DEPARTMENT OF HEALTH

Review of Commonwealth Funding of Services to Support the Diagnosis and Screening of Blood Borne Viruses

FINAL REPORT

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TABLE OF CONTENTS

ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
APL	Accredited Pathology Laboratory
ARCBS	Australian Red Cross Blood Service
ARTG	Australian Register of Therapeutic Goods
BBV	Blood borne viruses
CAC	Conformity Assessment Certification
the Code	Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products
The Department	The Australian Government Department of Health
DNA	Deoxyribonucleic acid
EQAS	External quality assessment scheme
GMP	Good Manufacturing Practice
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HMA	Healthcare Management Advisors
HTLV	Human T-lymphotropic virus
Ig	Immunoglobulin
ISO	International Organization for Standardization
IVD	In-vitro device
MBS	Medicare Benefits Schedule
NAT	Nucleic Acid Amplification Testing
NATA	National Association of Testing Authorities
NBA	National Blood Authority
NPAAC	National Pathology Accreditation Advisory Council
NRL	National Serology Reference Laboratory
OHP	Office of Health Protection
OTA	Organ and Tissue Authority
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RCPA	Royal College of Pathologists Australasia
RNA	Ribonucleic acid
TGA	Therapeutic Goods Administration
TGO	Therapeutic Goods Order
UK	United Kingdom
VIDRL	Victorian Infectious Diseases Reference Laboratory

EXECUTIVE SUMMARY

The Australian Government Department of Health (the Department) engaged Healthcare Management Advisors (HMA) to:

> *'conduct an independent review of Commonwealth funding of services that support the screening and diagnosis of blood borne viruses.'*

The Department funds a number of services aimed to support the quality of the Australian blood supply and to help prevent the spread of blood borne viruses (BBVs).

Funded services include:

- a Quality Control and Quality Assurance (QA) program for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) tests utilising Class 4 in-vitro diagnostic devices (Class 4 IVDs)
- a Quality Control (QC) and QA program for the Australian Red Cross Blood Service's (ARCBS) testing for HIV, HCV and hepatitis B virus (HBV) in fresh blood donations
- reference testing on HIV and human T-lymphotropic virus (HTLV) samples that require an adjudication as to their status (type 1 or type 2) and, for the ARCBS only, confirmatory testing on HIV, HCV, and HBV samples that have tested positive, equivocal or indeterminate by routine testing platforms, and
- performance monitoring of laboratories through data collection and analysis.

The funded services are currently provided by one service provider, the National Serology Reference Laboratory (NRL), and used by:

- self-selecting Australian pathology laboratories to support diagnostic and clinical monitoring services, and
- the ARCBS to support tests used for the screening of the Australian blood supply.

Funds provided to the NRL for these services total approximately $4.5 million per year. This includes funds to cover NRL administrative costs for funded services.

Blood first became regulated by the Therapeutic Goods Administration (TGA) in 2000. Under these regulations IVDs used to test for HIV and HCV were required to be registered on the Australian Register of Therapeutic Goods (ARTG). At the time, registration of HIV and HCV IVDs entailed:

- a pre-market laboratory-based performance evaluation, undertaken by the NRL on behalf of the TGA, and
- laboratories using the IVDs had to participate in an NRL QA program.

However, of particular note for this review, a new risk-based regulatory framework was introduced by the TGA in 2010 that significantly changed the role of the NRL in the TGA's regulatory process, as follows:

- the NRL no longer performs pre-market evaluations for the TGA, and
- participation in an NRL QA program is no longer a requirement for IVD inclusion on the ARTG and, although participation is a QA program is required, users of the IVDs are able to select a provider of choice.

Australian pathology laboratories are required to meet relevant national and international standards, including the National Pathology Accreditation Advisory Council (NPAAC) standards. Adherence to these requirements is assessed under a joint accreditation scheme administered by the National Association of Testing Authorities (NATA) and the Royal College of Australian Pathologists (RCPA). In relation to the in-scope services, this means pathology laboratories must have QC materials from third party providers and participate in external quality assurance programs that enable inter-laboratory comparison of results.

The ARCBS is required to adhere to the QA and QC requirements under the TGA Australian Code of Good Manufacturing Practice (the Code) and Therapeutic Goods Order (TGO) 88 (the Order).

All four laboratories of the ARCBS use the in-scope NRL services. An estimated 90 per cent or more of eligible pathology laboratories (67–70 of 74, based on NATA

accreditation) use one or more in-scope NRL services (approximately 45 per cent of eligible laboratories using at least one NRL service were privately owned pathology laboratories). All in-scope services are provided free of charge to recipient laboratories. Where the in-scope pathogens are provided in a multi-marker mix, recipient laboratories are required to pay a fee for out-of-scope pathogens included in the mix.

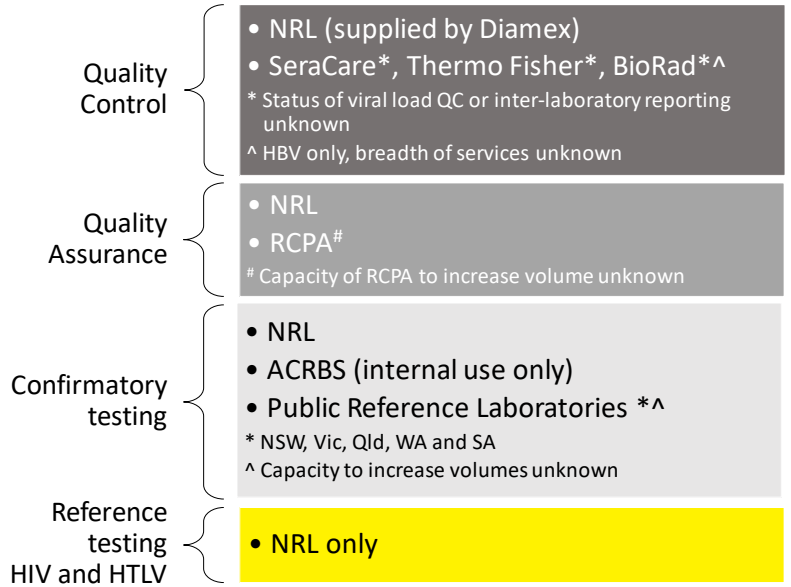
Laboratories using the funded services were surveyed to assess the use and current market for the funded services, including service use, factors influencing service uptake, cost comparisons, and identification of alternative providers.

Of the survey respondents, ability to meet regulatory requirements was the most important factor influencing choice of provider for both the ARCBS and the pathology laboratories utilising the funded services (hereafter referred to as participating laboratories). Of note, the survey questions did not allow for delineation of which 'regulations' the laboratories were aiming to meet by using the services. Therefore, it is unclear whether the 'regulatory requirements' referred to are those under the Code and/or NPAAC standards, or if some laboratories remain unaware of the changes under the new IVD regulatory framework. Testing platforms available were also factors for the ARCBS, whereas reliability and cost influenced provider choice for participating laboratories.

The current availability of other service providers to provide the in-scope services is represented in Figure ES1. In summary:

- there are two other providers of all in-scope materials (SeraCare and Thermo Fisher), and one service provider for HBV QC materials (BioRad), but the extent of inter-laboratory comparison of these service providers is unknown
- there is one other service provider for external quality assurance programs (RCPA), but the capacity to increase volume of services is unknown
- many pathology laboratories and most public reference laboratories are able to undertake confirmatory testing for the in-scope pathogens, but their capacity to increase volumes is unknown
- NRL is the only known provider of HIV and HTLV reference testing (adjudication) in Australia.

Figure ES1: Summary of market capacity



The currency, effectiveness and appropriateness of the current Australian Government funding of the services was assessed in consideration of the information gathered in this review and with reference to the funding objective of ensuring the quality of the Australian blood supply.

Historically, the funding of the in-scope services supported the ARCBS and pathology laboratories to meet regulatory and accreditation requirements for Class 4 IVDs used to detect BBVs. However, funding NRL to provide these services does not reflect regulatory changes introduced in 2010 that removed the regulatory requirement for laboratories using IVDs to participate in NRL QA programs. Funding of services used by the ARCBS is effective in meeting the funding objective of ensuring the quality of the Australian blood supply. Funding of services used by participating laboratories, i.e. non-ARCBS, supports those laboratories to meet

regulatory and accreditation requirements but does not make a meaningful contribution to achieving the funding objective.

It is appropriate that the Australian Government funds services used by the ARCBS but, as ensuring the quality of ARCBS processes is an important component of the National Blood Agreement, funding for these services would more appropriately be provided under the national blood agreement. Under this agreement, funding is a joint responsibility of the national and jurisdictional governments.

Funding of services used by participating laboratories may not be appropriate under the current funding arrangement as it does not clearly align with the funding objective. Decisions on future funding may need to consider whether these services contribute to any other Australian Government objectives or priorities. The impact of funding changes to market capacity and service delivery should be a part of any funding considerations.

Paragraph regarding future funding options has been redacted.

1 INTRODUCTION

The Australian Government Department of Health (the Department) has engaged Healthcare Management Advisors (HMA) to:

> *'conduct an independent review of Commonwealth funding of services that support the diagnosis and screening of blood borne viruses.'*

The Department funds a number of services to support the quality of the Australian blood supply and to prevent the spread of blood borne viruses (BBVs). The funding agreement is managed by the Department's Office of Health Protection (OHP).

1.1 SCOPE OF THE REVIEW

This review centred on Commonwealth funding of services provided by the National Serology Reference Laboratory (NRL). Funding is through a funding agreement between NRL host organisation, St Vincent's Institute of Medical Research, and the Australian Government as represented by the Department. The in-scope funded services relate to the use of in-vitro diagnostic devices (IVD) to test for BBVs, namely human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and human T-lymphotropic virus (HTLV). Funding arrangements for other relevant or similar services, such as the National Blood Authority (NBA), were considered as part of this review. However, evaluation of those arrangements was not in scope of this review.

1.2 SUMMARY OF NRL funding

The Australian Government currently funds the NRL to provide a number of services that support the diagnosis and screening of BBVs. The services are utilised by self-selecting participating laboratories to support diagnostic testing, and the Australian Red Cross Blood Service (ARCBS) to support screening of the Australian blood supply. The funded services are:

(1) For **participating laboratories**
- (a) Quality Control (QC) program for HIV and HCV
- (b) External Quality Assurance (QA) program for laboratories performing HIV and HCV tests that utilise IVDs for serology and therapeutic monitoring
- (c) Monitoring of the QC and QA programs
- (d) Reference testing for HIV and HTLV samples that require adjudication as to their status
- (e) Performance reporting to the Australian Government on funded services provided and a summary of testing outcomes

(2) For the **Australian Red Cross Blood Service**
- (a) QC program for HIV, HCV and HBV (including a negative control) for the ARCBS nucleic acid testing (NAT) program
- (b) External QA program covering HIV and HCV serology and HIV, HCV and HBV NAT
- (c) Monitoring of the ARCBS QC and QA programs
- (d) Reference testing on HIV and HTLV samples that require adjudication as to their status
- (e) Confirmatory testing for samples that test positive, equivocal or indeterminate for HIV, HCV or HBV
- (f) Specificity monitoring of HIV and HCV serological assays performed by the ARCBS
- (g) Provision of plasma control panels for staff training or proficiency testing

(h) Performance reporting to the Australian Government on services provided to the ARCBS and a summary of testing outcomes.

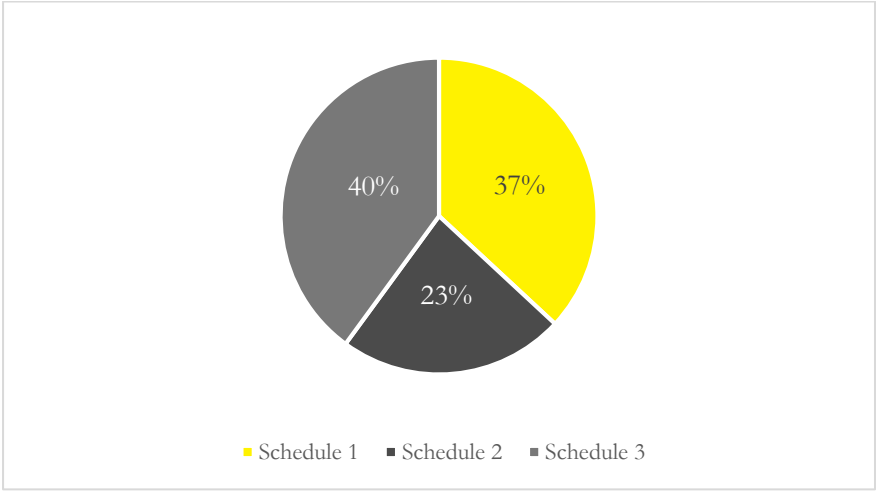
Funds provided to the NRL for these services total approximately $4.5 million per year. This includes administrative costs related to the delivery of the funded services. Under the current funding arrangement, administrative costs are calculated separately from the per unit costs of the delivered services. These costs include salaries and rent, as well as costs associated with the maintenance and calibration of relevant testing equipment. Funding to the NRL is delivered and managed through three schedules:

- **Schedule 1:** Management services
- **Schedule 2:** QA program for HCV and HIV tests utilising IVDs
- **Schedule 3:** QC and QA program for the ARCBS' NAT (IVDs)

The distribution of funding for the in-scope services is discussed below.

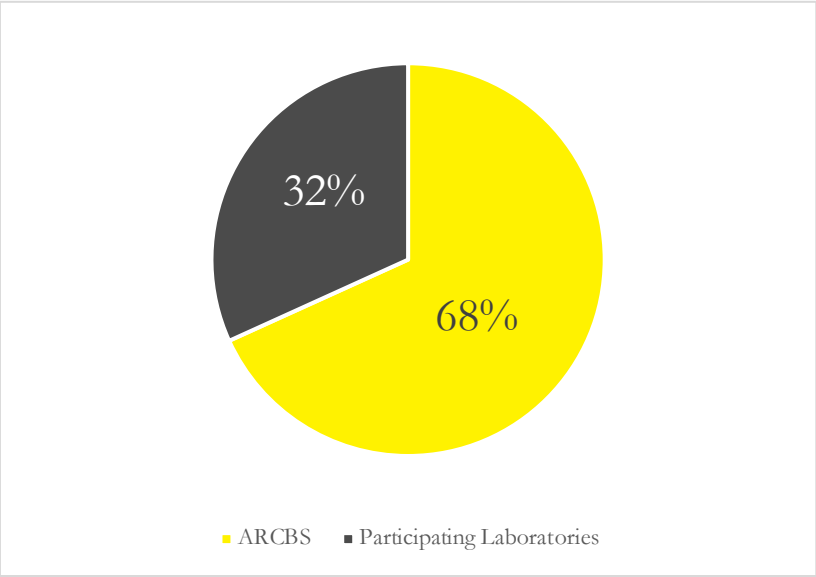
The approximate proportion of total funding per year by schedule is represented in Figure 1.1 and shows Schedule 3 receives the largest proportion of funding at 40%. Notably, a larger percentage of funding is provided for management services under Schedule 1 (37%) than Schedule 2 services (23%).

