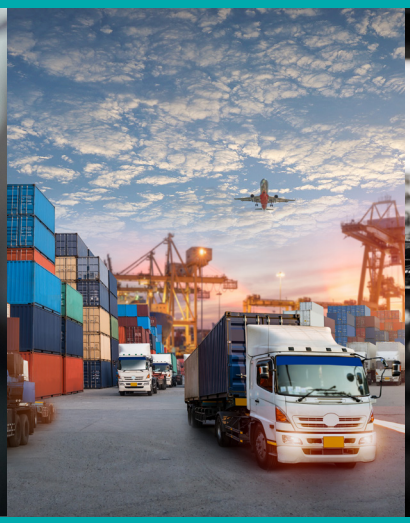
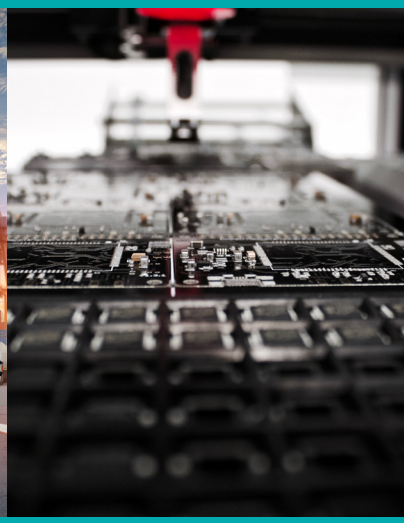
Diagnostic Technology Sovereign Capability & Resilience

A National Action Plan

August 2023


ADAPT
Australian Diagnostics Action Plan Team

MTPConnect
MedTech and Pharma Growth Centre

PATHOLOGY TECHNOLOGY AUSTRALIA

The MTP-IIGC Ltd Growth Centre is funded by the Australian Government under the Industry Growth Centre Programme. The National Action Plan is being delivered by MTPConnect in partnership with Pathology Technology Australia (PTA) and supported by **HT**ANALYSTS.

The National Action Plan (the Action Plan) addresses key supply chain resilience issues facing the health security of Australia, including our ability to produce critical diagnostic tests onshore.

Foreword (MTPConnect)

MTPConnect
MedTech and Pharma Growth Centre

Australians have for many years taken for granted that processes for detecting, diagnosing and monitoring illnesses and diseases will always work.

The COVID-19 pandemic that began in 2020 changed that. International supply lines that were previously reliable broke under the pressure of border closures, surging demand and international transport restrictions.

As this pandemic recedes, it leaves us with a much greater appreciation of both the risks to our society from global disease outbreaks and the importance of diagnostic technologies in combating them – and being able to access them when we need them.

There is also increased understanding that we rely almost exclusively on international manufacturers and suppliers for diagnostic products, making us unacceptably vulnerable to future pandemics and external shocks.

Now we need to act on that new understanding.

Over 2022-23 MTPConnect, as an Industry Growth Centre, developed a plan for establishing an end-to-end sovereign manufacturing capability for diagnostic products in Australia.

This Action Plan sets out the opportunities that lie in front of us.

We have an opportunity to strengthen our diagnostic capability, to compete in global markets and to boost our national prosperity. And while doing all that, we have an opportunity to support our own sovereign diagnostic capabilities to improve the nation's health, invest in Australian companies and create more high-paying jobs.

This strategy has come together through extensive, nationwide consultation and collaboration with many experts throughout the sector. Over the last 12 months, our Australian Diagnostics Action Plan Team (ADAPT) travelled the country to undertake 96 consultations to identify key challenges, opportunities and priorities for action. This stakeholder-centric approach allowed direct contributions from those at the frontline. Their input was critical in ensuring the Action Plan is grounded in the realities of the healthcare sector.

The resulting Action Plan does what effective industry plans around the world have traditionally done: it capitalises on the local industry's existing strengths, while prioritising innovation, boosting expertise and reducing investment risk. It outlines a framework for enhancing the diagnostic infrastructure, supporting commercialisation of new innovations, improving access to testing and strengthening the regulatory framework for diagnostic products and services.

Taking these actions will build a sustainable diagnostic industry – an industry that is commercially resilient and that supports the critical health needs of all Australians.

The Action Plan has come about through a fruitful partnership with Pathology Technology Australia (PTA), Australia's peak body for diagnostics manufacturers and suppliers. Our collaboration was critical in bringing together the necessary expertise, knowledge and networks to create a practical strategy that would deliver. I would like to thank Dean Whiting and Justin Meredith at PTA for their partnership and particularly acknowledge the dedication and hard work of MTPConnect's Dr Dharmica Mistry who expertly led the project to ensure that the Action Plan was comprehensive, feasible and reflective of the needs and priorities of all stakeholders involved.

We believe that with the right policies, investments and incentives, we can build a stronger and more resilient diagnostic technology ecosystem. And it needn't take long to start making the necessary changes.

We are committed to working closely with the Australian Government and other stakeholders to ensure the successful implementation of this Action Plan, and remain optimistic about the positive impact it will have on the health and wellbeing of our communities and the growth of our diagnostic industry.

Stuart Dignam
Chief Executive Officer

Foreword (PTA)

PATHOLOGY TECHNOLOGY AUSTRALIA

Pathology Technology Australia is a member-based organisation representing the manufacturers and suppliers of about 95 percent of diagnostics tests and technology utilised in pathology labs, hospitals and primary care facilities.

Our members include large multinational manufacturers all the way through to Australian innovation houses that have developed world-leading technology for diagnosing and monitoring health and disease.

Diagnostic technologies play a crucial role in medical diagnosis and management decisions. Over half a billion diagnostic tests are performed on patients in Australia each year, yet the technology that enables these is largely unknown to the health consumer. This is even more curious when you understand that more than 70 percent of all medical diagnostic and management decisions are based on these tests, as are 100 percent of cancer diagnoses. It is important to acknowledge that pathology testing in Australia is predominantly reliant on government funding, with nearly 100 percent of the financial reimbursement being provided through either the Medicare Benefits Schedule (MBS) or state public hospital procurement. As a consequence, suppliers have limited avenues to have influence. There is very little out-of-pocket or discretionary spending by health consumers in Australia therefore, avenues to commercialising IVDs rely almost solely on government taxpayer funding mechanisms.

The COVID-19 pandemic served as a critical platform for communicating the importance of diagnostic technologies – raising rapid awareness among millions of Australians of polymerase chain reaction (PCR) and genetic sequencing tests and why they are important. About 300 million rapid antigen tests were either self-administered or performed by a health professional during the height of the pandemic.

The pandemic also created serious consequences for the supply of critical diagnostic tests, as global supply chains closed and global manufacturing was compromised. The pandemic revealed Australia's parlous state with respect to our sovereign high-tech manufacturing capability and supply chain security.

When you consider that Australia has one of the most vibrant biotech and research and development (R&D) sectors in the world, responsible for some important medical innovations over the past 50 years, you would naturally think we are also at the forefront of manufacturing these technologies. But this could not be further from the truth. While Australia is in the top 95 percentile for innovation, we are in the bottom 5 percentile for manufacturing, leaving us almost completely dependent on imported products. And while the pandemic has subsided, critical geopolitical threats to our supply chain have not.

These factors led to PTA partnering with MTPConnect to investigate the barriers to commercialising diagnostic devices in Australia and to develop an Action Plan to remediate them. At the same time, we suggested that our supply chains be audited to determine the global sources of product and therefore the potential threats. The partnership with MTPConnect in delivering the Action Plan has been extremely fruitful and the study has been extremely thorough.

We are very pleased to present the findings from this study and stand ready to support the implementation of the findings as soon as practical. Rapid action on this plan will see Australia better placed to manage future health challenges and critical supply disruptions.

Dean Whiting
Chief Executive Officer

Contents

Executive Summary

In Australia, accessible and effective diagnostic technologies – from pregnancy tests and blood glucose monitors to rapid antigen tests and PCR tests – play a critical role in detecting, diagnosing and monitoring diseases.

The invaluable information they provide make them central to a robust and effective healthcare system which, in turn, is the cornerstone of a prosperous and healthy society.

A healthier society can also result in a more productive nation.

Australia is also home to some of the world's leading diagnostics research and development, yet our healthcare system remains vulnerable to a chronic reliance on overseas manufacturers and suppliers to deliver the diagnostics products on which the health of our population and protection of our biosecurity depends.

The problem

Australia needs the ability to diagnose health conditions, in business as usual periods and during emergencies

Australia has largely pursued a strategy of global sourcing for diagnostic products, as for other manufactured goods. As a result, we have few local suppliers.

COVID-19 exposed a weak point in this approach: it left Australia without the capacity to respond immediately to major global health events in which certain diagnostic products became at the same time both a) essential and b) impossible to obtain.

Diagnostic products play a key role in the response to events such as pandemics, but during such events, the markets for diagnostic products tend to break down: the products may become unobtainable at any price. In global health events, governments in countries of manufacture tend to respond to public pressure by restricting exports of diagnostic products. In these circumstances, manufacturers cannot override governments. And governments themselves are often under irresistible pressure to override normal trading patterns and agreements.

Lack of sovereign capability: Australian diagnostics companies source from the US and Europe

ROUTINE HARDWARE AND CONSUMABLES	US	EUROPE	ANZ
Immunology and chemistry tests	50.2%	43.9%	0.0%
Haematology and coagulation tests	21.5%	78.5%	0.0%
Therapeutic drug and drug abuse tests	40.4%	48.7%	0.0%
Acute illness and infectious tests (such as cardiac, respiratory, blood borne infectious, and sepsis)	52.1%	41.9%	0.0%
PCR tests (e.g. probes and primers)	39.8%	54.5%	1.1%
TOTAL	**48.2%**	**46.2%**	**0.0%**

Notes: Other area totals include China 4.08%; India 0%; other Asia-Pacific 1.46%.
Source: Diagnostic Technology Sovereign Capability & Resilience: A National Action Plan, p24.

Australia suffers a substantial gap between what we are likely to be able to buy from overseas, particularly in a global health emergency, and what we need as a country in order to protect Australians – our 'sovereign capability'. The need for greater sovereign capability became obvious in Australia between December 2020 and March 2021, when the nation experienced a severe shortage of rapid antigen tests.

The solution

Investing in onshore diagnostic technology manufacturing to close our capability gap

Australia can now take practical steps to close the capability gap and build a more resilient healthcare system. That conclusion is based on detailed consultation with over 144 industry stakeholders.

The actions outlined in this Action Plan provide a roadmap to achieve the goal of a flourishing sovereign diagnostics manufacturing ecosystem. These actions will enable translation and commercialisation of Australia's world-class diagnostics research and development, providing a long-term return on what would ultimately require relatively limited investment for the Australian taxpayer compared to the costs of inaction.

The most important of these steps is to:

- build a coordinated **Nationwide Diagnostics Policy** across states and territories, through prioritisation of innovations and products for commercialisation based on clinical needs as well as sovereign risk
- establish and legislate a **Diagnostics Advisory Council,** which informs Australian Government and supports industry, fostering deep connections and collaboration and maintenance of expertise to enable the supply of advanced diagnostic technologies and products
- establish a **National Diagnostics Development Centre** and dedicated **Diagnostics Manufacturing Fund** to support the commercialisation and in-country manufacture of diagnostic products
- implement sustainable **Procurement Practices** to harness federal, state and territory governments purchasing power and prioritise local diagnostic products and stimulate domestic manufacturing.

Bottom line

Sovereign industrial capability has for some years been an accepted principle in managing our defence industry. It should take its proper place in the management of our health industry as well.

The approach requires elevating the role of diagnostics in population health and biosecurity, growing and supporting businesses and talent here on Australia's shores, building strategic global partnerships and attracting international investment and skills.

With the implementation of these practical initiatives to build a resilient domestic diagnostics sector, we can not only help to protect the health of Australians but also foster the growth of dynamic, globally significant companies, create new high-paying jobs and spur economic growth in a field where Australia has already shown its competitiveness.

National Action Plan Priorities and Recommendations

Priorities

Elevate the role of diagnostics in population health and biosecurity

To unlock the potential of diagnostics, including point-of-care testing and digital diagnostics, systemic change and strong leadership are necessary. National priorities and demand signalling from the Australian Government can direct research, investment and attract domestic and foreign entities to invest in research and manufacturing in Australia. To ensure the successful integration of new technologies into the Australian healthcare system, it is crucial to focus on building and maintaining the necessary capacity, workforce, and infrastructure – which requires a strategic vision.

