyme disease and the immunological responses of patients.

---

49 Department of Health, *Submission 495*, p. 2.

50 Dr Stuart King, *Submission 1289*, *Attachment 1*, p. 1.

51 Lyme Disease Association of Australia, *Submission 528.1*, pp. 7–9

4. Determination of epizootiology of LB in Australia, and the importance of LB in Australian wild and domestic animal populations.[52]

2.71 It is unknown to what extent this research has been pursued or reviewed. The department did, however, address this research in a scoping study conducted in 2013, concluding that the results were unable to be replicated:

> To this date, there has only been one report of *Borrelia* species being found in *I. holocyclus* ticks, but the cultures were not confirmed and were unsustainable (Wills and Barry 1991)…. Spirochaetes morphologically similar and antigenically related to *Borrelia burgdorferi* were cultured from the gut contents of *I. holocyclus* and *Haemophysalis spp.* ticks by Wills and Barry (1991), but the cultures weren't sustainable and these results have not been able to be repeated from ticks collected more recently.[53]

2.72 The committee notes that the department does not conclusively rule out the presence of classical Lyme disease in Australia. Instead, the department expresses a more nuanced position, stating that there is no evidence to suggest the presence of the bacteria:

> [T]he likelihood that Australia has an indigenous form of classical Lyme disease is questionable, given that a causative micro-organism with a competent vector is yet to be found. Whether a form of tick-borne human borreliosis exists in Australia is yet to be determined.[54]

A different Borrelia?

2.73 Some witnesses suggest that—accepting that Lyme disease is caused by members of the *Borrelia burgdorferi* sensu lato complex which have not been found in Australia—a different species of *Borrelia* might be present in Australia:

> On that basis, I would like to say that as far as I can see—from the patients' clinical symptoms, from the scientific research and from the preliminary results from the tick-borne disease unit—we do not have *Borrelia burgdorferi*, or Lyme disease, in Australia. What we have is a unique *Borrelia* infection. The problem with this disease is the symptoms are non-specific, so not every single Lyme patient ends up with the same set of symptoms. It is very hard to diagnose clinically. You can check the literature: every single publication will say the same thing. In the US they ask for a history of tick bite, and in certain areas like Connecticut it is common to have an EM rash, or the 'bull's-eye' rash, so diagnosis is easier. But in Australia the symptomology is much broader, and there are a lot more neurological symptoms. So you will end up with patients having seizures, patients having MS-like symptoms, patients having atypical Parkinson—atypical. Most of their symptoms are atypical, so a classical

52 Lyme Disease Association of Australia, *Submission 528.1*, p. 7.

53 Department of Health, *Submission 495, Attachment D*, pp. 8–14.

54 Dr Gary Lum, Department of Health, *Committee Hansard*, 2 November 2016, p. 58.

> neurologist cannot put them in the perfect box of multiple sclerosis or whatever they are familiar with.[55]

2.74 The plausibility of this theory is supported by other evidence. Dr Horowitz pointed out that identification of new strains of *Borrelia* is progressing at a rapid rate, suggesting that there may be far more species of *Borrelia* than are currently identified:

> So with inadequate diagnostic testing, and with the multiple species of bacteria and parasites that are spreading with environmental toxins, the problem is that with over 100 strains of Lyme borreliosis in the United States and 300 strains worldwide, although most of them are not pathogenic, we are finding new species every two years. There have been 15 new *Borrelia* species discovered in the last 20 years. The problem is that the testing has a difficult time keeping up with it.[56]

2.75 The committee notes that, as Dr Horowitz states above, most of the new species found are not pathogenic, they will not cause illness in humans. However, the identification of new strains of *Borrelia*, as well as other bacteria, in ticks around the world, including Australia, is of considerable significance to this inquiry, as it is possible that some will be found to be pathogenic.