Figure 1.1: Approximate funding proportions provided to the NRL per year, by of schedule



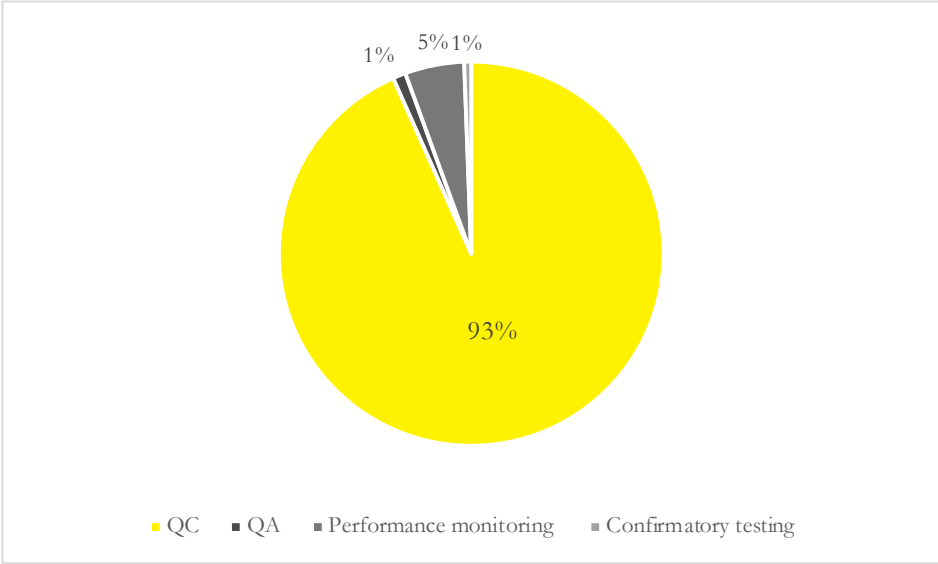
The approximate proportion of total funding per year by laboratory type is shown in Figure 1.2 which shows that the ARCBS receives two thirds of the service delivery funding (from Schedules 2 and 3).

Figure 1.2: Approximate proportion of Schedules 1, 2 and 3 funding by laboratory type



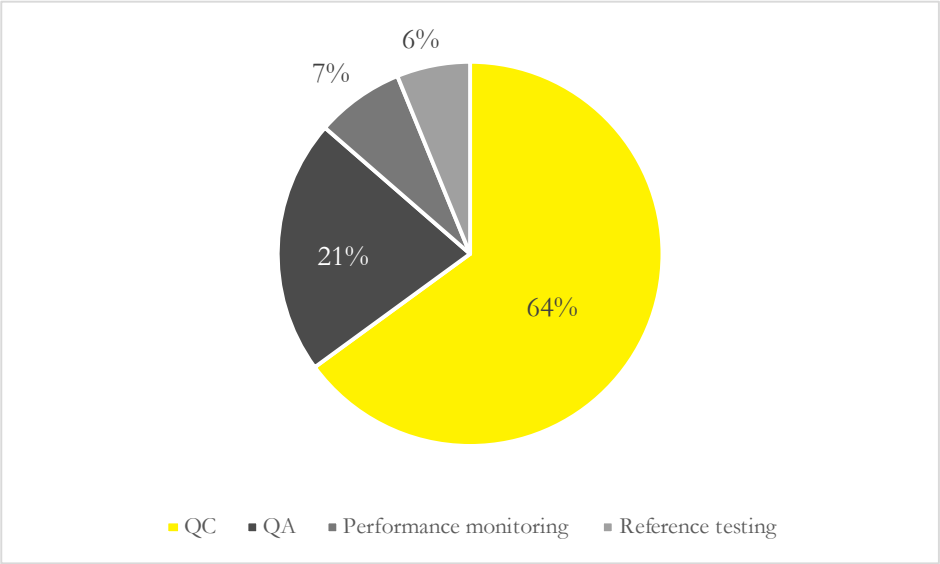
The approximate proportion of total funding per year by activity type for the ARCBS (from Schedules 2 and 3) is shown in Figure 1.3 which shows that the majority of service delivery funding (93%) contributes to QC processes.

Figure 1.3: Approximate proportion of funding for services provided to the ARCBS per year, by activity type (from Schedules 1, 2 and 3)



The approximate proportion of total funding per year by activity type for participating laboratories is shown in Figure 1.4 which shows that almost two thirds (64%) of service delivery funding contributes to QC processes, and approximately one fifth of service delivery funding (21%) contributes to QA activities.

Figure 1.4: Total funding for services provided to participating laboratories per year, by activity type (from Schedules 1 and 2)



1.3 PURPOSE OF THE REVIEW

The purpose of this review was to:

- assess the currency, effectiveness and appropriateness of Commonwealth funding of the services
- set out and clarify current practices in relation to the funded services and the clinical and regulatory environment, and
- provide possible variations and options to funding arrangements and the potential impacts these variations would have on the safety of the Australian blood supply.

1.4 OBJECTIVES OF THE REVIEW

The objectives of the review were to:

(1) analyse the regulatory framework for HIV, HCV and HBV testing in Australia including national regulations for IVD registration and use

(2) analyse relevant licensing and accreditation conditions, relevant national standards, and/or any relevant requirements under state and territory legislation

(3) analyse the current funding arrangements to assess cost/benefit comparisons of the Commonwealth funded services with services from other providers including:

  (a) review of current model and services, including the degree to which resources are allocated efficiently and effectively

  (b) assessment of the capacity of the market to provide required services for HIV, HCB, HBV and HTLV testing in Australia to the required level to meet the Australian Government's commitments to prevent the spread of blood borne viruses, including an assessment of the capacity of the market/existing laboratories to mobilise if required to provide the same services

  (c) analyse the potential impacts/risks on the safety of the Australian blood supply, industry, and consumers if there was a change to current

arrangements for the required services, including tendering arrangements or transitioning to a cost-recovery model

(4) provide options on the services and effective and efficient funding models to meet Australia's ongoing requirements for relevant HIV, HCV, HBV and HTLV testing (taking into account any perceived or actual impact on the safety of the blood supply), and

(5) provide options on potential integration and/or collaboration with existing services or programs administered by other entities, such as the National Blood Authority.

1.5 HISTORICAL CONTEXT

In Australia, the first HIV-related death was reported in 1984. In the same year, the first transfusion-related HIV infection was reported and a uniform donor declaration form was introduced [1].

In response, HIV serological testing for all blood donations was introduced in 1985 [1] and NRL was established to evaluate HIV tests and adjudicate on the interpretation of HIV test results [2]. At this time serological testing for HIV was new, testing was not yet regulated under the Therapeutic Goods Administration (TGA), and very few laboratories could perform HIV tests. Today, most pathology laboratories with microbiology capacity are able to test for HIV and HCV and reference laboratories located in most jurisdictions can perform HIV confirmatory testing by serology and NAT.

In 1989 HCV was identified and by 1990 HCV screening commenced in all transfusion services [1]. In 1996, the National ARCBS was established [1].

In 2003, the national blood arrangements were established to coordinate the blood supply at a national level. These arrangements, still in place, are managed by the NBA on behalf of all Australian governments, which all contribute to the funding arrangements [3].

At this time, the regulatory requirements for HIV and HCV required ARCBS to participate in the HIV and HCV QA program provide by the NRL (under TGA regulation established in 2000 under the *Therapeutic Goods Act 1989* [1]). Consequently, the NBA funding arrangement excluded these services, as they were already funded by the Australian Government.

In July 2010, a new regulatory framework was introduced for IVDs, which changed the regulatory involvement of NRL in the registration of IVD on the Australian Register of Therapeutic Goods (ARTG). Under the new regulations, laboratories are able to choose a supplier of a relevant QA program (which may or may not be NRL) [4].

To allow time for compliance, the new regulatory framework was introduced through a staged transition process. The transition period for the IVD regulatory framework ended on 30 June 2017.

It is timely to now review the funding arrangements for the in-scope services in consideration of the significant changes to regulatory requirements, and the expansion of testing service provision and market capacity. A timeline of events relating to HIV and HCV testing in Australia is provided at Appendix A.

1.6 SUMMARY OF REVIEW METHODOLOGY

This review was conducted in and informed by three key stages: desktop review, consultation with key stakeholders, and survey of laboratories utilising the funded services. More information on the review methodology is available at Appendix B.

2 TESTING FOR BLOOD BORNE VIRUSES

BBV is a term used to refer to viruses that can be transmitted through contact with contaminated blood. Tests used to detect BBVs work by testing for viral antigens, antibodies or nucleic acids. To ensure that test results are correct, it is important to ensure that the testing procedures and platforms used are reliable and performing at the expected standards. To this end, numerous regulatory processes and standards are in place to ensure that technology and kits available in Australia for testing of BBVs are maintained at a high standard, with minimal rates of error. This includes requirements for Australian pathology laboratories and the ARCBS laboratories that use Class 4 IVDs to participate in QA/QC programs. Requirements include QA designed to be a point-in-time check of the entire laboratory system, and QC measures designed to provide ongoing checks for specific assays.

The Australian Government is committed to ensuring the safety and security of the Australian blood supply. The impact of a blood donation returning a false negative result is the potential infection of multiple blood recipients (a single blood donation can be used to help three or more recipients (when separated into blood components) [5]). Similarly, an at-risk individual who falsely tests negative for a BBV could subsequently spread the infection to others, e.g. their sexual partner(s). Both of these scenarios pose a public health risk: the likelihood of harm if exposed and consequence if infection occurs is high for HIV and moderate for HBV and HCV Ensuring accurate and reliable testing for BBVs is therefore essential.

The primary purpose of the Australian Government funding under review is to provide QA and QC services for the use of Australian laboratories that test for BBVs, specifically HIV and HCV. In addition, funding is provided to support specificity monitoring for the ARCBS. Combined, these activities ensure the testing of BBV in Australia is reliable, accurate and that the blood supply is not contaminated.

Under the agreement, although not related to the safety of the blood supply, the NRL also performs a small amount of viral testing on HIV and HTLV samples that require adjudication as to their type status.

2.1 PURPOSE OF LABORATORY TESTING FOR BLOOD BORNE VIRUSES

In Australia, tests for BBVs are performed for three reasons:

- disease **diagnosis**
- **clinical monitoring**, and
- **screening** of donations (blood, organ and tissue).

Secondary testing includes:

- **confirmatory testing** for samples that test positive, equivocal or indeterminate and
- **reference testing** for samples that test that require adjudication as to their status.

2.2 QA AND QC OF BBV TESTS

QA and QC are critical to laboratories ensuring that the platforms and kits used to detect BBVs are performing as intended and producing correct results. QA and QC can be summarised as:

- **QA:** (usually conducted by an external agency) is primarily designed to determine the laboratory performance for specific tests or test procedures, and to monitor continuing performance of a laboratory [6].
- **QC:** results provide an objective means of assessing the reliability and comparative accuracy of the data through inter-laboratory comparisons [6].

The ARCBS and pathology laboratory testing processes are illustrated in Figure 2.1 and Figure 2.2, respectively.