ACTION ITEMS

- Build a coordinated Nationwide Diagnostics Policy
- Establish and legislate a Diagnostics Advisory Council
- Establish a National Diagnostics Development Centre

Accelerate and support commercialisation and translation

Australia's economic growth and productivity rely on innovation and research, but translating and commercialising research can be challenging. Stakeholders suggested universities prioritise scientific publications over commercialisation, and there is a misalignment between government investment across the manufacturing smile curve with government procurement practices. Strategic investment and policies can help Australia learn from successful local commercialisation stories and achieve stronger results, increasing the return on investment from publicly funded research.

ACTION ITEMS

- Create a digital National Resource
- Consider more financial incentives to attract investment
- Reform commercialisation and manufacturing grants
- Ensure equitable access to biological materials
- Establish a Diagnostics Manufacturing Fund to support commercialisation and manufacturing

Establish Sustainable Sovereign Manufacturing

Investing in domestic manufacturing capabilities for diagnostics is essential for Australia's healthcare system to be self-sufficient and resilient, particularly in times of crises. Domestic manufacturing capabilities also reduce the reliance on international supply chains, which can be unpredictable and vulnerable to disruption. By building sustainable manufacturing facilities for diagnostics in Australia, the country can not only strengthen its healthcare system but also foster innovation and research, create jobs and boost the economy.

ACTION ITEMS

- Enhance the Australian manufacturing workforce
- Provide incentives for entities with local manufacturing infrastructure to rent out facilities to SMEs
- Provide manufacturing subsidies or rebates

Enhance regulatory and reimbursement support for diagnostics

Australia's Therapeutic Goods Administration (TGA) is a globally respected regulator of diagnostic tests, medical devices, and medicines, ensuring high product safety and efficacy. Stakeholders in the industry report challenges with regulatory expertise, inadequate guidance, and high costs of obtaining consultant support. Additionally, the low reimbursement subsidies for diagnostics, often directed towards laboratories rather than manufacturers or suppliers, hinder uptake and adoption, driving companies overseas and away from building manufacturing capabilities in Australia.

ACTION ITEMS

- **Provide a sustainable funding model for the TGA**
- **Provide funding for regulatory support**
- **Improve reimbursement pathways for diagnostic technologies**

Implement sustainable procurement practices

Utilising government procurement is crucial to increase access to diagnostics and retain manufacturing capabilities in Australia. This central role played by the state, and territory governments in the local market for diagnostics shapes industrial outcomes and builds supply chain resilience.

ACTION ITEMS

- **Conduct an economic evaluation to assess the broader benefits of Australian-made diagnostics**
- **Improve state and territory government procurement**
- **Encourage the Australian Government to be involved in product development**

Increase resilience, responsiveness, and preparedness

The establishment of a strong local diagnostic industry is a critical aspect of Australia's health security, and it must be considered in conjunction with the development of a robust diagnostic supply chain. It is critical to take a long-term perspective and ensure that diagnostic manufacturing capabilities are not only temporary but a permanent feature of the health system. This necessitates making the system more adaptable and responsive to future needs, with strong demand signalling to direct preparation and response efforts.

ACTION ITEMS

- **Streamline and simplify import regulations**
- **Form collaborative partnerships with global companies**
- **Provide subsidies on freight during emergencies**
- **Strengthen export partnerships**

Introduction

The Vision

Create economic value, advance health outcomes and improve health security for all Australians by fostering sovereign capability and resilience. Develop a sustainable healthcare model which elevates the role and impact, and improves access to diagnostic technology.

The Mission

Work with stakeholders to understand and respond to problems in commercialising and supplying diagnostic technology to Australia.

97%

of in vitro diagnostics are being imported from overseas

Introduction

Diagnostics Matter

Diagnostics technologies and products show us the diseases people have and help us to make people well again. Diagnostic information drives critical public health decisions across Australia – decisions that affect millions of Australians.

How important are these diagnostics? More than 70 percent of medical diagnosis and management decisions rely on pathology test results. So do 100 percent of cancer diagnoses. And because diagnostics allow health professionals to spot conditions early, they reduce healthcare expenditure (Rohr et al., 2016).

The COVID-19 pandemic has highlighted that diagnostic products play a vital role in controlling emerging infectious diseases. It has also revealed the consequences of an internationally dependent and reactive healthcare ecosystem.

So for security, health and economic reasons, Australia should establish and retain the ability to manufacture key diagnostic products. Increasing sovereign manufacturing of diagnostics is critical for our national health security.

Australia produces some of the world's most advanced and future-focused diagnostics research and innovation. Australian researchers and small and medium-sized enterprises (SMEs) are at the frontline, working to make diagnostics more automated, accessible, rapid and intelligent. In the past 50 years, Australians have developed vaccines, sleep therapy, blood plasma medicine and hearing loss instruments, such as cochlear implants and, most recently, tests for contagious disease, drug-resistant micro-organisms and rapid tests. Scientists from The University of Queensland developed the world's first cervical cancer vaccine, which could save 62 million lives in the next 100 years (The University of Queensland, 2006).

Despite this track record in homegrown medical technology, biotechnology and pharmaceutical excellence, Australia remains almost entirely reliant on imported in vitro diagnostic (IVD) products and is thus left vulnerable to supply shortages during periods of high demand, external shocks and global supply chain stress.

Recent geopolitical pressures have only magnified the need for reliable and sustainable IVD product development and production within Australia. While Australia does not need to achieve full self-sufficiency in all health technologies and consumables, the risks of not being self-sufficient for critical technologies for our health security are too great to ignore.

To achieve this, Australia must harness its current diagnostics research and development leadership to become a regional centre of diagnostics development and manufacture. A focus on the full manufacturing value chain, from pre-production to post-production, will create high-paying jobs, generate export income and protect the health of Australians – in good times and during health emergencies.

MTPConnect's programs and other initiatives are supporting medical product development and workforce skills. But more can be done to remove barriers faced by innovative manufacturers seeking local market access. With simple changes to perspectives, structure and funding, we can find solutions to these issues and achieve a truly end-to-end approach that maximises Australia's potential in the IVD sector.

About diagnostics

Information generated by **diagnostics** underpins decisions on how to treat people's health issues.

In **vitro diagnostics (IVDs)** are tests performed outside the body, typically using blood, tissue and saliva samples (in vitro means 'in glass'). IVD tests can be done in laboratories, healthcare facilities or at home. They play a critical role in detecting diseases early, preventing their spread and keeping patients healthy.

Diagnostics are the starting point and backbone of the healthcare system

Equitable access to essential medical products and technologies is a fundamental aspect of any effective national healthcare system. In Australia, with our many rural, regional and remote communities, access matters even more.

Sovereign capabilities have long featured in Australia's defence debate. But outside that sector, they were not a topic of national discussion before COVID-19. The pandemic has made Australians more aware that critical health technologies rely largely on international supply chains. These technologies include most of our diagnostics, ranging from bowel screening technology to rapid antigen tests.

Information generated by diagnostics technologies underpins individual treatment decisions and systemwide healthcare policies, including vaccination. Without an effective diagnostics system, other essential healthcare functions operate less effectively and some may barely operate at all.

Diagnostic technologies or techniques can be classed in two groups:

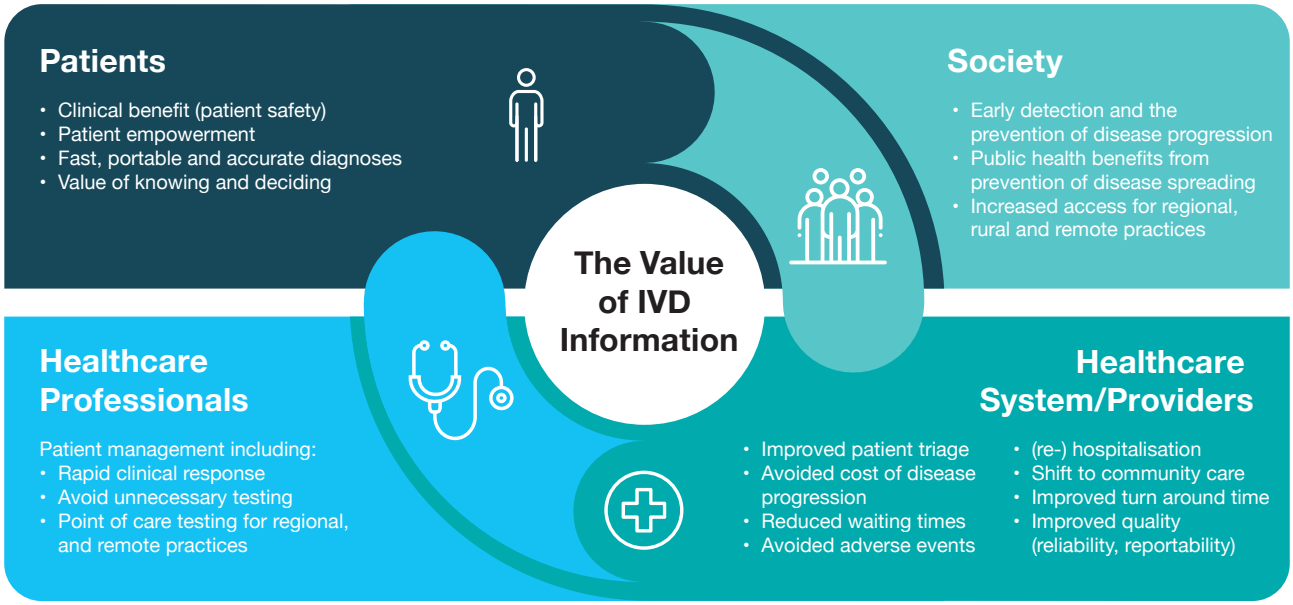
- **in vivo diagnostics** are tests performed with or within a living organism, including imaging tests, endoscopy, psychological tests and physical examination
- **in vitro diagnostics (IVDs)** are tests performed outside a living organism such as in a lab, healthcare facility or home, including non-invasive tests using samples from the human body (such as blood, urine or tissues).

New and innovative IVDs are also incorporating artificial intelligence. This combination of technologies has the potential to significantly improve healthcare technologies in the coming years (McRae, Rajsri, Alcorn, & McDevitt, 2022).

Global megatrends in healthcare, including the digital evolution, consumer control and value-based healthcare, mean growing demand for products and services that focus on prevention and enable the consumer to be more actively involved in the management of their health needs.

Point-of-care testing (PoCT), where the analysis is performed where healthcare is provided close to or near the patient, is becoming more important.

Here, IVDs have an increasing role to play.



Introduction

What is the value of IVDs?

This Action Plan focuses on IVDs because IVDs dominate healthcare decision-making and public health outcomes. *In vivo* diagnostics are typically used for diagnosis and management of *existing* conditions; IVDs allow early detection and prevention of *emerging* conditions.

Dynamic, resilient healthcare systems employ reliable and relevant diagnostics, medical technology and therapeutics. Treating illness generally starts with a diagnostic test, without which medicine flies blind. Non-diagnosis and inaccurate diagnosis impose real costs in lives, health levels and dollars.

IVDs play a key role in Australia's prevention-based healthcare model. The downstream benefits of this prevention-based approach include:

- early detection of disease and more effective, timely treatment
- improved patient and health outcomes and improved quality of life
- reduced long-term healthcare costs and chronic disease impact
- patient empowerment.

According to the Therapeutic Goods Administration (TGA), a medical device is defined as an IVD if it is a 'reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use' (Therapeutic Goods Administration, 2010). These can be further classified into six key categories (below):

IN VITRO DIAGNOSTICS

1. Biomarkers
2. Devices
3. Genomics
4. Point of care
5. Self-testing
6. Software as a medical device

This definition provided by the TGA excludes products that are not intended for therapeutic use, such as drug tests used for sport, alcohol or illicit drugs (Pathology Technology Australia, 2018). IVDs not intended for therapeutic use, as well as medical imaging devices, are out of scope for the Action Plan.

THE DUAL ROLE OF IVD INFORMATION DURING COVID-19

RISK MANAGEMENT

Slows to transmission by:

- detecting COVID-19 infection in pre symptomatic and asymptomatic people
- identifying who has been previously infected with COVID-19 and who still has antibodies against the virus once vaccination has been administered.