2.76 The department noted the recent discovery of new *Borrelia* species in some Australian ticks, but cautioned against premature conclusions in the absence of thorough research:

> The department welcomes the finding of new *Borrelia* species from ticks found on echidnas. This new *Borrelia* probably represents a new clade.[57] It is different from the *Borrelia* in the Lyme disease group, the relapsing fever group and the reptile group. While this is a significant finding, it is important not to jump to conclusions. Whether these micro-organisms cause disease in humans requires research into transmission and human pathogenicity. The same research group has been able to readily identify *Borrelia burgdorferi* sensu lato species in ticks collected from endemic areas overseas. This demonstrates that, to date, with state-of-the-art technology, there remains no evidence of a cause of classical Lyme disease in Australian ticks. The Australian government has previously highlighted, in the scoping study it commissioned, the importance of research not only in ticks but also in patients, and of the need to draw evidence-based connections, if they exist.[58]

2.77 The committee looks at research underway in the next section.

---

55 Dr Mualla McManus, *Committee Hansard*, 15 April 2016, p. 28.

56 Dr Richard Horowitz, *Committee Hansard*, 2 November 2016, p. 2.

57 A clade is a group of organisms, usually species, more closely related to one another than any group, implying a shared recent ancestor.

58 Dr Gary Lum, Department of Health, *Committee Hansard*, 2 November 2016, p. 59.

Committee view

2.78 The committee notes contradictory evidence received on the subject of *Borrelia* in Australian ticks, and reiterates that it is beyond the scope of this inquiry to establish whether *Borrelia* species which may cause Lyme disease are to be found in Australian ticks. The committee acknowledges the prevailing view that contracting Lyme disease in Australia is not possible, that our ticks have been studied and found not to harbour known Lyme disease-causing pathogens.

2.79 However, the committee also notes that evidence challenging this position has been presented during this inquiry. The committee refers particularly to the research of Dr Michelle Wills, which has been provided in evidence by more than one submitter, with consent from Dr Wills. The committee is persuaded that steps should be taken by the medical authorities to conduct a review of this evidence afresh if this has not already been done. To be authoritative and conclusive, such a review must be conducted by an independent, qualified team of scientists, with its methodology and results published in full.

More research is needed

2.80 Scientific research will play a critical part in identifying the pathogen, or pathogens, responsible for tick-borne illness in Australia. The committee's interim report outlined research currently underway. This was explored further at an additional hearing, with new evidence presented by Professor Peter Irwin, representing the Vector- and Water-borne Pathogen Research Group at Murdoch university, on recently discovered potential pathogens:

> Since the appearance of Professor Ryan and Dr Oskam before the committee, we have further characterised a number of bacteria which, in our opinion, represent potential candidates for tick-borne pathogens in Australia. These include *Neoehrlichia*, *Anaplasma*, *Ehrlichia* and *Borrelia*. Our work with *Borrelia* has confirmed that it is a unique Australian species. It is distinct from both the Lyme disease group and the relapsing fever disease group. Similar work with other bacterial species also reveals a unique phylogeny. Our conclusion, based on the evidence so far, is that Australian ticks harbour a relatively unique set of bacteria and therefore these are unknown to medical science in terms of their capacity to cause disease.[59]

2.81 Professor Irwin has emphasised that it is not appropriate to link these newly identified bacteria to illness in humans.[60] The next logical step in this research, Professor Irwin advised, will be to look at which, if any, of the newly identified organisms found in Australian ticks can be transmitted to humans. This, Professor Irwin concludes, is critical to determining causation.[61] Professor Irwin further

---

59 Professor Peter Irwin, Principal, College of Veterinary Medicine, Murdoch University, *Committee Hansard*, 2 November 2016, p. 25.

60 Department of Health, *Submission 495*, p. 4.

61 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 25.

explained that after potential pathogens are identified, work will need to be done to assess the impact these may have on humans:

> There are several phases in this research. Ours is to form the building blocks of what is here in the ticks. The whole determination of disease causation by which of those bugs could cause disease in people is a further set of work that will require quite significant epidemiological type studies.
>
> We are actually intending to start work in that space. We intend to apply for an NHMRC grant next year—in the next main funding round—to support this work. We are starting to gather together collaborators—doctors in various parts of Australia who see patients with tick bites. We want to investigate them in a longitudinal fashion to follow those patients into the future.[62]