Figure 2.1: ARCBS testing process and relationship of in-scope services

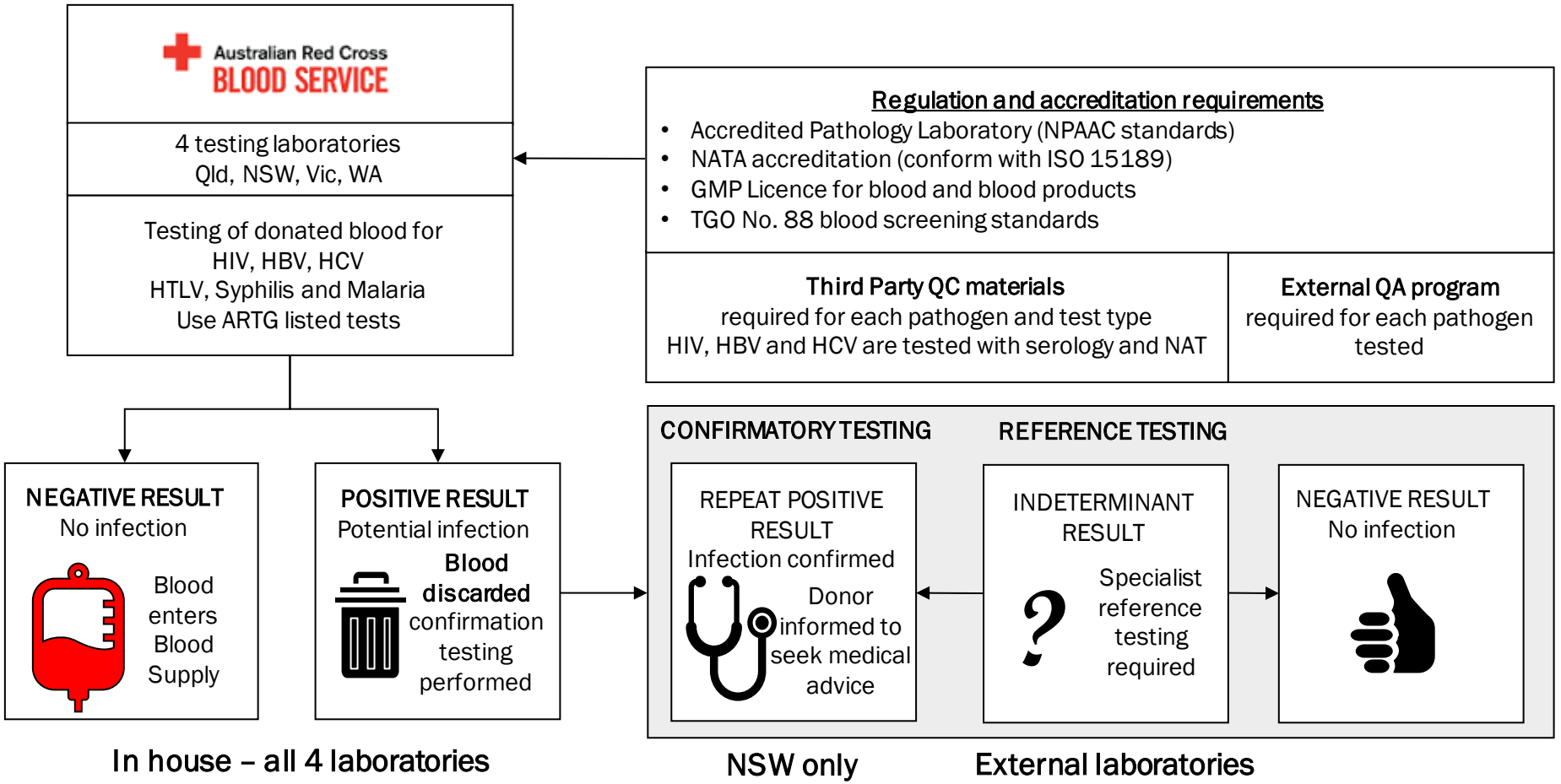
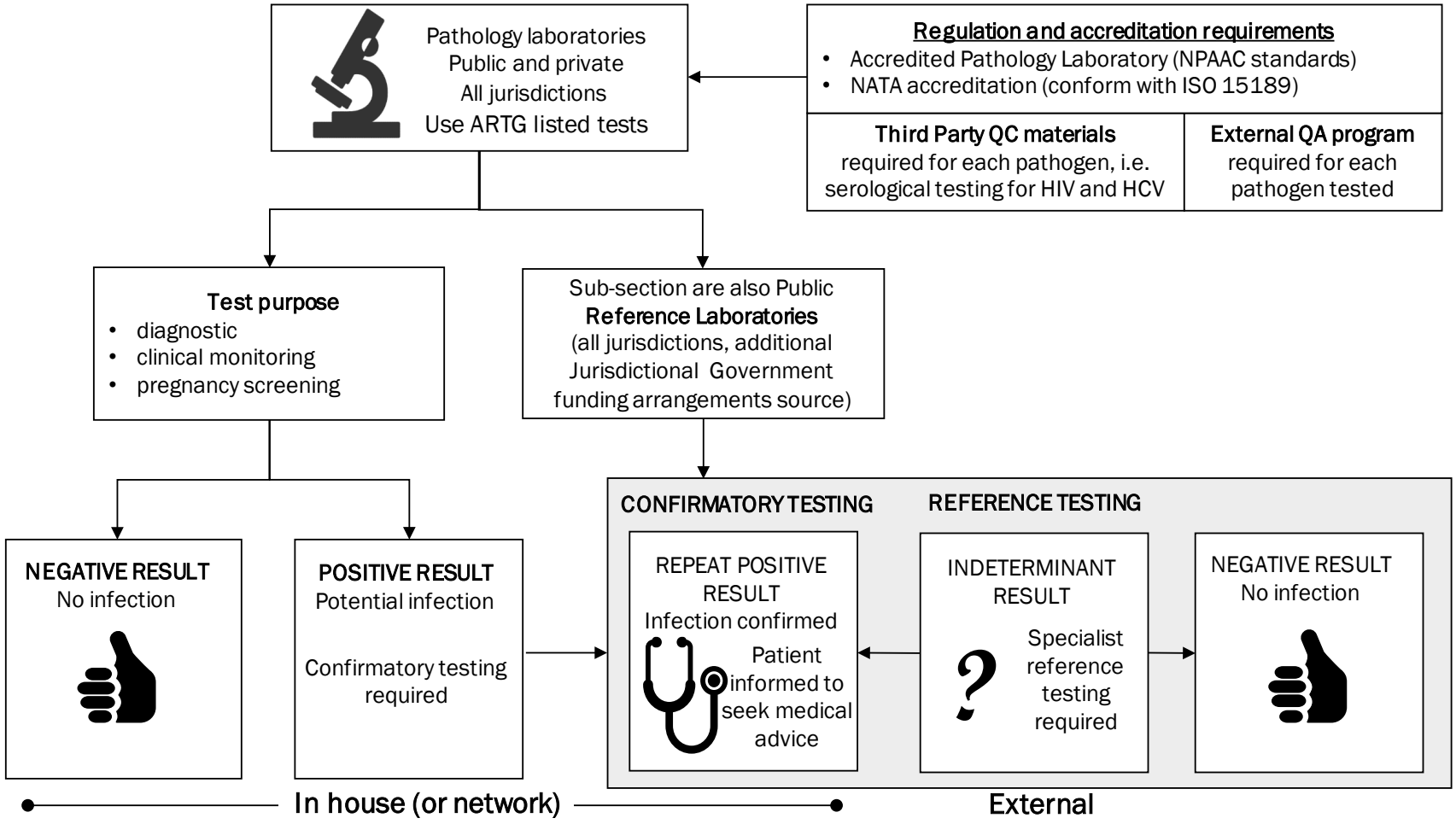


Figure 2.2: Accredited Pathology Laboratory testing process and relationship of in-scope services



3 REGULATORY AND ACCREDITATION FRAMEWORK

There are a number of risk-based regulations and standards that set out requirements to ensure quality, competency and efficacy of laboratory systems in Australia. An understanding of the regulatory and accreditation context for the funded services is needed in order to assess the currency, appropriateness, and effectiveness of the funding arrangements under review. This chapter sets out the current regulatory and accreditation framework applicable to the funded services, including:

- regulation of IVDs for use in Australia
- regulatory role of the NRL in relation to the funded services
- accreditation processes for laboratories, and
- regulations specific to the ARCBS.

3.1 REGULATIONS FOR IVD REGISTRATION AND USE

The TGA is part of the Australian Government Department of Health and is responsible for regulating therapeutic goods such as medicines and medical devices, including IVDs. The TGA regulates through a number of ways including pre-market assessment, post-market monitoring, and enforcement of standards [7].

An IVD is a medical device that is intended by the manufacturer to be used *in vitro* (alone or in combination with other diagnostic goods) to examine specimens from the human body, solely or principally to gain information about a physiological or pathological state in order to diagnose, monitor, screen and/or assess [8].

In Australia, IVDs are regulated under the Therapeutic Goods Act 1989 and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) [9]. The Regulations set out the regulatory requirements for IVDs including requirements for quality management and monitoring. Under the Regulations, IVDs are regulated according to risk and incorporate best practice relating to 'safety, quality and risk management procedures.'

ESSENTIAL PRINCIPLES

The TGA regulations include a set of essential principles that set out the requirements relating to the safety and performance characteristics of medical devices, including IVDs. Two essential principles relate to the QA and QC of IVDs:

- If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.
- An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer [10].

3.1.1 Changing IVD regulations and role of the NRL

In 1985 at the beginning of the HIV/AIDS epidemic, the NRL was established by the Australian Government to evaluate HIV tests and adjudicate on the interpretation of HIV test results. [2] This was at a time when serological testing for HIV was new, testing was not yet regulated under the TGA, and very few laboratories could perform HIV tests.

At this time, the role of the NRL was to ensure that the test kits in use for HIV testing were suitably sensitive and specific for screening and diagnosis, and to act as a referral source for HIV serological tests that could not be resolved by the testing laboratory (i.e. indeterminate results) [2].

In 2000, the testing of fresh blood became regulated by the TGA under the *Therapeutic Goods Act 1989* [11] and IVDs for HIV and HCV testing were required to be 'registered' on the ARTG. To be registered on the ARTG, HIV and HCV IVDs:

- underwent a pre-market laboratory-based performance evaluation, undertaken by the NRL on behalf of the TGA, and
- laboratories using the IVDs had to participate in the QA programs provided by the NRL.

In July 2010, a new regulatory framework was introduced for IVDs, with IVDs now regulated as a subset of medical devices under the Regulations. The new IVD regulations introduced a four-tier risk-based classification scheme. Under this scheme, IVDs used to detect diseases considered to pose a high risk to public health are classified at the highest IVD class – Class 4 – and are subject to a greater level of regulation [12]. Class 4 IVDs include those used to detect HIV, HBV, HCV, and HTLV, and donor screening tests for infectious diseases.

Under the new IVD regulations, commercially supplied IVDs to be used in Australian laboratories must be included in the ARTG (unless an exemption has been granted). To be included on the ARTG, manufacturers of Class 4 IVDs require TGA **conformity assessment certification** (CAC), which involves assessment of the manufacturer's quality management system (QMS certification) and a desktop evaluation of the design dossier for the device (Design Examination Certification) to assess safety and performance.

The new IVD framework significantly changed the role of the NRL in the ARTG regulatory process. Participation in an NRL QA program is no longer a requirement for IVD inclusion on the ARTG. Laboratories using IVDs are still required to participate in quality monitoring programs, but the program supplier can be selected at the discretion of the laboratory [4]. In addition, it is no longer a requirement under the new IVD framework to request pre-market performance evaluation of a Class 4 IVD to independently verify the manufacturer's performance claims. Accordingly, the TGA has ceased pre-market laboratory-based performance evaluations undertaken by the NRL [13]. Currently, the TGA performs the majority of desktop assessments as part of the CAC, however the TGA has a panel of external organisations that can be used to undertake an assessment if required. The NRL is a current member of the panel.

Post-market evaluations of IVDs included on the ARTG are performed by the TGA as required, e.g. in response to reports of adverse events or kit malfunctions. The TGA may consult with relevant experts when conducting a post-market evaluation, but it does not have an established arrangement with a third party to undertake post-market investigations on behalf of the TGA. Adverse events or identified problems with IVDs can be reported directly to the TGA by anyone, including the device manufacturer, sponsor, users/consumers, and quality performance organisations such as the NRL [13].

To allow time for compliance, the new regulatory framework was introduced through a staged transition process. The transition period for the IVD regulatory framework ended on 30 June 2017 [14].

3.2 LABORATORY ACCREDITATION

Diagnostic tests and other pathology services for HIV, HBV and HCV are subsidised by the Australian Government through the Medicare Benefits Schedule (MBS). In order to receive MBS benefits for pathology services, pathology laboratories in Australia must be an Accredited Pathology Laboratory (APL) under Section 23DN of the *Health Insurance Act 1973*. To be approved as an APL, laboratories must adhere to standards and guidelines that are developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC). The NPAAC standards are informed by other national and international standards and guidelines including the Australian Standard AS ISO 15189, which is an adaption of the International Organization for Standardization (ISO) standard ISO 15189 *Medical laboratories – Requirements for quality and competence.*

Adherence to the NPAAC standards is assessed under a joint accreditation program administered by the National Association of Testing Authorities, Australia (NATA) and the RCPA [15]. The standards include laboratory requirements for QA and QC [6].

3.2.1 National Pathology Accreditation Advisory Council Standards

NPAAC advises on the accreditation of pathology laboratories and is responsible for development and maintenance of the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017* which outline the legal requirements for laboratories to be approved as an APL. Requirements include the conditions of the premises, staffing qualifications, procedural types, material storage and reporting [11].

In relation to quality management processes relevant to the funded services, the NPAAC standards state that:

- Laboratories must have a documented and monitored **Quality System** in place that includes laboratory operations and testing procedures, and is reviewed and updated regularly [17].
- Laboratories must be enrolled, participate and perform to an acceptable standard in **external proficiency testing programs** that cover all test methods performed where such programs are available [17].
- All NAT assay runs must include **positive and negative controls** that are subject to the whole test process, including the extraction [18].

Key Finding 1:	Under NPAAC standards, pathology laboratories **must** have appropriate QA and QC processes in place that are performed and reviewed regularly. The use of external providers is not mandated in the standards.

NPAAC also has a standard specific for HIV and HCV testing; *Requirements for testing Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV): Third Edition (2013)*, however there are no additional or specialised quality measures specified for HIV or HCV in this standard [19].

Of note, the HIV and HCV specific standard does state that "laboratories conducting reference testing should include Nucleic Acid Testing (NAT) as part of their testing for corroboration of difficult diagnostic assessments". This type of testing is funded by the Australian Government for the ARCBS and participating laboratories.

Key Finding 2:	There are no specific QA or QC requirements for HIV or HCV testing under NPAAC standards (general QA and QC standards apply).
Key Finding 3:	The NPAAC standards state that laboratories providing reference testing should use NAT for corroboration of difficult diagnostic assessments for HIV and HCV.

3.3 REGULATIONS SPECIFIC TO ARCBS SCREENING OF BLOOD DONATIONS

The ARCBS is contracted by the NBA on behalf of all Australian governments to supply fresh blood and blood components from Australian donations. Screening of blood donations for specific pathogens is a critical part of maintaining the quality of the Australian blood supply and the funded services utilised by the ARCBS are an important component of the screening process, see Figure 2.1. In addition to general laboratory requirements and those specific to the use of IVDs, the ARCBS is required to adhere to all national and state/territory accreditation and regulations regarding the manufacture, QA and QC of blood and blood components [20]. This includes adherence to the Australian Code of Good Manufacturing Practice, and the *Therapeutic Goods Order (TGO) No. 88*.

3.3.1 Australian Code of Good Manufacturing Practice

The TGA regulates good manufacturing process (GMP) through a series of codes that need to be adhered to by Australian manufacturers. This includes the *Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products* (the Code) [21]. [

The ARCBS undertakes collection, processing, screening, storage and release for supply of blood and blood components. Therefore, the ARCBS must adhere to the Code [21]. The funded services support the ARCBS capability to meet some requirements of the Code. For example, under the requirements of the Code, the ARCBS:

- should participate in a formal system of proficiency testing such as an external quality assurance program (refer to the Code item 909), and
- should perform tests using qualified equipment and methodology that has been appropriately validated (refer to the Code item 907) [21].

Key Finding 4:	Under the Code, it is preferred but **not mandated** that ARCBS laboratories participate in external QA programs and use testing equipment and methodologies that are validated.