DISEASE MANAGEMENT

Ensures patients are accurately diagnosed and follow the right care pathway by:

- differentiating other types of acute respiratory infections with similar presentation from COVID-19 based on pathogen identification
- guiding treatment and care of acute respiratory infections following diagnosis.

The World Health Organization (World Health Organization [WHO], 2021) has recognised the importance of IVDs in population health and each year updates a list of essential IVDs that should be available in each country.

IVDs in prevention and healthcare decision-making

IVDs are indispensable for both routine patient management and public health decision-making, notably in preventative care. Appropriate testing allows for early-stage interventions, reducing late-stage healthcare expenditure (Rohr et al., 2016) and ultimately increasing the chances of better treatment outcomes. But even with in this crucial role, IVDs account for less than **2 percent of total healthcare expenditure** (Rohr et al., 2016).

Innovations in IVDs have the potential to reform healthcare. Developments in genomics, next-generation sequencing, biosensors and personalised health are shaping the future of diagnostics. These advancements enable more accurate, rapid and comprehensive disease detection, empowering healthcare providers to tailor treatments to individual patients. As IVDs continue to evolve, they will play a pivotal role in delivering personalised, efficient and effective care, ensuring better patient outcomes and transforming the healthcare landscape.

Supporting regional, rural and remote communities

IVDs have evolved from traditional laboratory examinations to point-of-care testing done both by healthcare professionals and untrained individuals in cases such as diabetes self-monitoring. Rapid, portable and accurate diagnoses allow better clinical support, particularly in regional, rural and remote areas (Wong, Marcu, Bezak, & Parange, 2020). In Australia's vast landscape, timely healthcare access remains a challenge, and there is still room for improvement in serving regional, rural and remote communities and reducing inequities of access. Primary and allied healthcare professionals can transform diagnostics by collaborating with pathology providers and leveraging PoCT to address Australia's unique healthcare challenges.

Sovereign capability and platform technology

Furthermore, diagnostics such as lateral flow tests (including COVID-19 rapid antigen tests) can be easily adapted for new uses and pressing need as required. Sovereign capability will position Australia to respond to threats more holistically and efficiently.

> EXAMPLE

ZERO Childhood Cancer

The Zero Childhood Cancer (ZERO) program is a pioneering Australian initiative that offers personalised cancer treatment for children with high-risk and aggressive cancers. By leveraging advanced genomic and molecular techniques, the program analyses each child's unique cancer profile to develop tailored therapies.

The program has successfully identified targeted treatments for more than 70 percent of enrolled patients, significantly improving prognosis and quality of life for many children.

The ZERO program aims to revolutionise paediatric cancer care by harnessing genomics and precision medicine and with continued growth, it will have an even more significant impact on cancer treatment, edging closer to a world with zero childhood cancer deaths.

Source: Zero Childhood Cancer(2020).

Introduction

What does the future hold without action?

> EMERGING HEALTH CHALLENGES

The incidence of chronic and infectious diseases is rising. Viral disease outbreaks are increasing in frequency and severity, and many have pandemic potential (CSIRO Futures, 2022). The ease of travel and trade means these outbreaks can now cross borders faster and evolve more rapidly.

Antimicrobial resistance (AMR) is also emerging as a significant global health threat. AMR occurs when bacteria, viruses, fungi and parasites become resistant to the medicines designed to kill them (MTPConnect, 2020b). AMR can lead to prolonged illness, increased healthcare costs and even death. Accurate diagnostic testing and tailored treatments are essential in combating the increasing AMR threat to human health and ensuring appropriate antibiotic use.

The population in Australia and other developed countries is ageing (Australian Institute of Health and Welfare, 2021). This is increasing burden on the health system and our vulnerability to disease outbreaks. This is raising the need for faster, more affordable and less invasive diagnostic testing.

> CHANGING PATIENT PREFERENCES AND TECHNOLOGICAL ADVANCES

Global megatrends in consumer control and value-based healthcare mean demand for diagnostic technology is on the rise. As public health challenges continue to evolve, so too do patient preferences. With COVID-19 normalising rapid antigen tests, there is likely to be a permanent increase in the use of point-of-care and in-home personalised testing. Patients will also expect more rapid testing and diagnosis.

Improvements in processing capacity and internet connectivity are being harnessed by diagnostics manufacturers to enable more widespread point-of-care testing. This has the potential to transform the care of rural and remote communities.

The diagnostics sector is also at the forefront of a growing adoption of automation and artificial intelligence, with growth in the use of automated instruments already observed (Hedlund, 2019). Moreover, the importance of feeding data back into the healthcare system, particularly for digital and PoCT, cannot be overstated, as it will enhance healthcare outcomes and inform future decision-making.

> GEOPOLITICAL INSTABILITY AND SUPPLY CHAIN DISRUPTIONS

Looking ahead, there is a potential for geopolitical instability to affect trade and supply routes (Naughtin et al., 2022). The Australian Strategic Policy Institute estimates that 80 percent of global trade is carried via sea and much of it through contested waters (Uren, 2020). This could potentially impact access to important supply chains. The recent conflict in Ukraine serves as an example of the risks associated with relying on any one country or region for critical goods.

> GROWING MARKET FOR IVDS AND THE RISK OF INACTION

The intersection of all of these trends means that the market for IVDs is robust and projected to grow to approximately A$150 billion by 2024 (PricewaterhouseCoopers [PWC], 2021). It is unrealistic for Australia to become fully self-sufficient in all aspects of health technologies and consumables. But Australia can move to develop and produce essential IVD products reliably and sustainably – to support the day-to-day operation of our world-class health system, boost health security and pandemic preparedness and support the growth of start-ups and SMEs and job creation.

If action is not taken, the nation risks falling behind in the rapidly evolving healthcare landscape. The growing demand for diagnostic solutions, coupled with emerging health challenges such as infectious diseases, AMR and an ageing population, highlights the urgent need for innovation and sovereign manufacturing of key diagnostic tests. Inaction could exacerbate supply chain vulnerabilities, create inequities in healthcare access (particularly in rural and remote communities) and be detrimental to the health of Australians. Australia will also miss out on the economic and competitive benefits of a thriving diagnostics sector, which is projected to grow significantly in the coming years.

Diagnostic Manufacturing Landscape

Sovereign capability means establishing, retaining and maturing our manufacturing capabilities for essential diagnostic products, ensuring a degree of self-sufficiency and security for Australia. Currently, only 26 percent of companies that responded to the supply chain resilience survey manufacture some products in Australia. To improve self-sufficiency and security, sovereign capability must encompass all the adjacent functions from research and development, logistics, production, market access and distribution, through to sales and services of diagnostic products (the manufacturing smile curve). In areas where Australia is not able to be fully self-sufficient, robust supply chains are vital in realising overall improvements and enhancing resilience.

Sovereign capability primarily relates to a security for a nation, reducing vulnerability due to external dependency in key areas of national interest, such as population health and biosecurity. This is especially true for medical products that cannot be easily stockpiled, as is the case for most diagnostic test consumables, which have a short shelf life and rigid storage temperature requirements.

In 2020, it was found that Australia ranks last on the Organisation for Economic Co-operation and Development (OECD) rankings for manufacturing self-sufficiency – making us the most underdeveloped manufacturing sector of any industrial country in the world (Stanford, 2020). Until now, Australia has focused on a goal of increased sovereign capability in the area of defence. However, COVID-19 has forced policymakers to pay greater attention to sovereign capability in other areas, particularly healthcare (Worrall, Gamble, Spoehr, & Hordacre, 2021). Australia has high healthcare operational capability, being able to deliver high-quality care through strong services and research sectors, but low industrial capability, being unable to locally manufacture healthcare technologies – a weakness exposed during the pandemic (Worrall et al., 2021).

> **Sovereign manufacturing does not necessarily mean Australia must increase the number of local manufacturing companies to be fully self-sufficient in all aspects of diagnostic products. It instead means, in areas where we are not manufacturing products, increasing and supporting the capability of existing local manufacturers to ensure supply is available at times of need (Worrall et al., 2021).**

Australia could thus become a manufacturing centre of excellence for priority diagnostic technologies such as point-of-care tests and genomics.

The benefits of sovereign manufacturing capability stretch beyond strengthening Australia's sovereignty and self-sufficiency. These technologies can provide Australia with essential health capability and a more prosperous and resilient economy, even as they address critical supply chain vulnerability.

BENEFITS

- Increased economic growth
- Greater participation in international value chains
- Increased employment opportunities and diversification of skills
- Ready supply of products
- Industrial capability, which can be maintained and redirected in crises
- Retention and growth of manufacturing skills

Above all, advanced manufacturing and reliable, robust supply chains are pivotal in ensuring overall improvements to the healthcare system and in protecting the health and wellbeing of Australians.

Furthermore, many diagnostics technologies are platform technologies that can be easily adapted for alternative applications in times of need. Having this sovereign capability will position Australia to respond to threats more holistically and efficiently.

The Australian Government acted during the pandemic to expand Australia's sovereign capabilities, partnering with organisations such as AusDiagnostics (see case study P16). More broadly, Australia's medical technology sector worked with Australian Government to ensure effective supply of the critical healthcare technologies, goods and services necessary to support the public health response to COVID-19 (MTPConnect, 2020a).

CASE STUDY

AusDiagnostics

Building Local Manufacturing Capacity for Global Impact: AusDiagnostics's Partnership with the Australian Government in Diagnostic Supply Chain

AusDiagnostics highlights the potential for fast and large impact when the Australian Government partners with Australia's diagnostic sector on strategically important sovereign manufacturing projects.

In June 2020, three months into the COVID-19 pandemic, the world was experiencing a shortage of diagnostic products to help identify and fight against outbreaks of the virus. As stated by AusDiagnostics at the time:

"Short supplies have been prioritised to other countries, and Australia and New Zealand has been consistently relegated by larger suppliers."

In response, local firm AusDiagnostics partnered with the Australian Government to establish a state-of-the-art facility to scale up and secure production of diagnostic kits locally. By September 2020, the facility was opened and operational. The Australian Government provided support in the form of initial cashflow funding, which was to be repaid by AusDiagnostics with proceeds from the sale of the diagnostic kits.

This partnership highlighted what can be achieved when the public sector and industry join forces with a clear common objective and the right resources to realise this objective. Importantly, AusDiagnostics had been and continues to be a globally-oriented business, exporting products worldwide. However, the signal of support shown by the Australian Government during this period was enough to pivot the focus back to AusDiagnostics's home market to rapidly achieve the outcome required for the Australian health system.

"We pivoted quite well during the pandemic. We really tried to bring resources here for the local community and we developed our extraction range portfolio in response to that and support from the Australian Government as well."

While the facility was important to secure supply of critical COVID-19 diagnostic tests during the pandemic, the platform nature of diagnostic manufacturing means the facility will continue to support the security of Australia's sovereign diagnostic sector into the future.

> **While the imminent focus is on viral extraction kits for COVID-19, AusDiagnostics is poised to rapidly expand the platform to meet the demands of the changing market beyond the pandemic.**

Diagnostic Manufacturing Landscape

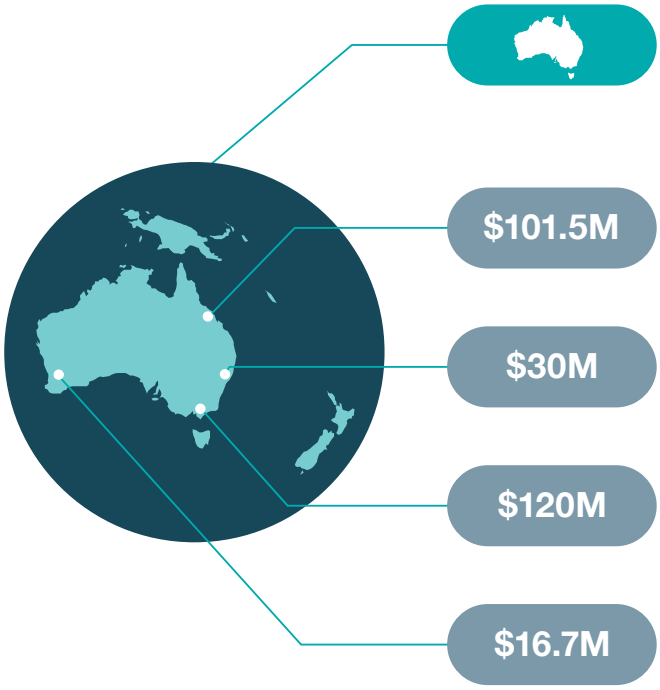
National Policy Landscape

The National Reconstruction Fund (NRF) is a $15 billion Australian Government initiative that will provide financing to projects that help rebuild Australia's industrial capability and reduce dependence on broken supply chains (Australian Government, 2022b). The NRF will make investments across priority areas of the economy including renewables and low emissions technologies, medical science, transport, value-add in the agriculture, forestry and fisheries sectors, value-add in resources, defence capability and enabling capabilities.