2.82 Professor Irwin reported having received a new grant which will fund some studies over the next three years, but called for an urgent increase in funding through the National Health and Medical Research Council (NHMRC):

> The NHMRC is the most relevant funding agency. However, an understanding of the importance, or relevance, of research into Lyme-disease-like illness may not be appreciated by all the reviewers and independent experts. We are aware of a grant application on this topic that was recently rejected by the NHMRC that scored relatively poorly for the category of 'significance'. I note also that Professor Kelso explained the NHMRC funding process in her submission to the committee in April, and I am encouraged by her comments that the NHMRC is putting in place targeted calls for research, which may recognise the priorities of not only government but also the wider Australian community. I believe that funding for research into tick-borne diseases in Australia is urgently needed.[63]

2.83 Research is also underway at the tick-borne diseases unit at Sydney University, which is currently conducting a study looking at whether ticks in Australia carry *Borrelia* or similar bacteria. The committee notes that the research has not been published yet, but that conclusive, direct evidence of *Borrelia* known to cause Lyme disease has not been found, but that other *Borrelia* have been found.[64]

2.84 Professor Irwin and Dr Ann Mitrovic[65] both extrapolated a further conclusion from the research already conducted: serological testing currently available, discussed earlier in this chapter, is quite likely ill-equipped to identify infection by the pathogens most likely at play in Australia:

> I heard the end of the discussion previously on serological testing, and, to my mind, it somewhat completely misses the point—that all the tests that are available at the moment are developed against known bacteria and

62 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 26.

63 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 25.

64 See discussion, *Committee Hansard*, 2 November 2016, pp. 25–26.

65 Dr Ann Mitrovic is a Research Fellow with the Tick-Borne Diseases Unit, School of Medical Sciences (Pharmacology), University of Sydney.

> disease. That is what they are designed for. I believe the Australian situation is completely different. We have organisms here that may be causing disease—we do not know what they are yet; we are working on that. In order to develop tests that are going to be more specific for what we have going on here, we need to isolate those organisms and develop tests from them.[66]

2.85 In making the same point, Dr Mitrovic brought the committee back to the issue of laboratory testing. In the US and Europe, where new strains of *Borrelia* are being discovered, these are not able to be detected by tests looking for infection with the *Borrelia burgdorferi* sensu lato complex.[67]

2.86 The committee notes evidence indicating that international bodies are expanding definitions around Lyme disease to include more than one strain of *Borrelia* and a number of co-infections.[68]

Committee view

2.87 The committee notes evidence outlined above indicating that unique pathogens have already been identified in Australian ticks, and that pathology tests currently conducted in Australia are not designed to look for those newly-identified pathogens. The committee is of the view that funding should be made available for this research to continue and be expanded as a matter of priority.

2.88 The committee is persuaded that it is possible that these unique pathogens may be causing Lyme-like illnesses and therefore further work is urgently needed to identify these pathogens and links to Lyme-like illnesses.

2.89 The committee however urges caution against extrapolating too much from the discovery of possible new pathogens, supporting the department's view that nothing should be assumed without further research.[69]

Recommendation 1

2.90 The committee recommends that the Australian Government Department of Health engage with stakeholders following the publication of the National Serology Reference Laboratory review to discuss the findings of the review and any bearing those may have on testing for Lyme disease in Australia.

Recommendation 2

2.91 The committee recommends that the Australian Government increase funding for research into tick-borne pathogens as a matter of urgency. This funding should include:

- **funding for research on pathogens which may cause infection;**

66 Professor Peter Irwin, *Committee Hansard*, 2 November 2016, p. 27.

67 Dr Ann Mitrovic, *Committee Hansard*, 2 November 2016, p. 27.

68 Ms Sharon Whiteman, President, Lyme Disease Association of Australia, *Committee Hansard*, 2 November 2016, p. 43.

69 See Department of Health, *Submission 495*, p. 4.

- **funding for research on whether newly-identified pathogens can cause illness in humans; and**
- **funding for the development of diagnostic tests which can detect infection by any newly-identified pathogens endemic to Australia.**