3.3.2 Therapeutic Goods Order No. 88

The ARCBS must adhere to the *TGO No. 88: Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products* [22] [23]. Under the Order, blood samples from all potential donors (blood, blood component, organ or tissue) must use serology to test for HIV, HCV, HBV, HTLV and syphilis. In addition, the Order states that donor material must be tested for HIV, HCV and HBV by serology and NAT [23]. Further detail on TGO No. 88 screening requirements are provided in Appendix C. It should be noted that TGO No. 88 applies to the ARCBS but not routinely to other laboratories. Therefore, this is additional to ARCBS and relates specifically to donor screening, as the use of donated blood, organs and tissues presents a higher risk to public health.

No further QA or QC requirements, other than abiding by the IVD regulatory framework are listed in the Order.

Key Finding 5:	Under TGO No. 88, ARCBS **must** screen blood samples for HIV, HCV and HBV by serology and NAT; and HTLV and syphilis by serology. The funded services do not include QC and QA for syphilis or QC for HTLV.

3.4 SPECIFICITY MONITORING

Specificity monitoring assesses rates of false reactivity (i.e. false positives), to ensure the false positive rate is maintained in an agreed and accepted range.

The TGA has issued Clinical performance requirements and risk mitigation strategies for HIV tests [24]. This document, published in 2015, provides manufacturers and sponsors with guidance on TGA's expectations in regard to clinical performance requirements (i.e. clinical sensitivity and specificity) and risk mitigation for IVD intended to be used to screen or diagnose HIV infection.

This guidance applies to Class 4 HIV serology tests that are intended to be used: in the laboratory for diagnostic and/or donor screening or reference testing

Key Finding 6:	Under the revised regulatory framework for IVDs, specificity monitoring is required to be undertaken prior to inclusion on the ARTG of the Class 4 IVD. There are **no requirements** for the ARCBS to undertake specific monitoring for BBV tests on blood donations.

4 CURRENT FUNDING ARRANGEMENTS

This chapter presents the current funding environment relevant to the funded services.

There is a mixture of funding mechanisms for pathology relating to the testing of BBVs in Australia. Current funding mechanisms were appraised throughout this review and used to inform potential future options. In summary:

- the Australian Government funds HIV and HCV QC, QA and monitoring activities for participating laboratories and HIV, HBV and HCV QC, QA and monitoring activities for the ARCBS
- the Australian Government funds reference testing for HIV and HTLV samples that require adjudication as to their status for participating laboratories and the ARCBS
- the Australian Government funds specificity monitoring of HIV and HCV serological assays performed by the ARCBS, and provision of plasma control panels for staff training or proficiency testing for the ARCBS
- diagnostic and monitoring testing is funded by the appropriate MBS rebate [24]
- donor blood screening is performed by the ARCBS and funded under the agreement between the ARCBS and the NBA, this includes QC and QA services for syphilis, malaria and QC for HTLV
- donor tissue and organ screening are funded by the States and Territories through hospital activity-based costing for organ/tissue procurement and transplantation procedures
- reference testing performed by jurisdictional reference laboratories is funded by individual arrangements with their jurisdictional government
- the Australian Government funds the NRL to provide reference testing to distinguish between HIV and HTLV viral types if this has not been resolved in previous tests
- direct patient payments fund some services such as specialised tests performed by private fertility clinics.

4.1 FUNDING FOR TESTS

Currently, diagnostic and clinical testing for HIV, HCV and HBV is subsidised by MBS claims (where appropriate) [24], [25]. Most pathology testing services are funded through this mechanism. A small proportion of screening (e.g. for fertility clinics) may be patient funded.

Through the service agreements with the NRL, the Australian Government funds HIV and HCV QC and QA services for participating laboratories and HIV, HBV and HCV QC and QA services and HTLV QA for the ARCBS. Other pathogens do not receive specific funding for QA and QC activities and laboratories must fund these activities from the combined revenue streams of the laboratory.

Confirmatory testing on reactive samples is funded through the MBS for HBV and HCV (same sample) or on a new sample for HIV testing [26], [27].

Testing that requires adjudication, such as distinction between HIV-1 and HIV-2 or HTLV-1 and HTLV-2, is only performed by the NRL via Australian Government funding. The distinction between the various forms of the viruses is important for: a) epidemiological monitoring of HIV and HTLV infection in Australia; and b) disease prognosis as HTLV-1 is associated with adult T-cell leukaemia or lymphoma

or associated myelopathy, while HTLV-2 infection is less clearly associated with diseases[a] [28].

Key Finding 7: There is a mix of funding arrangements in place for testing of the in-scope diseases. However, none have been identified for QA or QC services related to diagnostic/clinical testing of these diseases, with the exception of the QC and QA services within the funding arrangements under review

4.2 FUNDING FOR QC AND QA

The burden of cost of NATA accreditation required by pathology laboratories to be able to claim Medicare reimbursements is placed on the individual laboratories. Likewise, costs associated with maintaining accreditation, such as QA programs and QC material costs, are paid for by the laboratories. The Australian Government funding to deliver the in-scope QA and QC programs is an exception.

Key Finding 8: The costs associated with laboratory accreditation and regulatory requirements are typically borne by the individual laboratories. This includes, in general, all QA and QC programs, with the exception of the funding arrangements under review.

4.3 THE NATIONAL BLOOD AUTHORITY AND FUNDING TO ARCBS FOR SCREENING OF BLOOD DONATIONS

The NBA, on behalf of all Australian governments, manages national contracts to secure the supply of safe and affordable blood and blood components in Australia. The national blood arrangements were established in 2003 as a means to coordinate the blood supply at a national level. Australia's blood supply comprises domestically sourced donations for Australia's fresh blood component requirements and plasma derived products[b]. The NBA also manages the purchasing and supply arrangements of imported blood products [3].

Funding for the national blood arrangements is based on an annual national supply plan and budget, developed by the NBA and is jointly funded by all governments – the Australian Government provides 63% of funding and States and Territories collectively provide the remaining 37% [3].

The ARCBS is contracted under a nine-year Deed of Agreement from 1 July 2016, which includes a three-year funding and servicing agreement. The funding and service agreement includes an output-based funding model that derives a per unit price for blood components supplied by the ARCBS. The per unit price calculation includes the cost of the tests used to screen blood for the following diseases: HIV, HCV, HBV, HTLV and syphilis, and includes costs of QA/QC processes not covered under the Department's funding arrangements under review. It should be noted that the ARCBS purchases services funded through the NBA from NRL as well as other services providers.

4.3.1 Funding of Australian Red Cross Blood Service QA and QC activities

The per unit price calculations funded by NBA include costs for quality performance monitoring activities for syphilis, malaria and HBV (serology) and QA services for HTLV (NAT). However, equivalent services for HIV, HCV, and HBV (NAT) and QA for HTLV (serology) (as required for accreditation and regulatory purposes) are performed by NRL and funded by the Australian Government via the funding arrangement under review, see Table 4.1.

[a] However, emerging studies suggest HTLV-2 infection may be associated with neurologic problems including tropical spastic paraparesis (HAM/TSP), but at lower rates than HTLV-1 infection.

[b] While this is applicable to most products, there are some products (e.g. glues) that are not funded under the NBA arrangements

Table 4.1: QA/QC funding arrangements for diseases screened by the ARCBS

QA/QC funding arrangement	QA services	QC services
Australian Government via NRL services	HIV HCV HBV (NAT) HTLV (serology)	HIV HCV HBV (NAT)
NBA funding arrangements	HBV (serology) HTLV (NAT) Syphilis Malaria	HBV (serology) HTLV Syphilis Malaria

The current funding arrangements under review is a continuation of prior Australian Government funding that started in 2000. This predates the establishment of the national blood arrangements in 2003. The maintained separation of funding mechanisms is likely due to historical reasons, i.e. when the national blood arrangements were established, they only included funding for the services that were not already covered under the funding arrangements with the NRL.

Although not required for the quality and safety of the blood supply, blood donations that are reactive undergo confirmatory testing in in order to advise the donor to seek further clinical follow up. All donations that test positive or indeterminate on the primary test are withdrawn from the blood pool. Currently the confirmatory testing performed on reactive samples for HIV, HCV and HBV from the ARCBS are funded by the Australian Government and provided by NRL.

Key Finding 9: The majority of services provided by the ARCBS are funded through arrangements with the NBA, using a per unit price that allows for cost recovery. Services provided to ARCBS by NRL are not included in the per unit price funded by the NBA.

4.4 SCREENING OF ORGANS AND TISSUES FOR TRANSPLANTATION

Organ and tissue donation / transplantation is funded by the states and territory governments at the appropriate rates set by the Independent Hospital Pricing Authority[c].

The transplantation of donated organs and tissues pose similar risks to recipients as does the transfusion of blood and blood components. Tissue donations are required to be screened for the same BBVs as blood donations are. Organs are exempt from TGO88. Organs are only required to be tested by serology for HIV-1 antibody, HIV-2 antibody, hepatitis B surface antibody and surface antigen, hepatitis B core antibody, hepatitis C antibody.

There is no specified funding source from the Australian Government, or state/territory governments, for the relevant QA and QC services associated with the necessary screening tests for organs and tissues.

Key Finding 10: Despite similar BBV testing requirements for blood, organs and tissue donors, there is no specific Australian Government funding source for the QA and QC procedures associated with BBV testing for organs and tissues.

[c] *Note, certain low volume, high cost transplantation procedures are funded by all States and Territories under the Nationally Funded Centres Program, established in 1990.*

5 ASSESSING THE MARKET FOR THE FUNDED SERVICES

When considering funding options going forward it is important to understand the current market – users and providers – for funded services. A survey of all laboratories utilising the funded services (identified using NRL service provision data) was conducted. The survey sought to create a clear picture of service use, including key factors influencing uptake, as well as to identify other service providers in the market.

The survey was sent to all 79 pathology laboratories utilising the funded services. Follow up contact was made to laboratories that had not responded by the initial end date. In total, 30 (38%) laboratories responded and the survey results are presented in this chapter. Issues outlined in this section should be treated with caution due to the low response rate of laboratories. Difficulties with individual laboratory inventory/accounting systems, along with the need for multiple departments to complete the survey may have contributed to the low response rate. More details on the survey methodology can be found at Appendix D.

This chapter was also informed through consultations with key stakeholders, including the ARCBS. Further detail on the consultation questions is included in Appendix E.

5.1 SUMMARY OF FUNDED SERVICES

As specified in the schedule of services, the Department of Health provides funding to the NRL to provide specified QC and QA programs to participating laboratories and the ARCBS laboratories.

The review found that in addition to NRL, there were two other service providers in Australia that offered comparable QC services, SeraCare and Thermo Fisher.

SeraCare is used by the ARCBS as a back-up for NRL products and in the ARCBS New South Wales laboratory where confirmatory testing requires an independent test type to be used.

At the time of the review, NRL contracted Thermo Fisher to supply QC materials but was in the process of transitioning to a new supplier, Diamex. Thermo Fisher QC material is now available directly to laboratories in Australia.

NRL is now supplied by Diamex, who only distribute through NRL in Australia.

In addition, BioRad HBV controls were used by reference laboratories (NRL and PathWest) and the ARCBS for reference testing. No other laboratories indicated use of BioRad products and the scope of BioRad to provide other QC products was not explored in the review process.

The review found that, in addition to NRL, there was one other service provider in Australia that offers comparable QA services, the RCPA. RCPA is used by many laboratories for QA products, often in addition to NRL QA products. The necessity for multiple QA providers was not explored in the review.

In addition, one laboratory used a United Kingdom (UK) based company, Randox RIQAS, for QA of HIV, HCV and HBV serology testing processes. This laboratory was a fertility clinic in Western Australia. The capacity of Randox RIQAS to supply within Australia more broadly or the breadth of Randox services was not explored in the review process.

However, it should be noted that the true extent of the market capacity may not be realised unless an open tender process is initiated released and the market responds.

5.2 QUALITY CONTROL PROGRAMS

5.2.1 Participating laboratories

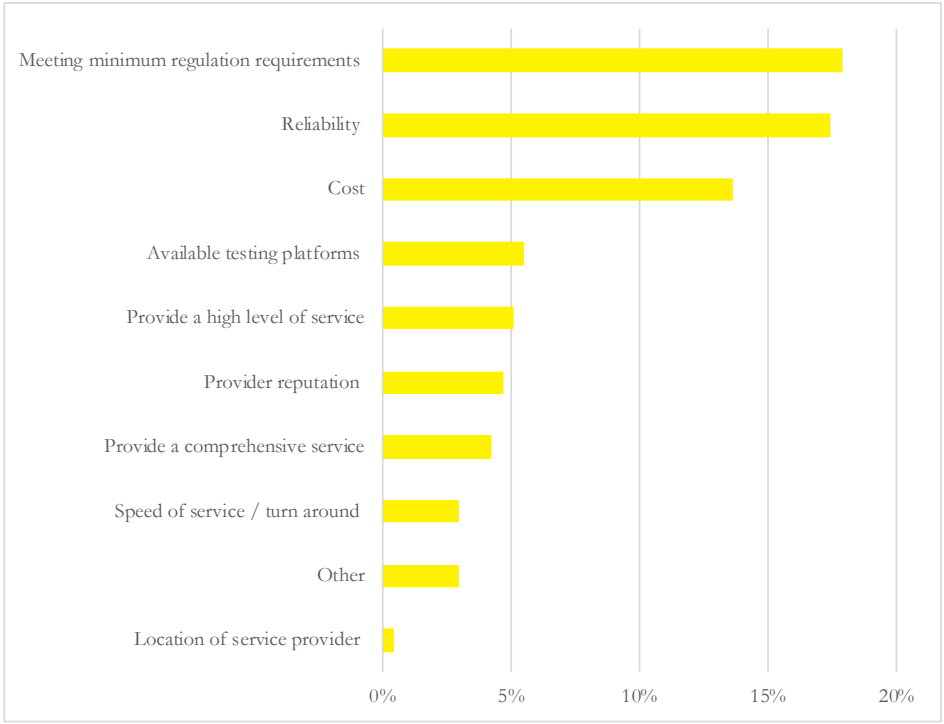
Based on survey responses from 30 laboratories using NRL products (38% response rate), the majority of laboratories used NRL serology multi-marker controls, at a median cost of $275 per kit (n=28, 93%), and NRL serology HIV p24 antigen control, at a median cost of $370 per kit (n=21, 70%). Conversely, fewer laboratories used NRL serology hepatitis controls, at a cost of between $675 and $1,000 per kit (n=6, 20%). One third of the responding laboratories (10 laboratories, 33%) used NRL NAT controls for HIV, HCV and HBV. HIV and HCV are provided free of charge to laboratories, while HBV is at a cost of $350 per kit. See Table 5.1.