Of the $15 billion of total funding, $8 billion has already been allocated to priority areas: $1.5 billion has been allocated to medical manufacturing, $1 billion to critical technologies and $1 billion to advanced manufacturing.

This funding is intended as an alternative to private market investors and lenders. It will increase the ability and confidence of industry participants to make strategic investments in onshore manufacturing capacity and in some cases to tilt the scales in favour of moving production to Australia ('onshoring'). This is anticipated to drive economic and industry growth as well as provide an opportunity to create secure jobs, facilitate domestic and overseas trade, and enhance and expand sovereign capability and resilience.

The Research and Development Tax Incentive program and state government initiatives, as detailed below, are also crucial for encouraging innovation, competitiveness and sustainability across the manufacturing sector.



National: R&D Tax Incentive

Established in 2011, this incentive provides a tax offset to support and encourage companies – SMEs in particular – to undertake R&D activities that they may not otherwise be willing to conduct.

QLD: Made in QLD grant program

This program supports SME manufacturers in boosting their international competitiveness, productivity and innovation.

NSW: Modern Manufacturing Taskforce

The commissioner has been appointed to accelerate the development of modern manufacturing capabilities.

VIC: Victorian Industry Fund

This fund offers grants to manufacturing firms in priority areas, such as medical technology.

WA: New Industries Fund

This is a four-year commitment to support the acceleration of new and emerging businesses in WA.

Sources: Australian Government (2021), Queensland Government (2022), NSW Government (2023), Victoria State Government (2023), Government of Western Australia (2023).

“Critical medical supplies should be made in Australia – and the Australian Government should be buying Australian-made medical supplies...

We will give first priority to Australian-made medical technology for government purchases in consumables and equipment...

If we don’t invest in making things here, we will always rely on others in a crisis.”

Joint media release by Anthony Albanese MP (now Prime Minister), with Richard Marles MP, Mark Butler MP and Ed Husic MP
30 January 2022

Consultation Process

Stakeholders were engaged across the sector to provide insights and understanding of the challenges with developing, commercialising, manufacturing and supplying diagnostic technology in the Australian market. To help guide this project, a dedicated External Advisory Group was convened. Comprised of local and international thought leaders and experts with deep knowledge and experience in the field, this group provided valuable insights throughout the course of the project from its August 2022 start.

External Advisory Group members

Dr Paul MacLeman
Chairman – AdAlta

Jo Root
Policy Director –
Consumers Health Forum of Australia

Dr Sean Parsons
Founder & Chief Executive – Ellume

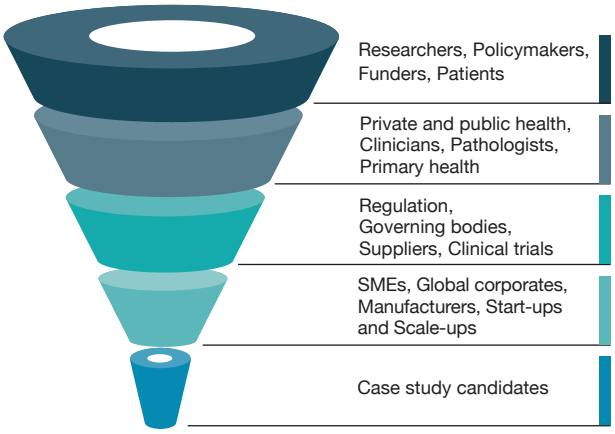
Kylie Sproston
Chief Executive – Bellberry Limited

Professor Chris Molloy
Chief Executive Officer –
Medicines Discovery Catapult

Preliminary work

A desktop literature search informed the consultation. This search sought to identify issues and categorise issues across the manufacturing smile curve.

The review then outlined potential solutions from overseas. These issues and their solutions formed part of the foundation for the later consultation process.



Consultation Process

PHASES

1 IDENTIFY

Identify issues and potential solutions

During Phase 1, 84 interviews were conducted with 144 people, a cross-section of the stakeholder funnel. These interviews focused on identifying priority issues and potential solutions across the manufacturing smile curve.

2 DEVELOP

Develop recommendations

The interviews showed a wide range of perspectives, but also a consensus among stakeholders on the core issues. A thematic analysis of the interviews informed the initial development of recommendations for the Action Plan.

3 TEST

Test the suitability and vialbility of recommendations

Initial recommendations for the Action Plan were tested across 12 interviews with 17 people, again a cross-section of the stakeholder funnel. This allowed testing of each recommendation's suitability and viability with the appropriate stakeholders.

Overview of consultation process

To gain a comprehensive understanding of Australia's current diagnostic testing capability and supply chain resilience, stakeholders across the value chain (both in Australia and internationally) were included in the consultation process.

Stakeholders were mapped using the funnel approach (Boaz, Hanney, Borst, O'Shea, & Kok, 2018). They included researchers, funders, pathologists, regulation, governing bodies, SMEs (including start-ups and scale-ups), manufacturers and multinationals.

Supply chain resilience survey

In addition to the stakeholder consultations, a survey was developed to capture quantitative data relating to the state of Australian IVD supply.

The survey was distributed to SMEs and multinational corporations that manufacture diagnostic products in Australia or overseas. The aim of the survey was to show where Australia's imported diagnostics come from and what potential alternatives may exist – the first time this has been done in Australia.

Twenty-one SMEs and multinationals completed the full survey (see Supply Chain Resilience for results, p24–28).

Phase 1

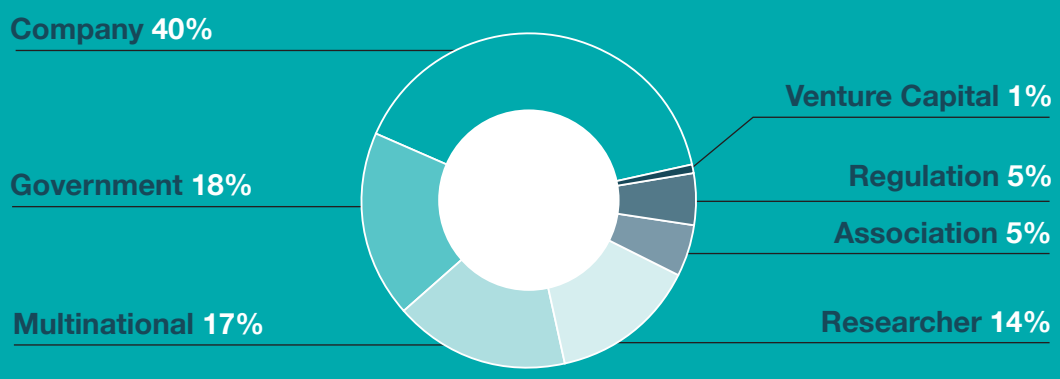
84 interviews conducted

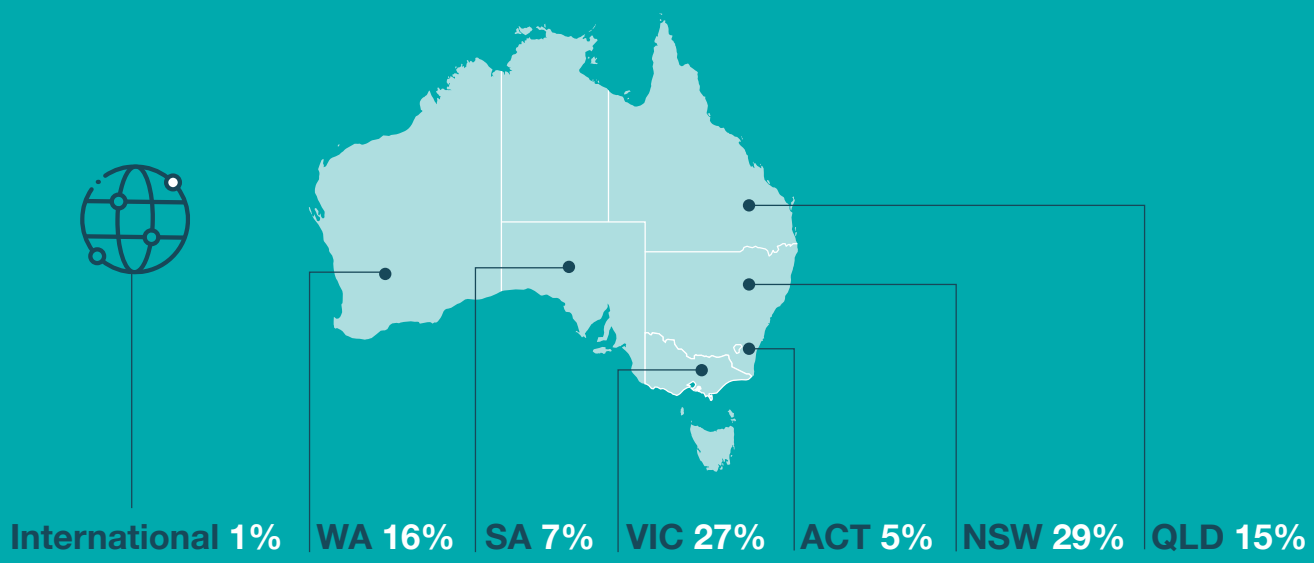
> 144 PEOPLE INTERVIEWED

Phase 3

12 interviews conducted

> 17 PEOPLE INTERVIEWED

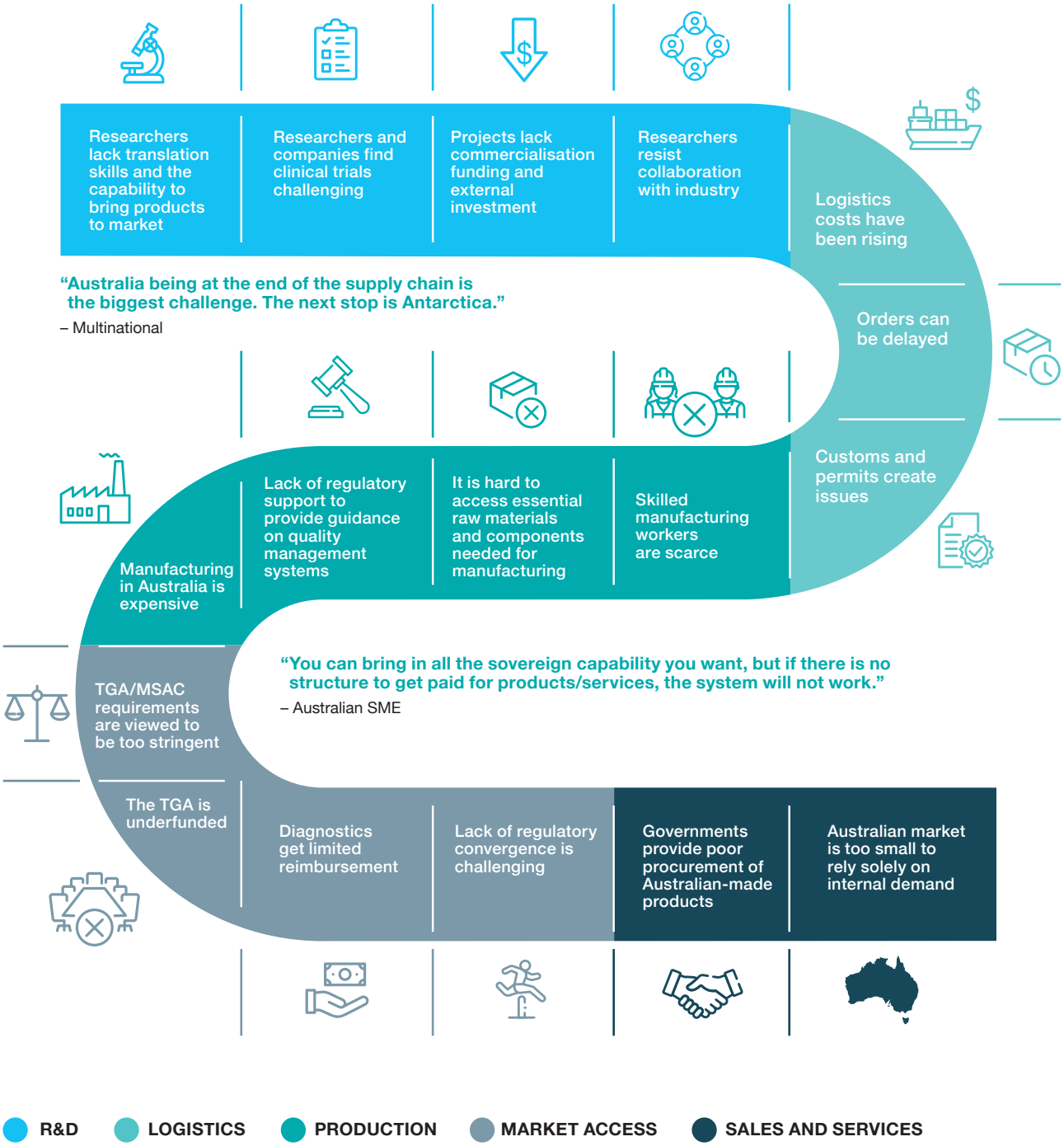




Barriers to Sovereign Manufacturing

Extensive stakeholder engagement painted a concerning picture on Australia's ability to be self-sufficient and introduce diagnostic products into the Australian market (Figure 1).