The majority of responding laboratories provided rankings on what *factors most influence their choice of service provider for QC programs* (n=27, 90%).

Reponses were assigned ranking points to determine the overall importance of influencing factors. Laboratories were assigned a total of 235 ranking points to factors influencing their choice of QC provider. As shown in Figure 5.1, the analysis showed that the top three factors influencing choice of QC service provider were:

(1) meeting minimum regulation requirements
(2) reliability, and
(3) cost.

Figure 5.1: Important factors in choice of QC provider for participating laboratories (ranking points method, percentage of total points)



Participating laboratory QC summary

- The estimated cost to the Department for participating laboratory QC programs is approximately $1.1 million per annum.
- The main factors influencing pathology laboratory choice of QC provider were meeting regulatory requirements, reliability and cost.

Table 5.1: Summary of QC products used by participating laboratories (does not include ARCBS)

QC sample	No. of laboratories (%)	Median price per kit*	Other providers used	Comment
NRL Serology Multi-marker – Anti-HIV-1 IgG – Anti-HCV IgG – Anti-HBc IgG – Anti-HTLV-1 IgG – Anti-Treponema IgG – HBsAg	28 (93%)	$275	Thermo Fisher	NRL transitioned from Thermo Fisher as a supplier for QC products, to Diamex in 2018. Thermo Fisher now supplies product directly. Several laboratories stated they would move to the new NRL products when available.
NRL hepatitis serology • HEPA – HBeAg – Anti-HBc IgM – Anti-HAV IgM – Anti-HEV IgM • HEPR – Anti-HBs IgG – Anti-HBe IgG – Anti-HBc IgG – Anti-HAV IgG – Anti-HEV IgG	6 (20%)	HEPA $1,000 HEPR $695	BioRad – HBV only	BioRad HBV controls were listed by two laboratories (NRL and PathWest). Costs range from $330 to $600.
NRL NAT	12 (40%)			
– HIV NAT	10 (33%)	Free of charge		
– HCV NAT	10 (33%)	Free of charge		
– HBV NAT	10 (33%)	$350		
– Tri screen NAT: HIV RNA, HCV RNA, HBV DNA	2 (7%)	$750		
– Negative NAT	1 (3%)	Unsure		

Note 1: Siemens, Roche and Abbott were listed as internal (manufacturer supplied) controls for HIV, HCV and HBV. These are not considered external QC for the purposes of accreditation. Laboratories using these controls also use relevant NRL products.
Note 2: Not all laboratories provided amounts for cost per kit. Where information was available, it has been extrapolated. Amounts may vary due to: under/over reporting and the use of different products in a multi-marker kit
Note 3: Free of charge refers to the price laboratories pay. These services are funded by the Australian Government through the funding arrangements under review.

5.2.2 Australian Red Cross Blood Service

The four ARCBS laboratories – Victoria, New South Wales, Queensland and Western Australia – were assessed as in-scope for the survey. One collective response for all four laboratories was completed by the key ARCBS contact provided by the Department of Health. Follow-up consultations occurred to expand on issues raised in the survey, and to clarify responses.

All four ARCBS laboratories used the following NRL QC products:

- serology multi-marker controls, at a cost of $275 per kit.
- serology HIV p24 antigen control, at a cost of $370 per kit.
- NAT controls for HIV, HCV and HBV provided free of charge.

Other products used by the ARCBS laboratories for contingency only were SeraCare HIV p24 and multi-marker controls. The ARCBS New South Wales laboratory performs additional testing compared with the other three ARCBS laboratories, and uses a selection of products from SeraCare and BioRad.

The top three factors influencing the ARCBS choice of QC service provider were:

(1) meeting minimum regulation requirements
(2) available testing platforms, and
(3) a comprehensive service (i.e. all products from one provider).

ARCBS QC Summary

- ARCBS use one other provider (SeraCare) of QC materials for HIV and HCV as a contingency, or for IVDs used in the New South Wales laboratory for confirmatory testing.
- The ability of other providers to provide specificity monitoring was not established. The estimated cost to the Department for ARCBS specificity monitoring is $150,000 per annum. This includes ongoing monitoring of the specificity of HIV and HCV serology assays for the ARCBS and monthly reports.
- The estimated cost to the Department for ARCBS QC programs is $3.5 million per annum.
- Factors influencing the ARCBS choice of QC provider were meeting regulatory requirements, testing platforms available and providing a comprehensive service.

5.2.3 Other QC providers

A general online search, review of NATA accreditation data, and survey of participating laboratories provided information on alternative QC service providers. Three companies offer QC products for HIV, HCV and HBV. These companies are SeraCare, BioRad, and Thermo Fisher.

Other service providers listed by participating laboratories included serology multi-marker and HIV QC by Thermo Fisher, and HBV QC by BioRad, see Table 5.1.

Other products used by the ARCBS laboratories for contingency only were SeraCare HIV p24 and multi-marker controls. The ARCBS New South Wales laboratory performs additional testing compared with the other three ARCBS laboratories, and uses a selection of products from SeraCare and BioRad.

Key Finding 11: Participating laboratories paid a fee for QC services, above what was subsidised by the Australian Government. This is due to the multi-marker assays containing several diseases not funded by the government, necessitating an additional payment from laboratories. This funding arrangement is ambiguous for laboratories and funders alike.

Although there are multiple companies providing QC programs, there will be some differences between providers, e.g. in the type of control provided and the level of service offered. For example, whether the QC products are generic or optimised for specific equipment, whether the provider has an online tool for recording QC results, whether there is a mechanism to compare between laboratories, whether the provider offers troubleshooting support for laboratories where results are sub-optimal.

The level of service provided will need to be transparent in any future funding arrangements or unit costs for equitable comparison across companies.

5.2.4 Comparison of QC costs

It is difficult to directly compare the cost of NRL QC products to other service providers for several reasons, including:

- the value of NRL QC product unit costs as per Schedule 2 or Schedule 3 of the funding agreement do not account for administrative or other semi-fixed costs (e.g. salaries) that are budgeted for under Schedule 1
- QC products are not always comparable and
- additional services such as specificity monitoring are unlikely to be included in the costs of QC products from other service providers (although the extent to which this does or does not occur was not explored in the survey process).

An estimated unit cost of NRL products that include the Schedule 1 components was prepared by allocating a proportion of Schedule 1 costs to the NRL product and service usage of Schedule 2 and 3 items, relative to the estimated value of each item (i.e. items with a higher estimated cost received a higher proportion of Schedule 1 funding distribution).

Based on the calculated costs (see Appendix F, Table 9.1), HMA estimated that total unit cost for NRL QC products range from $45 to $60 per unit.

However, specificity monitoring reports prepared monthly for the ARCBS have an estimated total unit cost of $13,000 per report. HMA is not aware of a comparative service for this item. Therefore, the appropriateness of the estimated total unit cost cannot be assessed.

It should be noted that the above unit cost estimates are based on HMA's assessment of costs, not an average of what laboratories pay now for the services. It is difficult to compare the unit costs estimated in this manner, and more investigation is required by the Department to determine if NRL-provided QC services represent good value for money.

Key Finding 12: Cost structures make it difficult to compare service costs with other providers.

Key Finding 13: A comparison of ARCBS specificity monitoring reports was not possible as no comparable/alternative programs were reported.

5.2.5 QA use by participating laboratories

Based on survey responses from 30 laboratories using NRL products (38% response rate), a summary of the QA products used by responding laboratories is provided in Table 5.2.

The majority of laboratories used NRL HIV serology EQAS, which is provided free-of-charge to participating laboratories (n=27, 90%) and half the responding laboratories used NRL HCV serology EQAS (n=15, 50%), provided to the laboratories free of charge. Approximately one third of responding laboratories used a hepatitis serology (hepatitis A virus (HAV), HBV or HCV) program at a cost of $560 per year (n=9, 30%) or HTLV serology EQAS (n=9, 30%), provided free of charge, see Table 5.2.

Viral load EQAS for HIV and HCV were used by approximately one third of survey respondents (HIV: n=10, 33%; HCV: n=9, 30%). HBV viral load EQAS was used by almost one quarter of responding laboratories (7 laboratories, 23%) at a cost of $975 per year. See Table 5.2.

The majority of responding laboratories provided rankings on what *factors most influence their choice of service provider for QA programs* (n=26, 87%). Using the ranking points methodology, laboratories assigned a total of 168 ranking points to factors influencing their choice of QA service provider. As shown in Figure 5.2, the analysis revealed that the top three factors influencing choice of QA service provider were:

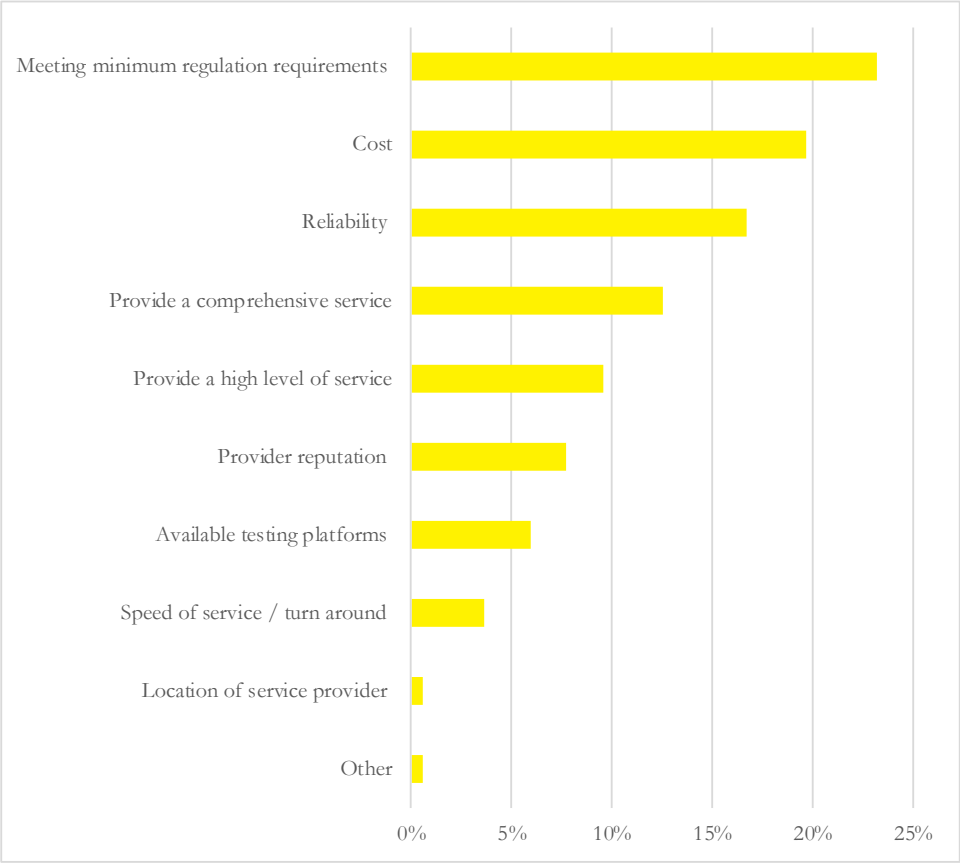
(1) meeting minimum regulation requirements
(2) cost, and
(3) reliability.

Participating laboratory QA summary

- RCPA also provide QA services for HIV, HCV and HTLV, and viral load QA services for HIV and HCV in the Australian market.

- The estimated cost to the Department for participating laboratory QA programs is approximately $370,000 per annum.
- Factors influencing the pathology laboratory choice of QA provider were meeting regulatory requirements, cost and reliability. Many laboratories indicated they used both NRL and RCPA QA products.

Figure 5.2: Important factors in choice of QA provider, ranking points method, (surveyed laboratories, percentage of total points)



5.2.6 QA use by Australian Red Cross Blood Service

All four ARCBS laboratories used NRL multi-marker EQAS (serology at a cost to the ARCBS of $560 per year (hepatitis) and $1,000 per year (blood screening), NAT (free of charge to the ARCBS) and HTLV EQAS (free of charge to the ARCBS)). All four ARCBS laboratories also used the RCPA antenatal EQAS program for syphilis and rubella serology at a cost of $473 per year.

The top three factors influencing the ARCBS choice of QA service provider were:

(1) meeting minimum regulation requirements
(2) available testing platforms, and
(3) a comprehensive service (i.e. all products from one provider).

ARCBS QA summary

- The ARCBS only use NRL QA services for HIV, HCV and HTLV serology, and for HIV, HCV and HBV NAT.
- The estimated cost to the Department for ARCBS QA programs is approximately $45,500 per annum.
- Factors influencing the ARCBS choice of QA service provider were meeting regulatory requirements, testing platforms available and providing a comprehensive service.

Table 5.2: Summary of NRL QA use by participating laboratories

NRL EQAS service	No. of laboratories (%) (total n=30)	Price per kit	Other providers used	Comments
NRL Multi-marker	**12 (40%)**		Randox RIQAS multi-marker HIV/Hep serology: – Anti-HIV-1, Anti-HCV, Anti-HTLV-II, HBsAg, Anti-HIV-2, Anti-HBc, Anti-HTLV-1&2 (combined), Anti-HIV-1&2 (combined), Anti-HTLV-I, Anti-CMV	Randox is a UK company. The RIQAS for 1x4 surveys per year. $933 per year (EQAS). One laboratory used Randox RIQAS for HIV, HCV and HBV serology. This laboratory (Pivet IVF Laboratory in Western Australia) used NRL EQAS for HCV only (free of charge).
– Multi-marker blood screening serology	1 (3%)	$2,250* (or $750 per survey)		
– Multi-marker blood screening NAT	2 (7%)	$2,400 (or $800 per survey)		
– Hepatitis serology – Hepatitis A, B and/or C option	9 (30%)	$560 (or $187 per survey)		
NRL HIV	**27 (90%)**			
– Serology	27 (90%)	Free of charge	RCPA – 7 labs (most labs also use NRL for this service)^	$650 per survey, 2 samples x 6 surveys per year
– Viral load	10 (33%)	Free of charge	RCPA quantification – 1 lab (lab also uses NRL for this service)	$800 per survey, 6 samples x 2 surveys per year
– HIV-1 genotypic drug resistance	3 (10%)	$1,800 (or $600 per survey)		
NRL HCV	**18 (60%)**			
– Hepatitis serology – Hepatitis C only	15 (50%)	Free of charge	RCPA – 16 labs (labs also use NRL for this service)	$650 per survey, 2 samples x 6 surveys per year
– HCV RNA viral load	9 (30%)	Free of charge	RCPA – 3 labs (labs also use NRL for this service)	$800 per survey, 6 samples x 2 surveys per year
– HCV RNA qualitative	6 (20%)	Free of charge		
– HCV genotyping	4 (13%)	$975 (or $325 per survey)	RCPA – 1 lab (does not use NRL for this service)	$800 per survey, 6 samples x 2 surveys per year

NRL EQAS service	No. of laboratories (%) (total n=30)	Price per kit	Other providers used	Comments
NRL HBV – HBV DNA viral load	7 (23%)	$975 (or $325 per survey)	QCMD for HBV genotyping (not offered by NRL) RCPA serology for HBV – 19 labs RCPA NAT for HBV – 3 labs (2 labs also use NRL services)	QCMD is a UK based company. RCPA $650 per survey (serology), 2 samples per survey, 6 surveys per year or $800 per survey (NAT), 6 samples x 2 survey per year EQAS for HBV serology and general NAT or genotyping is not offered by NRL
NRL HTLV – HTLV serology	9 (30%)	Free of charge	RCPA serology – 5 labs (3 labs also use NRL services)	$325 per survey per year, 2 samples per survey x 6 surveys per year.