Figure 1: Major barriers to sovereign manufacturing in the diagnostic industry as identified through stakeholder consultations



Source: Stakeholder consultations.
Note: Individual barriers have been thematically analysed and group as presented.

The findings from 84 interviews conducted in late 2022 show stakeholders agree that aspiring and current diagnostic manufacturers (SMEs and multinationals) face substantial commercialisation, regulation, reimbursement and procurement obstacles.

It is critical that these are addressed. Without action, there may be no Australian diagnostics manufacturers in the future.

Stringent TGA and MSAC requirements

The TGA is praised for its ability to protect the health of Australians and lead global regulation.

However, stakeholders reported that the TGA has complex dossier requirements (especially for Class 3 & 4 IVDs products) and long timeframes. The need for additional engagement support for industry was also highlighted.

These barriers are deterring companies from seeking regulatory approval in Australia, and potentially reducing Australia's access to diagnostic tests. As a result, Australian companies are seeking regulatory approval overseas. This is risky for Australia's diagnostic ecosystem, as these companies then tend to establish manufacturing facilities abroad.

In other cases, some companies – but especially SMEs – find the process for obtaining Medical Services Advisory Committee (MSAC) approval highly uncertain with long timeframes for approval (up to three to five years).

In particular, stakeholders reported that the MSAC model is outdated, provides minimal reimbursement and has stringent application requirements.

Poor local procurement of Australian made diagnostics

Many companies view governments as their primary customers. The misalignment between government incentive programs and procurement practices was reported as a significant impediment to the growth and sustainability of these companies.

The COVID-19 pandemic highlighted that both the federal and state and territory governments prioritised product pricing over quality when procuring products. This is challenging for local SMEs that are unable to compete on price. These companies also reported additional obstacles during the tender process, as the terms and conditions are typically more suited to the business models of multinational companies.

Skilled workforce shortage

While Australian universities were found to have strong innovation capabilities, many researchers working in the field of diagnostics lack commercialisation expertise and struggle to bring ideas and products to market.

Stakeholders described the problem as having multiple causes, including:

- Australian researchers are too risk adverse, especially by comparison with the US researchers
- Australian researchers lack the necessary skills to understand what ideas have market potential
- commercialisation is not always a key aim of Australian research.

Concurrently, industry professionals face significant difficulties recruiting skilled workers, particularly those with engineering and regulatory expertise. This means SMEs must seek out international talent – which can present its own challenges.

> **Due to poor procurement, slow regulation and minimal reimbursement the domestic market is not attractive enough to pursue alone.**
> – Multinational

Supply Chain Resilience

Building resilient supply chains in Australia has taken a new urgency in light of the weaknesses exposed during the COVID-19 pandemic, across all industries but especially the healthcare sector.

To help address the vulnerabilities stemming from the diagnostic industry, MTPConnect and PTA mapped where SMEs and multinationals source their diagnostic raw materials, components and products from around the world. This is the first time a comprehensive audit of the diagnostic supply chain has been conducted in Australia to understand the interdependencies and potential supply chain risks (Figure 2). The respondents to the survey constitute a substantial proportion of the IVD market in Australia.

The findings have the potential to inform policy decisions, enhance Australia's national security, drive innovation and improve Australia's health outcomes by providing governments and companies with greater insight into how future crises could impact supply.

Together with Actions 6.1 to 6.4, this analysis provides the diagnostic industry with an opportunity to build more robust and resilient supply chains that can withstand unexpected disruptions. It is imperative that both governments and companies undertake independent stress-testing of their respective supply chains to identify any additional vulnerabilities.

> **"The Australian Government needs to be future-proofing, not working from crisis to crisis."**
>
> – Government Department

Supply Chain Resilience

The last few years of supply chain disruptions have shown it is more important than ever for diagnostic companies to build resilient supply chains.

Impact of COVID-19

Building resilient supply chains in Australia has taken on a new urgency in light of the weaknesses exposed during the COVID-19 pandemic. In particular, it magnified the importance of having access to raw materials (such as **oligonucleotides**), components (such as **plastics**), and products (such as **lateral flow tests**), which stakeholders considered vital to the health and security of Australians.

92%
of companies had their supply chain impacted by COVID-19

100%
of companies experienced increased freight costs

65%
of companies experienced shipping delays

Recovery from COVID-19

Today, many companies are still recovering from the COVID-19 crisis due to the costs incurred from inbound logistics such as stock delays, customs delays and damaged products (e.g. frozen goods being thawed).

> **"In times of geopolitical instability, we will NOT have an industry that can make or replace products at the quality or quantity that is required."**

To further understand Australia's risk, MTPConnect and Pathology Technology Australia conducted an audit of current sources for our diagnostic raw materials and components.
52 diagnostic companies were approached with 24 companies completing the survey.

Overview of participating companies

41%
were Australian owned/based companies

67%
Manufacture offshore

7%
Manufacture onshore

26%
Manufacture offshore and onshore

Australia is heavily reliant on the import of diagnostic raw materials and components.

97%
Sourced from overseas

Raw materials and components

Location of raw materials and components according to multinationals and SMEs

48%
Sourced from US

46%
Sourced from Europe

4%
Sourced from China

The future geopolitical concerns leaves Australia extremely exposed

Future concerns to supply chains

52%
Supply shortages

43%
Freight costs

43%
Order delays

29%
Freight availability

Alternative supply chains

87% of companies now have a business continuity strategy in place following the disruptions from COVID-19, to ensure security of supply and thus sustainability of manufacturing.

> "Australia lacks a bias for action in supply chain resilience. The bias is for INACTION."

Australian Government action

The Australian Government must support industry and be more proactive in their approach to achieve supply chain resilience. This can be accomplished by implementing the action points in Priority 6.

Supply Chain Resilience

Figure 2: Global analysis of where diagnostic multinationals and SMEs source their raw materials and components

Industry members identified Europe and the Asia-Pacific as key regions of future concern.

US AND CANADA

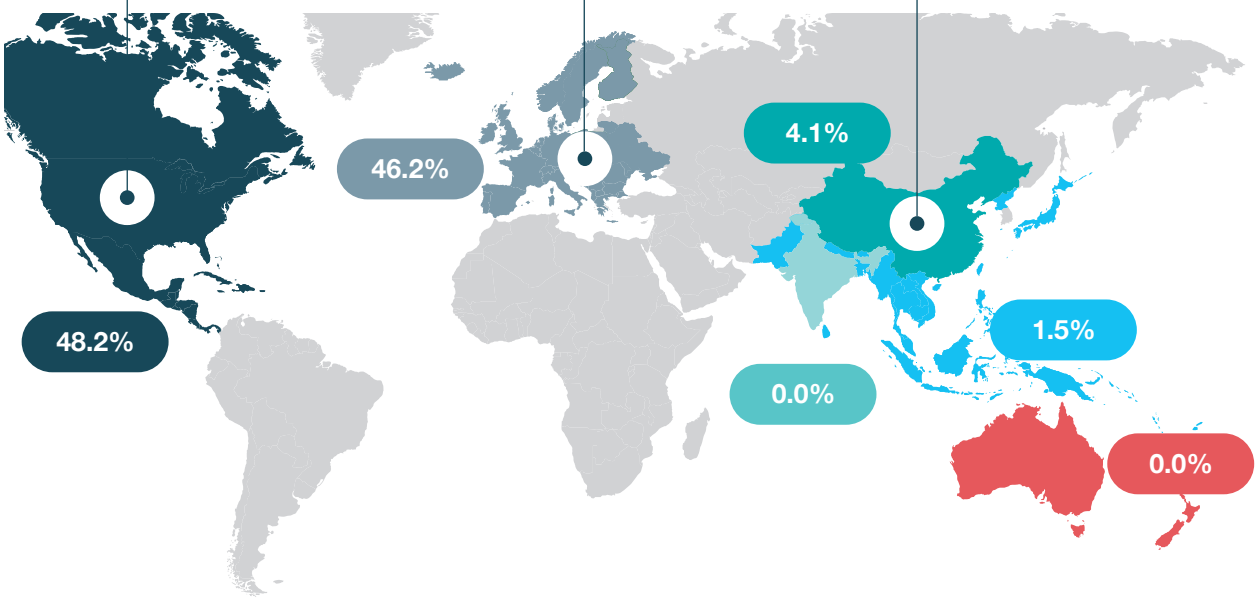
Although the US was not identified as an area of future concern, COVID-19 lockdowns and previous rail strikes have demonstrated that US-related supply chain disruptions can occur.

EUROPE

The Ukraine-Russia war and related energy issues continue to affect supply chains. Delays and shortages of some raw materials, together with increasing freight costs, present challenges for Australian manufacturers.

CHINA

COVID-19 in China lowered global trade. There is increasing concern that supply chains will be threated again with the increasing geopolitical tensions in China and the South China Sea.



ROUTINE HARDWARE AND CONSUMABLES	US AND CANADA	EUROPE	CHINA	INDIA	ASIA-PACIFIC	ANZ
Immunology and chemistry tests	50.2%	43.9%	4.3%	0.0%	1.6%	0.0%
Haematology and coagulation tests	21.5%	78.5%	0.0%	0.0%	0.0%	0.0%
Therapeutic drug and drug abuse tests	40.4%	48.7%	6.5%	0.0%	4.4%	0.0%
Acute illness and infectious tests (such as cardiac, respiratory, blood borne infectious, and sepsis)	52.1%	41.9%	5.2%	0.0%	0.8%	0.0%
PCR tests (such as probes and primers)	39.8%	54.5%	4.4%	0.0%	0.2%	1.1%
TOTAL	**48.2%**	**46.2%**	**4.1%**	**0.0%**	**1.5%**	**0.0%**

Source: Supply chain resilience survey.
Note: Data used to conduct the analyses by 10 THOUSAND FEET was based on 24 responses from multinationals (74%) and Australian SMEs (26%). Results presented are relative to the base sizes regarding the number of tests sold for each type of consumable. For each company, the supply was mapped back to their manufacturing locations, and may not necessarily indicate origin of all raw components and materials.

National Action Plan priorities and recommendations

National Action Plan Priorities and Recommendations

Australia should have sovereign manufacturing and supply chain resilience for diagnostic technology

AGILITY
Quickly adapt to changes in demand for diagnostics and supply chain disruptions

CAPABILITY
Produce, deliver and support high-quality diagnostics to promote Australia's self-sufficiency and sovereignty over domestic supply chains.

SOVEREIGNTY
Secure or retain Australia's ability to control and manage its own domestic supply of diagnostics, promoting self-sufficiency

PRIORITY

- Elevate the role of diagnostics in population health and biosecurity
- Accelerate and support commercialisation and translation
- Establish Sustainable Sovereign Manufacturing
- Enhance regulatory and reimbursement support for diagnostics
- Implement sustainable procurement practices
- Increase resilience, responsiveness and preparedness

Industry stakeholders highlighted that a focus on investment and funding of manufacturing facilities alone will not be enough to drive transformation. We must ensure that investments into establishing sovereign manufacturing (including through the NRF) have the commercial and social outcomes desired. To do this, we need to reform and support the diagnostics sector at every link in the value chain. This includes research and development, logistics and supply chain, market access and regulation, manufacturing scalability and a viable market for products that are manufactured.

This Action Plan outlines the actions that stakeholders working within Australia's diagnostics sector see as most impactful across each of these areas. Industry stakeholders are optimistic that with the right support, Australia can develop a vibrant diagnostics sector.

They believe development of the sector can:

- support Australia's healthcare preparedness
- create sustainable local jobs
- help address regional health and economic inequalities
- improve patient outcomes
- contribute to a high-value national advanced manufacturing ecosystem.

Collectively, all actions within each priority (listed below) represent an end-to-end approach to support the development and adoption of diagnostic technologies to ultimately create a more prosperous and resilient Australia.

Supporting hi-tech industry and manufacturing

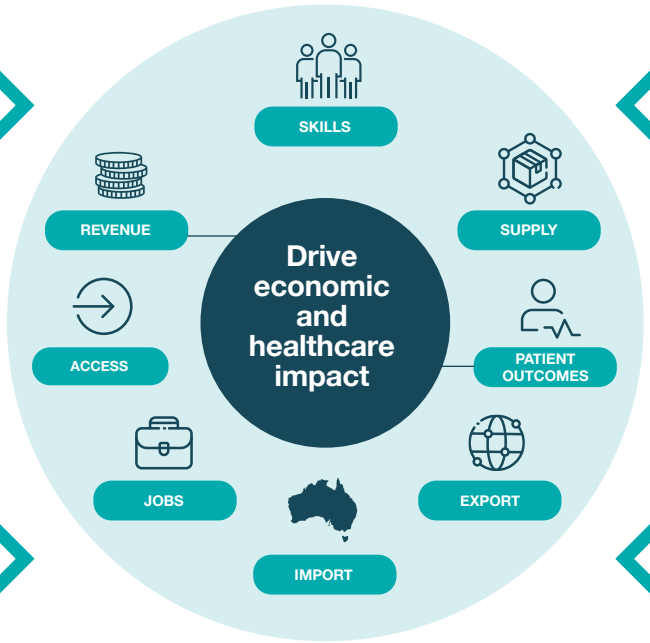
Upstream Economic Impacts

Sustainable strategic partners

Global market for IVDs is robust and projected to grow to approximately AU$150 billion by 2024

Grow and support Australian Businesses

Global instability, emerging health challenges, changing patient preferences will see an increase in Australia's IVD market



Attract and retain global talent

In a lifetime, the average primary skilled independent visa holder contributes 4.68B to GDP

Build and develop local talent

5.9% of additional GDP potential due to upskilling in Australia

Priority

Elevate the role of diagnostics in population health and biosecurity

All priorities outlined in this Action Plan are interdependent and provide support across the full value chain of diagnostics commercialisation. Meeting all priorities is crucial for achieving a fit-for-future, prevention-focused healthcare system in Australia.

But we need systemic change and strong leadership to fully realise the potential of diagnostics including point-of-care testing, genomics, digital diagnostics and syndromic testing and self-care. It is imperative that we focus on embedding these new technologies, and we need to build and retain the necessary capacity, workforce and infrastructure within the Australian healthcare system to support their use.

Existing policies such as the National Medicines Policy do not cover the full scope of the diagnostics ecosystem. The role of diagnostics and their impact on population health and biosecurity should be recognised.

Action 1.1
Build a coordinated Nationwide Diagnostics Policy

Importance: Foundation

Timeframe: 1–2 years

Action 1.2
Establish and legislate a Diagnostics Advisory Council

Importance: Foundation

Timeframe: 1–2 years

Action 1.3
Establish a National Diagnostics Development Centre

Importance: Foundation

Timeframe: 1–2 years

A well-articulated policy with national priorities for research, clinical needs, and commercialisation can guide research efforts to meet population needs and increase the use of diagnostics in population health and biosecurity – thus promoting future sovereign manufacturing capabilities to futureproof Australia's healthcare system. The Advisory Council's collaboration can identify gaps and lead to innovative solutions and partnerships between researchers, industry and government, while the National Diagnostics Development Centre should fund and develop key industry initiatives.

Action 1.1: Build a coordinated Nationwide Diagnostics Policy

Federal, state and territory governments should develop a coordinated Nationwide Diagnostics Policy alongside industry representatives and health system stakeholders. The policy should be legislated and include:

- a vision for the role of diagnostics in Australian population health and biosecurity, including targets for availability and rates of usage
- a mechanism to identify emerging diagnostic products to be prioritised for commercialisation based on clinical needs and sovereign risk
- a mechanism to determine research priorities and clinical needs at a national and/or state/territory level
- a clear plan to develop awareness and expedite the adoption of diagnostics into clinical workflow.

Why is this important?

Looking beyond COVID-19, federal, state and territory governments need to collaborate and take steps over the coming years to futureproof the healthcare system and capitalise on diagnostic innovations and embed and expand diagnostic capability across the system. Taking these steps will set a vision to help drive sovereign manufacturing capacity in Australia. That capacity in turn will boost preparedness and ensure capability is available in a future health emergency. It will also ensure patient safety and overall population health outcomes during 'business as usual' periods.

A One Health approach encompassing human, animal and environmental health is also critical to strengthening Australia's biosecurity measures.

Early detection, prevention and biosecurity should be a primary goal of any healthcare system, and this can only be enabled by access to diagnostic products. Stakeholders identified that Australia is falling behind other developed countries such as the US and the UK. As a consequence, Australian communities do not have the same access to diagnostic tests as citizens of other comparable OECD countries.

> **People will not invest in prevention if you (Australian Government) don't make it a priority.**
>
> – SME

The use of automation and new technologies such as artificial intelligence in Australia's pathology infrastructure has great potential to improve health system efficiency while maintaining patient safety. By reducing the scope for human error with technology, the system can free up workforce capacity to operate more productively elsewhere in the sector. This process of rationalisation is the key to modernisation and to delivering a national step-change in patient safety outcomes. However, realisation of these benefits is not certain unless there is coordination of efforts and support for such future-focused and leading-edge technologies.

The recently revised National Medicines Policy 2022 focuses on diagnostics as they relate to the use of medicines. The proposed Nationwide Diagnostics Policy will cover the full scope of diagnostics including prevention, diagnosis and monitoring.

> **Australia is unlikely to ever be a manufacturing powerhouse (for diagnostic technology) but we don't need to be. We should figure out what the best return on investment is in our healthcare system because it is important to have access to innovation.**
>
> – Multinational

PRIORITY

Action 1.1: Build a coordinated Nationwide Diagnostics Policy

How to implement

A coordinated Nationwide Diagnostics Policy will establish a shared vision for Australia's diagnostics ecosystem. This will create alignment on the goals and targets for this sector over the long term, and identify the strategic initiatives required to achieve these goals. This policy will therefore provide a constant reference point for industry participants and policymakers to help guide prioritisation of resources and policy over time.

The policy will bring together stakeholders from across the diagnostics industry, including the public and private sectors. These stakeholders will co-create a set of measurable goals and targets that will 'define success' over the next five to 10 years. The policy will then identify the strategic priority areas for change in order to achieve these goals, including areas of emerging clinical need, and emerging research or technologies that would benefit from accelerated commercialisation.

To fully realise the benefits of increased availability and utilisation of diagnostic technology, careful planning will also be required in three key areas of reform: primary care, secondary care and pathology networks. The planning will require detailed consideration of how to maximise the potential of diagnostics in both population health and Australia's biosecurity, and how to educate and support healthcare professionals to expedite the adoption of diagnostics into clinical workflow. This could be through educating or incentivising healthcare professionals and the broader healthcare system who adopt these technologies.

The Nationwide Diagnostics Policy will also require prioritisation and a concerted program of education, support and promotion to ensure that take-up across the country is sufficient to deliver the systemic shift in patient safety outcomes, and a prevention-centric healthcare model. This effort should be a core component of the Nationwide Diagnostics Policy, which should be the vehicle to plan, articulate and deliver this shift. In the process of formulation, the Nationwide Diagnostics Policy should be cognisant of current legislation, programs and initiatives to ensure there is no duplication.

A well-articulated policy with clear national priorities for research, clinical needs and commercialisation will guide research efforts and ensure that diagnostic testing is meeting the needs of the population. A critical materials list should also be included and adapted regularly, or this can be aligned with the Office of Supply Chain Resilience. Making these priorities and needs transparent will underpin future sovereign manufacturing capabilities.

> EXAMPLE

Australia is in a unique position to lead the way in next-generation sequencing (NGS) for diagnostics. But Australia lacks the system-wide support needed to fully develop this technology.

We need to create a clear role for NGS in the Nationwide Diagnostics Policy.

We need to create a stable regulatory environment for NGS-based diagnostics. A local ecosystem also needs to be established with the involvement of research institutions, diagnostic companies, technology providers and other stakeholders to attract investment and expertise. Creating this environment will allow policymakers, funding bodies and private companies to speed up the development of artificial intelligence-supported diagnostic products and establish a foothold in the market before larger companies enter en masse.

Action 1.2: Establish and legislate a Diagnostics Advisory Council

Establish and legislate a multidisciplinary Diagnostics Advisory Council (including domestic and international healthcare professionals, pathologists, health economists, epidemiologists, researchers and industry representatives) to:

- build and embed a deeper and more connected diagnostics ecosystem in Australia (including consumer advocacy groups, rural health and peak bodies)
- advise on developing and implementing a Nationwide Diagnostics Policy (Action 1.1)
- develop awareness and assist in expediting the adoption of both existing and emerging diagnostics into clinical workflow, aligning with the Nationwide Diagnostics Policy (Action 1.1)
- initiate industry forums to raise problems, remove barriers and collaborate on solutions
- highlight and showcase success stories
- open discussions and build regular communications with the Australian Government to highlight the benefits of emerging diagnostic technologies and industry trends
- review processes for regulation and reimbursement to ensure these are futureproofed, and capable of capturing the full economic and social benefits of early adoption of future-focused and innovative diagnostic technologies
- communicate and collaborate with the proposed Australian Centre for Disease Control (ACDC), Department of Defence and representatives from states and territories.

Why is this important?

Establishing and legislating a multidisciplinary Diagnostics Advisory Council (Advisory Council) can help in building and connecting the diagnostics ecosystem in Australia.

A range of stakeholders now undertake important work across the ecosystem. But the sector remains siloed or is absorbed into the medical device sector. Few forums exist that map the specific activities occurring across the sector from a centralised vantage point.

This means, in turn, there are fewer mutually beneficial connections established between companies and researchers working in similar or complementary areas. Further, compared to other more established sectors there are limited opportunities to consolidate the views of the sector, and provide a single, shared voice to the Australian Government. Finally, in line with Action 1.1, there is a need to develop a policy which can only be done by bringing together stakeholders with perspectives and visibility across the entire diagnostics ecosystem in a single forum.

How to implement

The Advisory Council will require representation from across the diagnostics sector and given the impact on population health, the Australian Department of Health and Aged Care would be well placed to lead this initiative. A process should be established for individuals to be nominated by the Australian Government, followed by a consultation period and selection of the final Advisory Council membership.

The Advisory Council will then convene at regular intervals (e.g. monthly or quarterly) and will also establish points of regular engagement with the broader industry (e.g. forums and open meetings) and key public sector bodies.

By bringing together experts with diverse backgrounds, areas of expertise and perspectives across the supply chain, the Advisory Council can help to identify gaps and opportunities within the diagnostics industry and promote collaboration among stakeholders to address key issues. This can lead to the development of innovative solutions, the creation of new business models, and the establishment of strong partnerships between academia, industry and government.

The Advisory Council will also communicate and collaborate with the ACDC, Department of Defence and representatives from states and territories to ensure a holistic and coordinated approach to addressing key issues within the diagnostics industry and the nation's health security.