Note, not all laboratories provided amounts for cost per kit. Where information was available, it has been extrapolated.
**based on NRL EQAS order form*
^Reasons laboratories would use two QA programs from difference suppliers was not explored in the survey process.
Note 3: Free of charge refers to the price laboratories pay. These services are funded by the Australian Government through the funding arrangements under review.

5.2.7 Other QA providers

A summary of NRL QA services is provided in Table 5.2. There is one other QA service provider in Australia, RCPA. Based on survey responses, many participating laboratories used RCPA QA programs for hepatitis serology, including HCV, HBV and HAV. A few participating laboratories also used RCPA QA programs for HIV or HTLV serology, and for HIV, HCV and HBV NAT. See Table 5.2.

RCPA QA programs cost $650 per survey for serology programs and $800 per survey for NAT programs. RCPA serology EQAS include two samples per survey, six surveys per year. RCPA NAT EQAS include six samples per survey, two surveys per year. See Table 5.2.

Two other UK-based companies were listed by survey respondents as providing QA services:

- **Randox RIQAS** – One laboratory used HIV/Hepatitis serology multi-maker EQAS at a cost of $933 per year.
- **QCMD** – One laboratory used HBV genotyping EQAS, a service not offered by NRL. The cost was not specified.

5.2.8 Comparability of available QA services

It is difficult to compare services between providers based on the available information. There are differences between the frequency of EQAS surveys, both in number of samples sent and number of surveys per year. There may also be differences in other factors such as the level of reporting back to laboratories and the similarity of QA samples to blood samples. For example, whole plasma samples

can be used to mimic testing of blood samples as closely as possible, or samples can be diluted to known dilution factors.

RCPA QA products use predominately serum and plasma. Information on dilution factors (if any) and sample preparation are not specified and therefore cannot be directly compared to NRL QA products (known to be whole plasma). Available RCPA EQAS programs are as follows:

- hepatitis and HTLV serology EQAS programs use serum/plasma
- HIV serology EQAS use serum/plasma/inactivated viral culture lysate
- NAT for HIV, HCV and HBV EQAS use plasma [29].

Key Finding 14: Direct comparability of QA products from NRL and RCPA is not possible. A more detailed comparison of services offered by different organisations should be a key part of any future funding considerations and related tenders.

5.2.9 Comparison of QA costs

It is difficult to directly compare the cost of NRL QA products to other service providers for several reasons, including:

- the value of NRL QA product unit costs as per Schedule 2 or Schedule 3 of the funding agreement do not include administrative costs (e.g. salaries) budgeted for under Schedule 1. It is unconfirmed but assumed that administrative fees are included in the reported total unit costs from alternative providers.
- QA products have different compositions and are not directly comparable, and
- other service providers may have additional costs or fees not associated with the unit cost of QA services, e.g. membership fees, that may subsidise EQAS program fees (this was not explored in the survey or consultation process).

An estimated unit cost of NRL products that include the Schedule 1 components was prepared by allocating a proportion of Schedule 1 costs to the NRL product and service usage of Schedule 2 and 3 items, relative to the estimated value of each item (i.e. items with a higher estimated cost received a higher proportion of Schedule 1 funding distribution).

Based on the calculated costs (see Appendix F, Table 9.2), HMA estimated that total unit cost for NRL EQAS programs is as follows:

- serology EQAS is approximately $600 per survey
- viral load EQAS is approximately $700 per survey, and
- NAT blood screening EQAS is approximately $2,700 per survey.

The estimates for NRL EQAS program unit costs for serology and viral load are comparable to the RCPA EQAS programs at $600 per survey for serology. NRL NAT blood screening EQAS program designed for the ARCBS is also comparable to the RCPA NAT EQAS when the three in-scope pathogens for which NAT is relevant (HIV, HCV and HBV) are considered (3*$800 = $2,400).

Key Finding 15: Direct comparability of QA service costs is difficult. However, HMA estimates of total unit costs for NRL EQAS programs show they are comparable to reported costs for RCPA EQAS programs.

6 CONFIRMATORY AND REFERENCE TESTING

6.1 SUMMARY OF SERVICES

As specified in the schedule of services, the Department of Health provides funding to the NRL to provide specified confirmatory testing for the ARCBS, and reference testing for indeterminate HIV and HTLV test results to the ARCBS and participating laboratories. The following sections provide a snapshot of market use of the funded NRL confirmatory and reference testing services, and other providers in the market.

SUMMARY OF CONFIRMATORY/REFERENCE TESTING

- The estimated cost to the Department for confirmatory testing was $26,000 per annum (including administrative costs from Schedule 1).
- The estimated cost to the Department for reference testing was $106,000 per annum (including administrative costs from Schedule 1).

6.2 CONFIRMATORY AND REFERENCE TESTING – USE OF SERVICES AND OTHER PROVIDERS

6.2.1 Participating laboratories

The NRL are not funded to provide confirmatory testing for participating laboratories. These laboratories perform the tests in-house, refer samples to a larger laboratory in their network, or to the state reference laboratory where available.

Reference testing for HIV adjudication was performed via NAT at two reference laboratories: VIDRL in Victoria, and SydPath at St Vincent's Hospital Darlinghurst.

NRL performs refence testing for HIV adjudication when testing elsewhere has not resolved the viral type. NRL use Western blot techniques for this analysis and is the only laboratory in Australia able to do this type of analysis.

Samples for serological confirmatory or reference testing for HTLV were sent to NRL by participating laboratories and the ARCBS. NRL indicated they performed serological confirmatory and reference testing for HTLV in-house (NAT testing was not applicable for HTLV). NRL was the only Australian laboratory to provide serological confirmatory or reference testing for HTLV.

It is estimated that through the funding arrangements under review, the Australian Government, paid a unit-cost of approximately $340 (including service costs from Schedule 2 and administrative costs from Schedule 1) for references testing of HIV for participating laboratories and of HTLV for participating laboratories and the ARCBS.

The top three factors influencing the participating laboratory choice of reference testing service provider were:

(1) Reliability
(2) Meeting minimum regulation requirements, and
(3) Speed of service/turn around.

Of note, no participating laboratories said that *cost* was the most important requirement.

6.2.2 Australian Red Cross Blood Service

Although not necessary under the regulatory requirements for testing of blood donations, the ARCBS laboratories typically perform confirmatory testing in-house by serology and NAT for HIV, HCV, HBV and by serology for HTLV. Syphilis does not undergo confirmatory testing. If external providers are required for confirmatory testing of samples with equivocal or indeterminate results, the ARCBS sends reactive samples to:

- South Eastern Area Laboratory Service (SEALS; located at Prince of Wales Hospital in New South Wales) for serology testing of HIV, HCV, HBV, and Syphilis, or
- NRL for NAT testing of HIV, HCV, HBV and serological testing of HTLV.

NRL confirmatory testing of HIV, HCV and HBV and reference testing of HTLV are provided to the ARCBS free of charge (under Schedule 3 of the current funding agreement). It is estimated that through the funding arrangements under review, the Australian Government, paid a unit-cost of approximately $180 (including service costs from Schedule 3 and administrative costs from Schedule 1) for confirmatory testing provided to the ARCBS. (Reference test unit costs for ARCBS are include in the reference testing for participating laboratories estimated in section 6.2.1).

The top three factors influencing the ARCBS choice of confirmatory and reference testing service provider were:

(1) Meeting minimum regulation requirements
(2) Available testing platforms, and
(3) Cost.

6.3 UNIT COSTS OF CONFIRMATORY AND REFERENCE TESTING

A summary of the estimated unit costs for in-scope confirmatory and reference testing services provided by NRL is provided in Appendix F, Table 9.3.

7 DISCUSSION: CURRENCY, EFFECTIVENESS AND APPROPRIATENESS

This section provides a discussion around the currency, effectiveness and appropriateness of current funding models, as identified in the objectives of the project. This analysis is used to inform the funding options identified in Chapter 8.

7.1 CURRENCY OF THE AUSTRALIAN GOVERNMENT FUNDING OF NRL SERVICES

7.1.1 Regulatory considerations

The primary consideration regarding currency of the funding of NRL services is whether the services and funding align with regulatory requirements and standards.

QA and QC are critical components of current TGA and NATA regulatory and accreditation requirements for laboratories using Class 4 IVDs to test for BBVs. This includes the ARCBS laboratories.

The TGA's new IVD framework, introduced in 2010, included substantial changes to the pre- and post-market regulatory role of the NRL in the ARTG listing process. The most significant of these changes, in relation to the current funding arrangement, is the removal of the requirement for laboratories using Class 4 IVDs to participate in NRL QA and QC programs. This regulatory change has not been reflected in the funding of NRL services that are no longer legislated or regulatory requirements.

The Department funds the regulatory costs incurred by NRL to include HIV and HCV QC material as an IVD on the ARTG. When NRL commenced in 1985 there was no other service provider in Australia to provide QC material for HIV and HCV testing. At the time of this review, there was at least one other company supplying the relevant QC materials in Australia, SeraCare. In addition, Thermo Fisher (previous supplier to NRL until 2018) may distribute directly in the Australian market as of 2019. Both SeraCare and Thermo Fisher are large multi-national companies and do not receive Australian Government funding to register their products on the ARTG.

The change in regulatory requirements for pathology testing, plus availability of alternative providers in Australia for the funded QA (RCPA) and QC (SeraCare and Thermo Fisher) services, highlights the need for a fair and competitive tender process (should the Australian Government funding of the services continue). These factors should be considered when assessing future funding options regarding QA and QC services.

Key Finding 16: The funded NRL QA/QC services allow laboratories to meet current regulatory and accreditation requirements but the NRL funding arrangements does not reflect regulatory changes introduced from 2010 to 2017 or current market availability of alternative service providers.

7.1.2 ARCBS funding arrangements

All Australian governments have a responsibility to protect the safety and quality of the Australian blood supply managed by the ARCBS. As such, safety and quality of the Australian blood supply is a core part of the national blood arrangements, managed by the NBA. When the ARCBS was established in 1996, NRL was the sole provider of QA/QC services for HIV and HCV to pathology laboratories across Australia. At this time, and when the NBA was established in 2003, it was a regulatory requirement for laboratories to use NRL QA/QC services for HIV and HCV testing.

The 2010 TGA regulatory changes removed the requirement for laboratories (including the ARCBS) to use NRL as a service provider. The scope of the national blood agreement between NBA and ARCBS has not been reviewed in light of these reforms. The services provided to ARCBS by NRL that are currently funded by the Department, align with the objectives of the national blood agreement to protect the Australian blood supply. Furthermore, QA and QC for other BBVs (e.g. HTLV and syphilis) are currently funded via the NBA funding arrangements.

Integration of services pertinent to the ARCBS into the national blood agreement is a sensible funding option. This would increase funding transparency and streamline administration, but would require a consistent costing mechanism, such as unit costs, to be applied to the in-scope services.

Key Finding 17: Services used by the ARCBS align with the objectives of the NBA. Funding the in-scope services under the NBA arrangements would increase transparency.

7.2 EFFECTIVENESS OF THE FUNDING IN MEETING FUNDER OBJECTIVES

The objective of the Government funding in scope of this review is to support the quality of the Australian blood supply. Accurate and reliable testing of blood donors for BBVs is essential to achieve this objective.

The consequences of testing providing a false negative result could potentially see multiple blood transfusion recipients becoming infected, with the risk of onward transmission.

TGA regulations, NPAAC standards, NATA accreditation requirements, and ARCBS blood screening protocols collectively reduce the risk of transmission of BBVs from blood donations. This includes the requirements for QA and QC processes. Therefore, funding in-scope QA and QC services used by the ARCBS to ensure confidence in the quality of donated blood effectively meets the objective to ensure the safety of the Australian blood supply. Confirmatory testing for samples that test positive, equivocal or indeterminate for HIV, HCV or HBV does not directly contribute to the quality of the blood supply (as any sample that tests positive is removed from the donation pool). Therefore, funding of these services for the ARCBS does not meet the funder objectives.

It is a requirement in Australia that pathology laboratories also have appropriate QA and QC processes in place for all tests performed, including tests for BBVs (see Chapter 3, sections 3.1 and 3.2 for further discussion). However, these processes do not directly contribute to the safety of the blood supply. While HIV and HCV QA/QC services are covered by funding arrangements under review, pathology laboratories meet the QC/QA requirements for out-of-scope pathogens (including other high-risk BBVs, such as HBV and HTLV) without government funding.

Future funding of services used by the participating laboratories should consider whether the services support other government objectives such as those outlined in the national BBV and sexually transmissible infections strategies.

Key Finding 18: Funded services, excluding reference and confirmatory testing, used by the ARCBS effectively meet the objective to ensure the safety and quality of the blood supply.

Key Finding 19: Funded QA and QC services used by participating laboratories for diagnostic testing and/or clinical monitoring do not directly contribute to ensuring the safety and quality of the Australian blood supply.