Action 1.3: Establish a National Diagnostics Development Centre

Establish a National Diagnostics Development Centre, run by an independent entity with national reach, that is responsible for:

- **creating and managing digital National Resource (Action 2.1) and a National Network Alliance (Action 3.2)**
- **funding diagnostic commercialisation and manufacturing through a Diagnostics Manufacturing Fund (Action 2.5)**
- **enhancing the diagnostics technology workforce (Action 3.1) by funding development and training programs to address identified skills gaps.**

Why is this important?

Establishing a National Diagnostics Development Centre is crucial to consolidate and coordinate efforts related to industry initiatives. The industry initiatives that the National Diagnostics Development Centre is responsible for will ensure that industry professionals have the skills, capability and knowledge to develop, commercialise and market diagnostic products. The importance of each initiative alone is described within the corresponding actions (see Action 2.1, 2.5, 3.1 and 3.2).

Instead of having multiple entities working independently to achieve the specific industry actions, a single National Diagnostics Development Centre can consolidate efforts, resources and expertise towards achieving the same objective. This avoids duplication of efforts and streamlines the development, commercialisation and accessibility of diagnostic technologies.

A National Diagnostics Development Centre can also provide a common platform for researchers, clinicians and industry players to collaborate and share knowledge and resources, leading to improved outcomes.

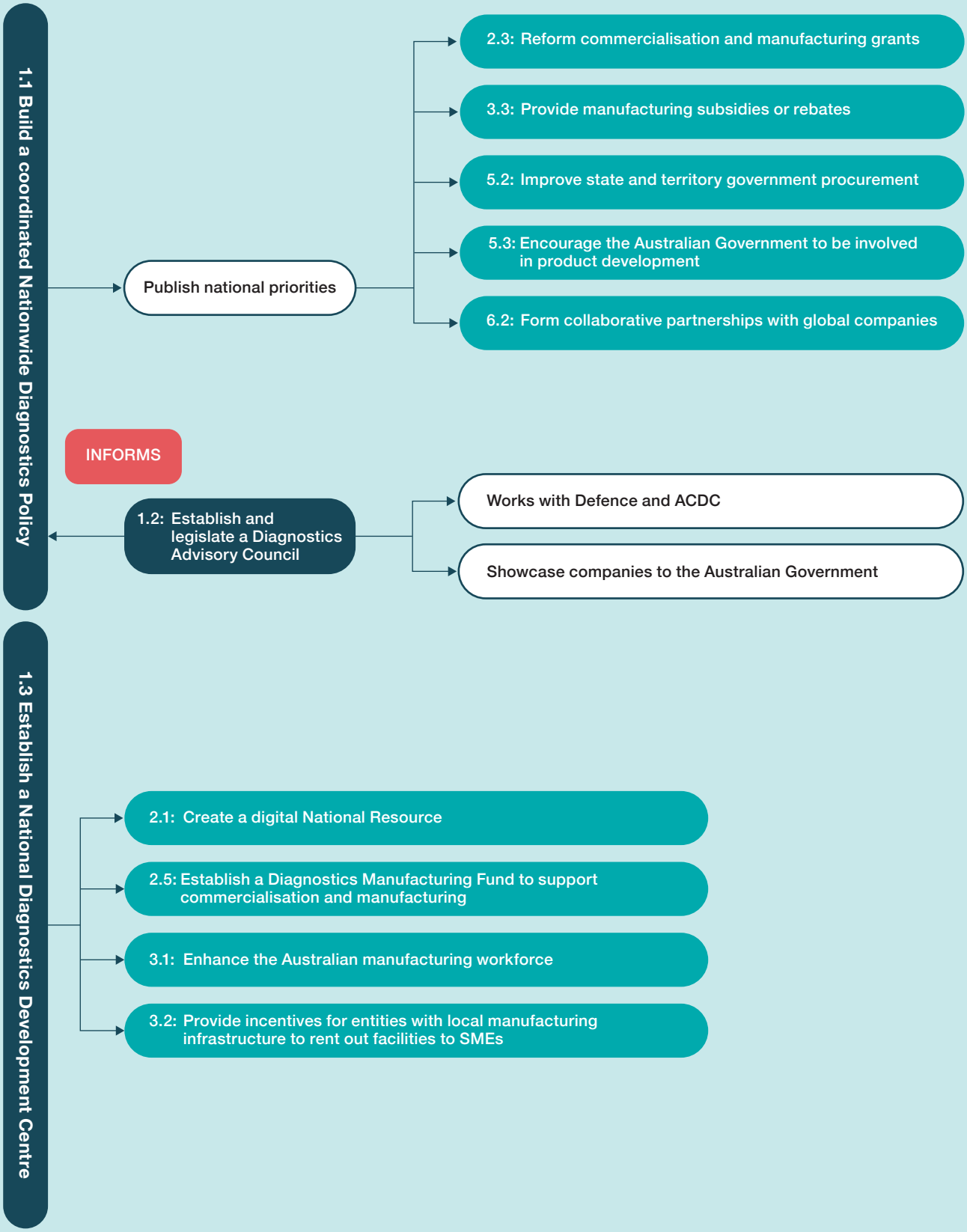
How to implement

Implementing a National Diagnostics Development Centre requires a strategic approach that involves multiple stakeholders, including healthcare professionals, pathologists, health economists, epidemiologists, researchers, industry representatives, commercialisation experts and government officials.

A governance structure could also be established by the Australian Government that provides clear leadership and accountability for the National Diagnostics Development Centre's activities. This could also involve setting up a steering committee comprising stakeholders with relevant expertise and experience in diagnostic development, commercialisation and accessibility.

The National Diagnostics Development Centre would require a sustainable funding base to provide certainty for ongoing initiatives.

Figure 3: Overview of the link between Action 1.1, 1.2 and 1.3 and key actions within the National Action Plan



Abbreviations: ACDC (Australian Centre for Disease Control); Defence (Australian Department of Defence)

Priority

Accelerate and support commercialisation and translation

Innovation and research are essential for driving economic growth and productivity. While Australia excels in producing high-quality foundational research, there are currently issues with translating and commercialising these innovations. Reasons for this include universities prioritising scientific publications over commercialisation outcomes, a lack of collaboration between industry and research, a scepticism of commercialisation organisation motives as well as misalignment between university research and both federal, state and territory governments procurement priorities. This results in challenges with obtaining investment as biotechnology (including diagnostics) is high risk, particularly in the early stages. This limits the impact of our universities and reduces the return on investment from publicly funded research. By investing strategically and implementing effective policies, we can learn from local and international commercialisation success stories and achieve stronger results.

Action 2.1
Create a digital National Resource

Importance: Driver

Timeframe: 2–4 years

Action 2.2
Consider more financial incentives to attract investment

Importance: Driver

Timeframe: 2–4 years

Action 2.3
Reform commercialisation and manufacturing grants

Importance: Driver

Timeframe: 2–4 years

Action 2.4
Ensure equitable access to biological materials

Importance: Driver

Timeframe: 2–4 years

Action 2.5
Establish a Diagnostics Manufacturing Fund to support commercialisation and manufacturing

Importance: Foundation

Timeframe: 2–4 years

Creating a National Resource is intended to support researchers and industry professionals to achieve commercial milestones, such as regulation and reimbursement, by providing accessible digital information, resources and training materials.

Given that the biotechnology industry is regarded as having a relatively high level of investment risk, introducing financial incentives should encourage more national and foreign investors into the diagnostic industry. In addition, reforming commercialisation and manufacturing grants will support researchers and SMEs through the 'valley of death' as well as make Australia a more attractive place to manufacture. This can also be achieved by establishing a Diagnostics Manufacturing Fund, for SMEs developing critical diagnostic technologies.

Furthermore, ensuring equitable access to biological material, such as controls and samples within the CSIRO Australian Health Biobank, will facilitate discovery breakthroughs and adapt to pressing clinical needs across industry.

Action 2.1: Create a digital National Resource

Create and promote a digital National Resource (information portal) for diagnostics as a key service of the National Diagnostics Development Centre (Action 1.3) to:

- develop a digital knowledge resource and training materials covering intellectual property (IP) frameworks for collaboration, logistics, tax, reimbursement, regulation, quality management system (QMS) and venture capital support. Resources and training for diagnostic regulatory applications could also be developed in collaboration with the TGA
- define a resource list of available national and state/territory grants
- identify and raise awareness of the National Network Alliance of available manufacturing facilities within industry and academia able to lease their infrastructure (Action 3.2), and to provide services to early-stage companies
- identify available clinical trial partners, biobanks and testing facilities that could be paired with early-stage companies to build technical files and validation data
- include a curated list of industry partners, companies, peak bodies, logistic services, local export services and other contacts for commercialisation
- organise supported regular pitch opportunities with investors interested in investing in Australian-made diagnostics.

Why is this important?

While Australia is recognised as one of the leading countries for innovation, many companies require guidance through the 'commercialisation valley of death'. Stakeholders highlighted this is because the diagnostic industry has a slow path to market due to a complex regulatory and reimbursement environment and challenging public procurement process.

Thus, there is high demand for digital resources and training materials that support researchers and industry professionals with each commercial milestone – research and development, logistics, manufacturing, regulation and reimbursement, procurement and sales and services.

> **An industry playbook detailing what needs to happen [...] would be useful.**
>
> – Australian SME

How to implement

The National Resource would be a key service of the National Diagnostics Development Centre (Action 1.3).

As highlighted by stakeholders, resources must include information on collaboration while managing intellectual property, commercialisation activities, clinical trials and ethics, manufacturing support, federal and state/territory grants and funding, and tenders and procurement.

Promoting and building awareness of the National Resource is key to ensuring its contents and available opportunities are known throughout the diagnostic sector.

> EXAMPLE

National Freight Data Hub

Funded by the Australian Government, the National Freight Data Hub is a data-sharing network for industry, government and others to improve the efficiency, safety, productivity and resilience of the freight sector.

The hub has three primary functions:

- **improve access to government data**
- **facilitate data exchange**
- **enable collaboration between freight data users.**

Source: (Australian Government, n.d.).

PRIORITY

Action 2.2: Consider more financial incentives to attract investment

Consider further tax or other financial incentives to encourage national and foreign investors and companies to invest in Australian-made diagnostics.

Why is this important?

The biotechnology sector in Australia is regarded as having a relatively high level of investment risk, especially when compared to the US. According to stakeholders, key reasons for this include:

- Australia has a small market and therefore a smaller return on investment
- International investors perceive Australia as too expensive
- Investors want a return on investment within three years
- Limited manufacturing infrastructure suggests the diagnostic ecosystem is still developing
- Low reimbursement for diagnostics can limit adoption
- Research activities are considered conservative in Australia, as academics can be afraid to fail
- Stringent regulation requirements for biotechnology companies

Therefore, limited local and foreign funding is available for the design, development and production of diagnostic technologies. This can have a significant impact on researchers and Australian SMEs, who rely heavily on external financial investment to commercialise their technologies. For those who do not receive government grant funding, this is even more important.

> **Getting access to venture capital is where a lot of people fall over. While Australia's venture capital market is maturing, we are still ridiculously risk adverse compared to the rest of the world.**
>
> – Australian SME

How to implement

Tax and other financial incentives are a way to encourage more national and foreign investors into the diagnostic industry. However, there are currently no active incentives in Australia that specifically aim to attract national and foreign investors, including venture capital to the diagnostic sector.

Of note, and well favoured by stakeholders, is the Research and Development Tax Incentive, but this is directed at providing offsets to companies that undertake R&D activities in Australia rather than manufacturing. Furthermore, MTPConnect delivers grant programs that support diagnostics companies, but they are not targeted specifically at diagnostics innovation and translation.

> **You end up with this vicious circle of needing the funding to de-risk the process, but the likely funding sources want the de-risking before they will release the funding.**
>
> – Researcher

The Australian Government has previously supported tax or other financial incentives in other phases of product development, such as the Early Stage Innovation Company scheme, which aimed to improve investment in early-stage innovation (e.g. start-ups) (The Treasury, 2016). This scheme provided investors with a 20 percent non-refundable tax offset on the investment amount (The Treasury, 2016).

Another option would be to structure future investor incentives in a similar way to the £300 million UK Enterprise Capital Funds program and the £50 million Business Angels Co-Investment Fund, both targeted at SMEs. These schemes have successfully supported many venture capital opportunities and subsequently the growth of companies and innovation (Department for Business Innovation and Skills, 2011).