7.3 APPROPRIATENESS OF THE FUNDING MODEL

7.3.1 The Department as the funder

The Department has a role to:

> *'protect the health of the Australian community through effective national leadership and coordination and building of appropriate capacity and capability to detect, prevent and respond to threats to public health and safety.' [30]*

Funding of regulatory requirements for pathology laboratories is not a standard responsibility of the Department.

7.3.2 Market access and equity

The appropriateness of the current funding model should be considered in terms of equity of access and market competition. Since the TGA regulatory changes in 2010, there is no longer a regulatory requirement for laboratories using HIV and HCV IVDs to participate in the QA programs provided by the NRL.

There is a rationale for the Australian Government to more accurately assess the capability, capacity and costs of all potential service providers by going out to market through a tender process. This approach would strengthen market competition and possibly improve value for money for the funded services.

However, future funding options need to consider market capacity to ensure laboratories can meet ongoing regulatory and accreditation requirements.

Key Finding 20: Future funding models should promote fair market competition via a tender process.

8 FUNDING OPTIONS

This chapter has been redacted.

9 APPENDICES

APPENDIX A HISTORY OF SCREENING FOR BLOOD BORNE DISEASES IN AUSTRALIA

The first Red Cross blood transfusion service was established in Victoria in 1929. Separate state and territory Red Cross blood banks collected and managed blood donations for nearly 70 years until the formal establishment of the ARCBS in 1996. The following provides a brief history of screening for blood borne diseases in Australia.

In 1965, the HBV surface antigen was discovered and in 1971 the Red Cross commenced routine serological screening for HBV in blood donations [1].

In the early 1980s, there was an international HIV/Acquired Immune Deficiency Syndrome (AIDS) epidemic. The first reported case of HIV infection in Australia was in 1983, and the first HIV-related death in Australia was reported in 1984. In the same year, the first transfusion-related HIV infection was reported and the Red Cross introduced a uniform donor declaration form [1].

In 1985, HIV serological testing for all blood donations was introduced [1] and the NRL was established to evaluate HIV tests and adjudicate on the interpretation of HIV test results [2].

In 1989, the first National HIV/AIDS Strategy was produced by the Australian Government [1]. The strategy is updated every four years. The latest strategy (the Eighth National HIV Strategy 2018-22) was released in 2018 [30].In 1989 HCV was identified and by 1990 HCV screening commenced in all transfusion services [1].

In 1996, the ARCBS was established [1].

In 1999, the first National Hepatitis C Strategy and the first National Aboriginal and Torres Strait Islander BBV and STI Strategy were released (1999-2004). The latest strategies (Fifth National Hepatitis C Strategy 2018-2022 and Fifth National Aboriginal and Torres Strait Islander BBV and STI Strategy 2018-2022) were released in 2018.

In 1999, the first transfusion-related HIV infection since routine screening commenced in 1985 was reported in Melbourne, from a blood donation taken in the 'window period'.

In 2000, regulation of fresh blood commenced under the *Therapeutic Goods Act 1989* [1]. In this year, NAT was introduced to screen blood donations for HIV and HCV in addition to the serological testing routinely performed [1].

In 2003, the NBA was established [1].

In 2005, the First National STI Strategy was released. The latest strategy (Fourth National STI Strategy 2018-2022) was released in 2018.

In 2010 the first National Hepatitis B Strategy was released. The latest strategy (Third National Hepatitis B Strategy 2018-2022) was released in 2018.

In July 2010, a new regulatory framework was introduced for IVDs, with IVDs now regulated as a subset of medical devices under the Regulations. To allow time for compliance, the new regulatory framework was introduced through a staged transition process. The transition period for the IVD regulatory framework ended on 30 June 2017 [30].

These key milestones are depicted in Figure 9.1 and Figure 9.2 on the following pages.

Figure 9.1: BBV timelines 1980 to 2005

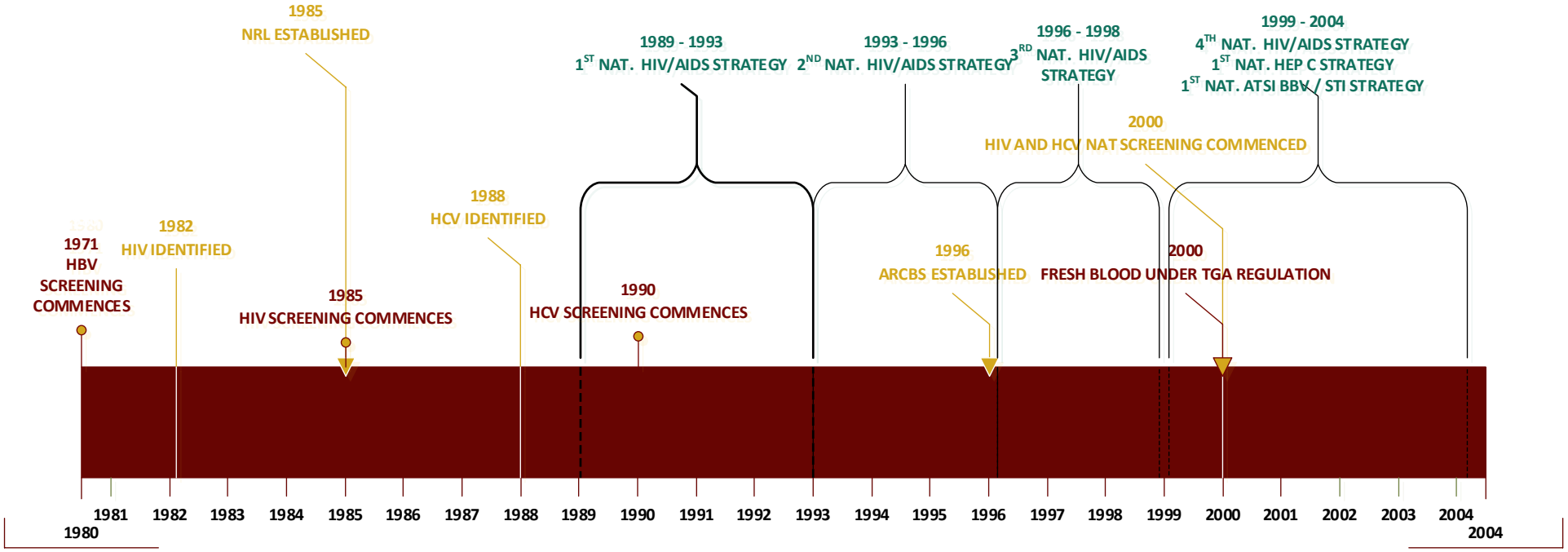
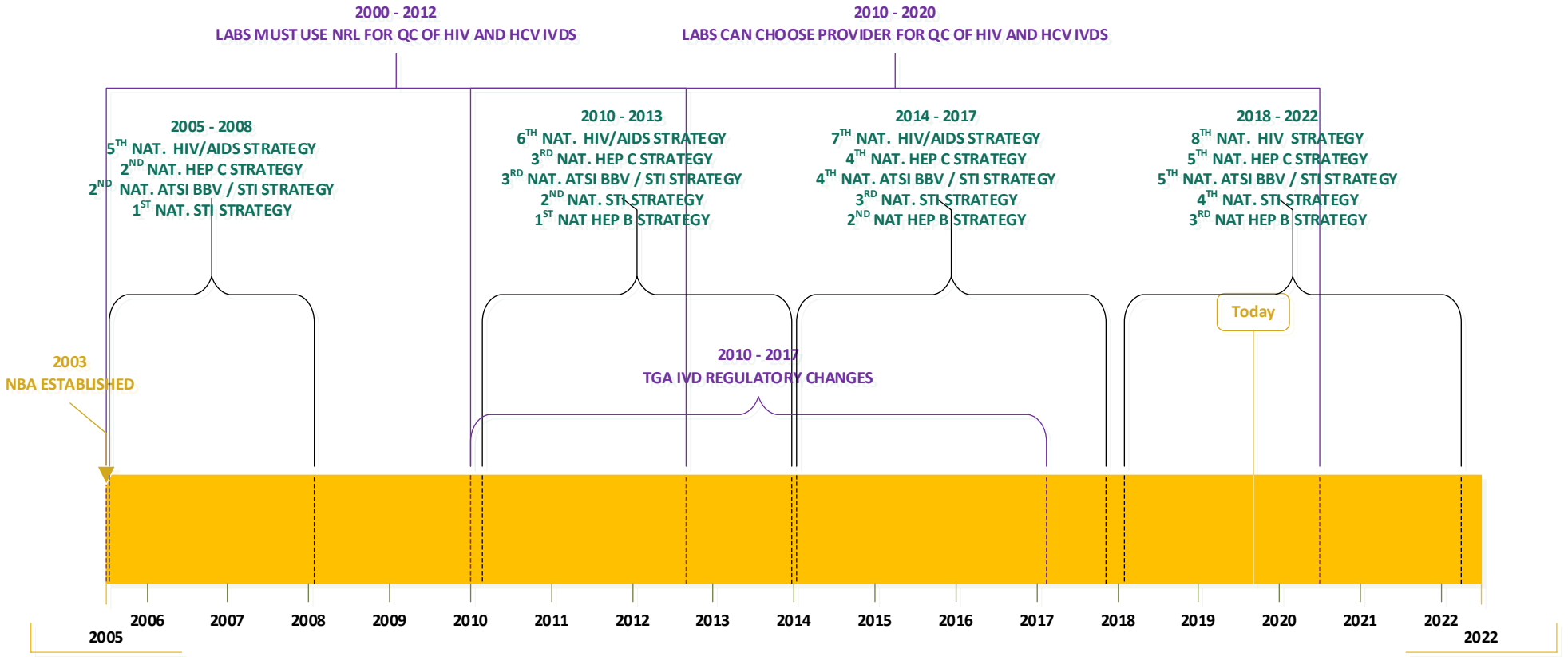


Figure 9.2: BBV timelines 2005 to 2022



APPENDIX B SUMMARY OF REVIEW METHODOLOGY

This review was conducted in and informed by three key stages: desktop review, consultation with key stakeholders, and survey of laboratories using the funded services.

The Desktop Review included:

- Review of the current funding model between the Department of Health and St Vincent's Medical Research Institute as NRL's host organisation
- A description and analysis of the regulatory framework for HIV, HCV and HBV testing in Australia, including national legislative requirements for IVD registration and use
- Review of relevant policies and publicly available information on laboratory accreditation and QA and QC requirements (in Australia and internationally)
- Review of minimum diagnostic requirements of diseases relevant to the in-scope services.

The Desktop Review was supported by consultations with NRL, TGA, NBA and the Organ and Tissue Authority (OTA).

APPENDIX C TGO NO. 88 TESTING REQUIREMENTS FOR BLOOD AND TISSUE DONATIONS

Donor group		Deceased donors	Cornea only donors	Living donors									
				Allogeneic use						Autologous use			
				Blood / components	Plasma for fractionation	HPC-A HPC-M	HPC-C	Domino donor	Other	Blood/ components	HPC-A HPC-M	HPC-C	Other
Testing requirement													
Serology test Initial sample	anti HIV-1 anti HIV-2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	anti HCV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	HBsAg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	HTLV-1/2 (antibodies)	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
	syphilis	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
AND													
NAT Initial sample	HIV	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	HCV	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	HBV	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
OR	**OR**			**OR**		**OR**	**OR**	**OR**	**OR**	**OR**	**OR**	**OR**	**OR**
Serology ≥180 day sample	anti HIV-1 anti HIV-2			✓		✓	✓	✓	✓	✓	✓	✓	✓
	anti HCV			✓		✓	✓	✓	✓	✓	✓	✓	✓
	HBsAg			✓		✓	✓	✓	✓	✓	✓	✓	✓

Source: TGO No. 88, Table 3, page 16. [34]

APPENDIX D SURVEY METHODOLOGY

In collaboration with the Steering Committee, HMA prepared a survey to be completed by laboratories using in-scope NRL services.

PARTICIPATING LABORATORIES

HMA was provided a list of 79 Australian laboratories that participate in one or more ins-scope NRL programs. The list was provided by the NRL and included key contacts at each laboratory. All 79 laboratories were asked to complete the survey. Surveys were sent to one contact only at each participating laboratory, and each laboratory was requested to circulate the survey to the appropriate personnel for completion. Follow-up phone calls were made to individuals at each laboratory to encourage survey completion and ensure there was no confusion around any of the questions.

A total of 30 survey responses were returned to HMA for analysis.

AUSTRALIAN RED CROSS BLOOD SERVICE

There are four ARCBS laboratories – Victoria, New South Wales, Queensland and Western Australia. One collective response for all four laboratories was completed by the key ARCBS contact provided by the Department of Health, as follows:

Sue Ismay
Scientific Director Manufacturing
Australian Red Cross Blood Service

APPENDIX E CONSULTATION QUESTIONS

ARCBS

OVERVIEW

(1) Can you please provide a brief outline of the ARCBS services and associated funding streams?
(2) Are HIV, HBV, HCV, HTLV, syphilis and malaria the only pathogens being screened for by the ARCBS in live blood donations?
(3) Does the ARCBS test for pathogen in tissue samples or cadaver specimens?
(4) Are Serology and NAT based testing performed on blood samples for all diseases screened for?

QUALITY CONTROL

(5) Are external QC kits available for all screening tests performed?
(6) In selected providers for QC tests – what are your considerations?
(7) Can you please comment on the use of additional tests in New South Wales compared to other states, i.e. does the New South Wales laboratory use different or additional equipment compared to the other states?
(8) Can you please comment on your reasons for selecting a provider other than NRL for HBV?
(9) With overseas providers – SeraCare and BioRad – are they purchased directly or via an Australian distributor?
(10) With QC products purchased for contingency purposes, are they order as required or are reagents kept in store?
(11) What is the funding mechanism for non-NRL services, or non-subsidised NRL services?

EQAS

(12) Can you please comment on the need for separate Hepatitis specific EQAS in addition to the multivariate EQAS which also includes HCV and HBV?
(13) What are the funding mechanisms for this product?
(14) Could you please confirm that HTLV serology EQAS is free of charge from NRL?
(15) In order to access RCPA services, is the ARCBS required to be an RCPA member? Does this incur membership fees? What is the funding mechanism that RCPA services are funded by?
(16) Regarding the use of RCPA antennal EQAS, is this the most convenient way to access syphilis EQAS, or is there another reason?
(17) What is the funding mechanism for the EQAS for HTLV (serology and NAT) and HBV serology?
(18) Can you briefly describe the need for both serology and NAT for screening for HIV, HIC, HBV and HTLV?

Confirmatory testing

(19) Can you please comment on when samples are sent to external laboratories for testing or not?
(20) Is the cost provided in the survey response the in-house cost or external provider cost?
(21) What is the funding mechanism for confirmatory tests provided in-house and externally?
(22) What is the rationale for not using NRL for confirmatory testing?

Reference testing

(23) What is the rationale for not using NRL for serology reference testing?
(24) Can you please confirm that HBV and HCV reference testing via NAT is free of charge from NRL?

Funding model

(25) Are there any foreseeable consequences of rolling NRL free of charge services into the existing unit cost prices for NBA?

ORGAN AND TISSUE AUTHORITY

Ms Rebecca Steele, Assistant Director,
Organ and Tissue Donation Policy and Programs Section
Healthcare Services Branch, Health Services Division
Australian Government Department of Health

(1) What are the general processes for testing tissues and organ donors for BBV and other infectious diseases?
(2) Who is responsible for testing the donated tissues/organs?
(3) Which laboratories typically perform the relevant testing?
(4) How is testing of donated tissues and organs funded? If through the OTA, what are the funding arrangements?

APPENDIX F ESTIMATED UNIT COSTS FOR NRL SERVICES UNDER REVIEW

Table 9.1: Estimated total unit cost of NRL QC products/services (including allocation of Schedule 1 funds) based on four months product/service usage, July to October 2016

Item [schedule no.]	Description as per schedule	NRL invoice terminology	No. of units per trimester	Amount per unit from Schedule 2 or 3 $, excluding GST	Amount per unit from Schedule 1 $, excluding GST	Total unit cost $, excluding GST
QC for HIV and HCV [2]	QC activities for participating laboratories	Serology QC material and HIV/HCV	5925	29.35	17.45	46.80
		Diagnostic PCR QC material	1740	35.27	20.96	56.23
QC Program [3]	QC activities for the ARCBS for HIV, HBV and HCV NAT	NAT blood screening QC material	16,110	31.08	27.31	58.39
Specificity Monitoring [2]	Ongoing monitoring of the specificity of HIV and HCV serology assays for the ARCBS using EDCNet. Includes provision of quarterly reports to the ARCBS	Specificity Monitoring report	4	7,856.72	4,669.94	12,526.66

Table 9.2: Estimated total unit cost of NRL QA products/services (including allocation of Schedule 1 funds) based on four months product/service usage, July to October 2016

Item [schedule no.]	Description as per schedule	NRL invoice terminology	No. of units per trimester	Amount per unit from Schedule 2 or 3 $, excluding GST	Amount per unit from Schedule 1 $, excluding GST	Total unit cost $, excluding GST
QA for HIV, HCV and HTLV [2]	EQAS activities for clinical laboratories	HIV, HCV and HTLV Serology EQAS	213	364.63	216.73	581.36
Monitoring [2]	Ongoing monitoring of QC and QA performance of laboratories using EDCNet	HIV and HCV Viral Load EQAS	62	434.09	258.02	692.11
QA Program [3]	EQAS activities for the ARCBS for HIV, HBV and HCV NAT	NAT blood screening EQAS material	4	1,448.29	1,272.65	2,720.94

Table 9.3: Estimated total unit cost of NRL confirmatory and reference testing services (including allocation of Schedule 1 funds) based on four months product/service usage, July to October 2016

Item [schedule no.]	Description as per schedule	NRL invoice terminology	No. of units per trimester	Amount per unit from Schedule 2 or 3 $, excluding GST	Amount per unit from Schedule 1 $, excluding GST	Total unit cost $, excluding GST
Confirmatory Testing [3]	For ARCBS activities that test positive, equivocal or indeterminate for HIV, HBV or HCV Serology and NAT	HIV, HCV, HBV NAT confirmatory testing	33	95.06	83.53	178.59
Reference Testing [2]	Provision of HIV and HTLV reference testing including the maintenance of expertise in in-house IVDs and ensuring necessary registration of these through the TGA	HIV and HTLV diagnostic specimens tested	105	212.78	126.47	339.25

APPENDIX G REFINEMENT OF FUNDING OPTIONS

PAYMENT BASE MODELS

Three broad types of payment bases for possible funding models were considered as a part of this review. These were:

(1) individualised (consumer directed)
(2) activity-based (output derived), and
(3) performance-based (outcome derived) funding models.

Activity-based funding models fund service providers for the cost of the inputs required to undertake specified activities. This is the model by which NRL services are currently funded. Conversely, performance-based funding models fund service providers when desired outcomes have been achieved, while individualised funding aims to tailor services based on the varying needs of individual consumers.

There are advantages and disadvantages of the funding options (see Table 9.4). Selecting the most appropriate model (or hybrid) will depend largely on the type of program to be funded.

Table 9.4: Advantages and disadvantages of funding model options

Funding model	Advantages	Disadvantages
Individualised Funding allocated based on the individual needs of the consumer	• Tailored funding options for individual need	• Assumes competitive market of service provision • Assumes consumers have varying needs
Performance-based Funding based on outcomes produced	• Flexible service arrangements to achieve desired outcomes • Drives efficiency	• Decreased transparency of services provided in order to produce outcomes • Performance indicators need to be developed in such a way that quality is not compromised • Efficient price needs to be set at a level that ensures viability for service providers
Activity-based Funding based on input costs of outputs produced	• Funds are designed to reflect costs incurred • Efficient prices can be used to drive efficiency	• Disconnect between activity provided and desired outcome • Increasing costs as activity volume increases • Limits flexibility of services

REFINEMENT OF HIGH-LEVEL OPTIONS

Based on consideration of the positives and negatives of each type of funding model, HMA considered an activity-based model to be the most appropriate for the services in-scope of this review. Both *individualised* and *performance-based* funding options were discounted for the following reasons:

(1) **Individualised.** Although the level of services required by pathology laboratories may vary among individual laboratories, all laboratories testing for HIV and HCV need to be able to access external QC and QA services in order to meet minimum regulatory requirements. Similarly, although volume may vary, the need for reference testing of intermediate HIV and HTLV results (i.e. distinguishing between HIV-1/HIV-2 and HTLV-1/HTLV-2) among these laboratories remains unchanged. Likewise, all four laboratories of the ARCBS have the same requirements for QC, QA, confirmation and reference testing to meet regulatory requirements and maintain best laboratory practices for these tests. Therefore, there was no need to consider the varying needs of individual

laboratories and this model was discounted. In addition, tailoring funding to each participating laboratory would be administratively onerous.

(2) **Performance-based.** Performance-based funding can ensure that outcomes are delivered as intended in a cost-effective manner and is an attractive option for governments. However, in this case, performance-based funding could also have negative impacts. Performance-based funding would:

(a) Shift responsibility from the service provider to the consumer (ARCBS and Australian Pathology Laboratories). This could lead to additional strain on laboratories, poor negotiations of inefficient funding agreements, and reduced transparency.

(b) Place unrealistic expectations on the service provider's ability to change or manage processes within the laboratories, many of which are private businesses.

This funding model has the potential to be viewed as a reward for successful outcomes and a punishment for sub-optimal results, which could reduce openness and transparency between laboratories. Linking funding to quality improvement activities has potential to undermine their intended objectives. Therefore, the performance-based funding model was discounted.

FUNDING TYPE

Within an activity-based funding model, three funding types were considered, as follows:

- Fixed costs (i.e. block funding)
- Unit costs (i.e. variable-cost funding)
- Hybrid (i.e. a mix of block and unit-cost funding).

The advantages and disadvantages of these funding types are presented in Table 9.5. Currently, the in-scope services are funded under a hybrid model, whereby NRL receives block funding for fixed costs under schedule 1 of the service agreement and unit-cost based payments for the variable costs under schedules 2 and 3 of the funding agreement.

Table 9.5: High-level comparison of funding types, advantages and disadvantages

Funding type	Advantages	Disadvantages
(1) Fixed costs (i.e. block funding)	• Provides service providers with a funding base to fund purchases of infrastructure and inventory • Potential for lower administration costs	• Very low transparency • Lack of variability based on different activity levels • Less agile than alternative funding models
(1) Unit costs (i.e. variable-costs funding)	• Very high transparency • Ability to account for changing activity levels • Low ongoing administration costs	• Large initial investment in establishing unit costs (for service provider) • Can lead to surplus of inventory if necessary to predict activity levels in advance
(2) Hybrid (i.e. mix of fixed- and unit-cost funding)	• Some transparency • Provides service providers with a funding base to fund purchases of infrastructure and inventory	• Complex system that is difficult for the Australian Government and laboratories to understand • Difficult to unpack costs to determine outputs/outcomes of invested funds

In HMA's assessment, a unit-cost model for the in-scope services is the most appropriate as it will allow for greater flexibility of service provider and funder. The fixed cost (block funding) and hybrid models have been discounted for the following reasons:

- limited transparency of fixed costs
- limited transferability of service provider or funder type, and
- difficulty disaggregating components of total QA and QC programs.

Practical considerations

Consultations with stakeholders have indicated that a unit cost-based funding type is the most practical option. Unit cost funding could give greater transparency than the current hybrid model, decreasing the administration costs to the Australian Government and allowing activities of the service provider to be accounted for in a simple funding mechanism.

Compared to block funding, unit costing does not allow for significant upfront purchase of equipment or inventory. As a practical consideration, funding could be delivered in a front-ended contract, where initial unit costs are weighted at a higher amount to allow for purchase of inventory and equipment. Alternatively, equipment rental agreements, with costs built into the total unit cost, could be arranged with manufacturers. However, the feasibility of this option is beyond the scope of this review.

Funder type

The in-scope services are provided to maintain a safe and secure blood supply in Australia *and to protect the Australian public from the spread of BBV and STI through safe blood and plasma supplies*. The activity-based funding elements that have been identified provide scope for Australian Government, laboratory and provider funding contributions.

Services as a public good

A public good or service is defined as one that is *non-excludable and non-rivalrous*. An individual or firm can consume the service without reducing its availability to another. Additionally, no individual or firm can be effectively excluded from its use. The provision of public goods can lead to examples of market failure, such as when private organisations are required to pay for services, leading to inefficiency in the market. [53]

Several peer reviewed articles identify the provision of a safe blood supply as a public service. [54] The authors argue that as a public service, it is the responsibility of government to manage supply of the good (and related services, such as QA and QC activities) to ensure cooperation of public and private organisations [45].

Regualtions are in place to ensure that laboratories testing for in the in-scope pathogens maintaing QA and QC procedures (see Chapter 3 for furhter detail).

Exploring cost recovery

Cost recovery through manufacturer contributions has been used by the Australian Government to fund prostheses listing arrangements. Charges are levied against prosthesis manufacturers for costs of administering the prostheses listing arrangements [46]. The program has been successful in recovering costs of Australian Government activities related to listing prostheses and has placed an incentive on ensuring provision of quality products from the manufacturers. The costs recovered from prostheses listing arrangements are substantial but largely from administrative activity. However, the in-scope services are not administrative and may not lend themselves to this model.

A cost-recovery model is more at risk of market failure and a potential reduction in equitable access to quality services. The advantages and disadvantages of public and private funder types are outlined in Table 9.6.

Table 9.6: High-level comparison of funder type, advantages and disadvantages

Funder type	Advantages	Disadvantages
(1) Public (government)	• No impacts on laboratories or service providers • No additional costs for government in modifying funding levels • Funding in-scope services as a public good the responsibility of the Australian Government	• Lack of incentive for service providers to decrease costs • Laboratories less likely to consider factors other than cost
(1) Private (e.g. cost-recovery through IVD manufacturers)	• Additional incentive (lower cost) for providers to enter the market • Increased focus on QA and QC quality for manufacturers • Align with cost-recovery format of other regulatory agencies (e.g. TGA)	• Laboratories may not be able to meet cost (gap payments) • Additional incentive for laboratories to increase costs of other services • Ambiguous responsibility (laboratories vs Australian Government) regarding in-scope services • Risk that the manufacturers will incorporate the additional cost into the price of equipment, which would transfer the financial burden to laboratories.

APPENDIX H EXTENT OF NRL QA COVERAGE

There are 74 Accredited Pathology Laboratories that are NATA accredited for virology or extended serology plus/minus extended NAT, for which it is reasonable to assume capability of testing for HIV and hepatitis. Over 90% of these laboratories use NRL external quality assessment schemes (EQAS) for HIV serology (n=70, 95%) or for hepatitis serology (n=67, 91%), see **Error! Reference source not found.**. Thirty-one of the laboratories using NRL products for HIV and hepatitis serology (approximately 45%) were private pathology laboratories, see **Error! Reference source not found.**.

It is not expected that all laboratories would perform NAT for clinical diagnostic or clinical viral load determination. Therefore, the proportion of NATA accredited laboratories using NRL EQAS for NAT is expected to be less. Analysis indicated that 24% of NATA accredited laboratories used NRL EQAS for HCV diagnostic NAT, 30% for HCV viral load NAT and 28% for HIV viral load NAT, see **Error! Reference source not found.**.

Table 9.7: NRL EQAS coverage among NATA accredited laboratories

EQAS type	No. laboratories participating			% of identified NATA accredited laboratories (n=74)
	Public	Private	Total	
HIV serology	39	31	70	95%
Hepatitis serology	36	31	67	91%
HCV NAT viral load	14	8	22	30%
HIV NAT viral load	15	6	21	28%
HCV NAT diagnostic	10	8	18	24%
HTLV	14	6	20	27%

Few laboratories perform testing for HTLV. Of the 74 identified NATA accredited laboratories, 27% use NRL EQAS for HTLV serology, see **Error! Reference source not found.**.

There are a further 35 pathology laboratories that have NATA accreditation for virology, which are part of a larger pathology network (public or private), and are likely to refer HIV and hepatitis testing samples to the relevant central laboratory. There are two other APLs with NATA accreditation for virology, but are known not to test for HIV or hepatitis (Forensic Science Service in Queensland and

Molecular Diagnostic Unit in Victoria). Therefore, theses laboratories were not considered in the above analysis.

In addition, there were nine pathology laboratories that used NRL EQAS for hepatitis serology and seven using NRL EQAS for HIV serology that did not appear to have relevant NATA accreditation for HIV or hepatitis testing (no virology accreditation or only limited serology/microbiology). Seven of these nine laboratories were fertility groups located in New South Wales, Queensland, and Western Australia.

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