Action 2.3: Reform commercialisation and manufacturing grants

Provide and reform commercialisation and manufacturing grants to include:

- research projects aligned with the priorities in the Nationwide Diagnostics Policy (Action 1.1)
- a stronger evaluation of the proposed product commercialisation potential for researchers and SMEs
- collaboration and technology transfer requirements between companies and universities. This should be managed by addressing IP considerations
- exit clauses for the grant awardee allowing for the discontinuation of funding
- dedicated grants for SMEs at scaling stage, including appropriate grant conditions relevant to the size of the company
- detailed feedback for unsuccessful applicants to improve future applications.

Why is this important?

Researchers and SMEs in diagnostics explained there are limited grants dedicated to support commercialisation and manufacturing. Specifically for commercialisation, grants are heavily weighted towards early-stage research, and many do not encourage or incentivise research-industry collaboration. This contributes to Australia's inability to bridge the so-called 'valley of death'. For manufacturing, stakeholders reported that it is extremely expensive to manufacture in Australia – especially due to labour, set-up (such as clean rooms) and operation costs – and that there is not enough grant funding available to support the high levels of investment required.

Grant application and reporting requirements were frequently identified as common challenges among SMEs, as these smaller companies often do not have the resources to support grant applications.

> **Applicants are spending more than 50 percent of their time applying for funding when they should actually be working on their research or product development.**
>
> – Government agency

In addition, the structure of grants was a commonly reported issue. For example, having the same grant conditions for larger companies as well as SMEs ultimately penalises the latter, as many of the grant specifications or requirements that are appropriate for companies with >400 employees are not relevant for companies with five employees. Therefore, many SMEs in need of funding are losing out on grant opportunities. For those who are unsuccessful, feedback on application strengths and weaknesses is infrequently provided, which limits their ability to improve future applications.

How to implement

Federal and state/territory grant structures and reporting requirements are significant barriers for SMEs. Governments should reform commercialisation and manufacturing grants to ensure they are fairly structured, incentivise researcher-industry collaboration, provide unsuccessful applicants with adequate feedback and include exit clauses for the grant receiver to discontinue funding if they are not able to meet key set milestones.

In addition, there could be more commercialisation granting programs focused on later-stage projects, to complement existing schemes focused on early-stage research. An increased emphasis on supporting emerging diagnostic products that address sovereign capabilities would also be beneficial (Action 1.1). Furthermore, late-stage (technology readiness level 5+) activities such as regulatory approval, reimbursement, manufacturing and quality systems management should be focused on to ensure there is funding for key commercial milestones and the required resources to support commercialisation.

Action 2.4: Ensure equitable access to biological materials

Ensure equitable access to biological materials, such as blood or biopsy samples and control measures, for both diagnostic industry and researcher members, and establish a mandatory portion reserved for high-risk, high-potential research.

Why is this important?

Biobanks collect, process and store biological materials (plant, animal, or human), which can contain specimens such as cells, blood, urine bone or hair (CSIRO, n.d.). It is vital that researchers and companies have access to these materials to facilitate the research, development and validation of diagnostic products.

Currently, Australia does not have a centralised national biobank; however, the Department of Health and Aged Care has now provided funding to the CSIRO for the development of the Australian Health Biobank (AHB) (CSIRO, n.d.).

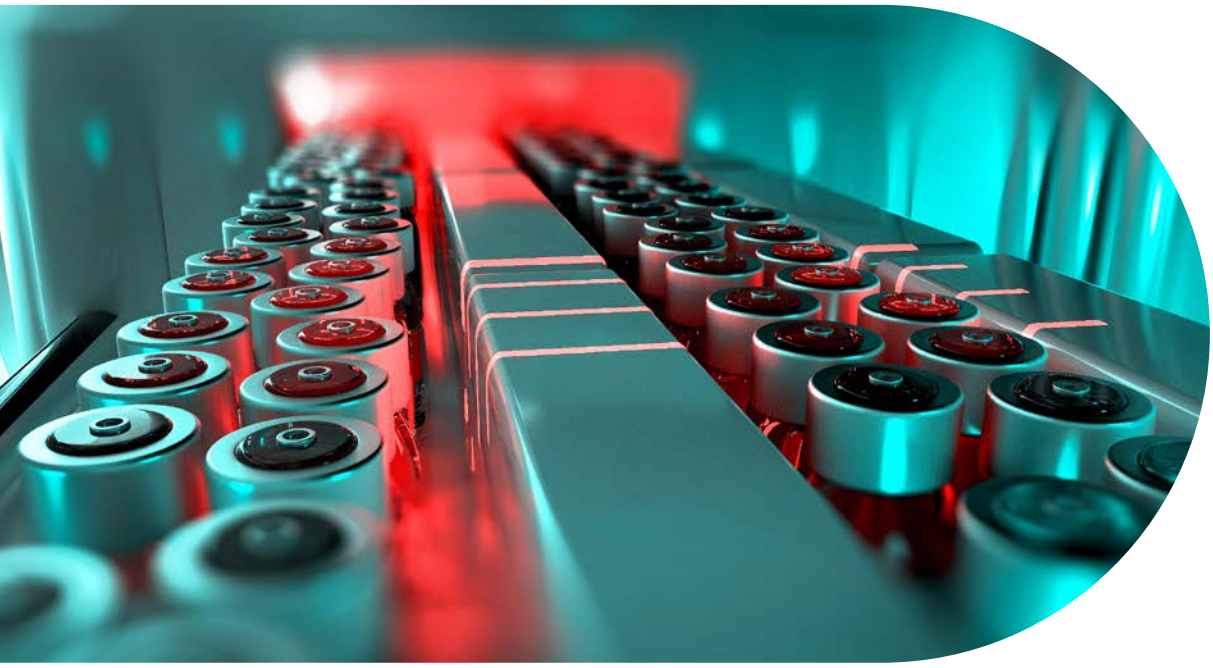
Until the AHB becomes operational, researchers and SMEs will still be reliant on accessing samples and controls from pathology laboratories, universities or international biobanks, which has historically proven challenging. Domestically, stakeholders have described how accessing samples and control materials from laboratories or universities is almost impossible, because of strict ethics requirements and low availability. As a result, researchers and SMEs are forced to buy materials from overseas. Importing samples and controls presents a risk to Australia's biosecurity and therefore many researchers and companies have faced customs challenges when trying to obtain materials from international biobanks. These challenges were experienced during COVID-19 and the 2022 monkeypox outbreak.

Australia is therefore left with limited or delayed access to the biological materials required for research and has a reduced capability to develop and validate diagnostics tests. In the event of another disease outbreak, this would present a major risk for Australia's health and security.

How to implement

Once the AHB is operational, researchers and SMEs should have secure access to a portion of the stored biological materials, to reduce reliance on state biobanks, pathology laboratories and universities. This is particularly true for high-risk, high-potential research, as improved access will facilitate discovery breakthroughs. However, even with the national biobank in place, SMEs will continue to encounter challenges when developing disease-specific tests without equitable access.

Equitable access could be achieved by reserving a mandated portion of the AHB biological samples and controls for SMEs; this would be stipulated in the Nationwide Diagnostics Policy (Action 1.1). This is not expected to negatively impact researcher groups, as they do usually have easier access to samples through their universities.



Action 2.5: Establish a Diagnostics Manufacturing Fund to support commercialisation and manufacturing

Establish a dedicated Diagnostics Manufacturing Fund to support diagnostic translation, commercialisation and manufacturing, to be managed and operated by the National Diagnostics Development Centre (Action 1.3). The fund would:

- develop a national assessment model and pathway for future-focused and innovative diagnostic technologies without a clear path to market
- evaluate, assess and fund the commercialisation of diagnostic innovations and products in alignment with national priorities (Action 1.1)
- be supported by a diverse, independent evaluation group including industry, commercialisation experts, research and healthcare professionals to assess applications and award funding. The fund should be linked to:
  - conditional reimbursement (Action 4.3)
  - procurement orders from state and territory governments (Action 5.2) if milestones are met
- include a focus on later-stage projects and ensure support is provided for regulation, reimbursement and manufacturing
- collaborate with the Diagnostics Advisory Council (Action 1.2) to showcase successful applicants to the Australian Government.

Why is this important?

Our analyses show that researchers in the field of diagnostics generally lack the translation skills required for technology transfer and to successfully commercialise their research. Stakeholders described this as a multifunctional problem, driven by several factors:

- Grants are heavily weighted towards early-stage research
- TGA/MSAC requirements are viewed as hindering Australia's access to diagnostic technologies
- There is limited funding and incentives to manufacture in Australia
- There is a disconnect between the R&D Tax Incentive and procurement
- Researchers do not have the skills to determine the market potential of new products

Thus, there is a need to provide more support to researchers, universities and companies to take innovations to market.

PRIORITY

Action 2.5: Establish a Diagnostics Manufacturing Fund to support commercialisation and manufacturing

How to implement

To adequately support the commercialisation and manufacturing of diagnostic technologies identified as critical to Australia's national interest (Action 1.1), the provision of adequate funding is key, particularly to support the later-stage activities.

Establishing a dedicated Diagnostics Manufacturing Fund would enable the findings of diagnostic research to be adequately translated into commercial products, rather than remaining within the research and university environment. The National Diagnostics Development Centre (Action 1.3), operated by an independent organisation experienced in deployment of granting programs, should establish and manage the fund.

> **The government needs to be willing to adopt Australian products. If your own country does not want it then the rest of the world is simply less interested.**
>
> – Multinational

To ensure the funding stream addresses the current system gaps and identifies future opportunities, its creation should be accompanied by the establishment of an independent evaluation group comprised of a diverse range of sector experts. This group should be identified by the National Diagnostics Development Centre and be independent from the Diagnostics Advisory Council (Action 1.2). Nonetheless, these groups should work in collaboration to ensure technologies funded through the Diagnostics Manufacturing Fund align with the Nationwide Diagnostics Policy (identified in Action 1.1).

Operating within a robust governance framework, the Diagnostics Manufacturing Fund evaluation group would support the assessment of applications, funding decisions and ensure a focus on the Nationwide Diagnostics Policy priorities is maintained.

Successful applications and products funded through this initiative should be showcased to the Australian Government, to improve awareness about the importance of developing cutting-edge diagnostics for the future of healthcare and about the crucial role they play in ensuring these technologies are procured in the domestic market. This should be done in collaboration with the Diagnostics Advisory Council (Action 1.2).

CASE STUDY

AVICENA

Scaling Local Manufacturing for Global Impact in Biosecurity: Avicena Systems

Australian company Avicena Systems developed the Avicena Sentinel, a revolutionary diagnostic instrument which is capable of rapidly detecting pathogens like COVID-19 and influenza using saliva and nasal samples. The instrument, listed on the Australian Register of Therapeutic Goods (ARTG), processes over 90,000 samples per day, delivering results in under 45 minutes, making it crucial for rapid pandemic response efforts.

Initially, Avicena Systems faced grant-related challenges in commercialising its product but overcame them by raising private funds and building partnerships with prestigious research entities like the Perron Institute, The University of Western Australia, and Curtin University. These collaborations have helped expand Avicena's capabilities.

"Linking innovators and people that are trying to build businesses and be able to get access to those types of entities at a reasonable cost is valuable."

In 2021, Avicena Systems secured $3 million funding through Round 1 of the Modern Manufacturing Initiative (MMI) Translation and Integration streams to upscale the Sentinel automated pathogen screening system. Manufacturing of the system takes place in Perth. The scalability of Avicena Systems' products holds significant potential for generating export earnings.

To further scale up manufacturing in Australia, Avicena Systems adopts a consortium approach, partnering with local specialists and larger multinationals to present integrated biosecurity solutions to clients. This approach addresses three key challenges in securing large contracts with global clients. Firstly, it ensures greater supply chain resilience by engaging key suppliers from the bidding phase. Secondly, Avicena Systems benefits from the partners' expertise in navigating complex regulatory processes and obtaining necessary clearances to contract with foreign government departments. Lastly, the integrated consortium approach simplifies coordination and contracting with multiple suppliers, providing clients with a streamlined diagnostic program at scale.

Avicena Systems is in discussions with a global diagnostic reagent supply company to provide a comprehensive solution for rapid testing on a large scale. They also aim to involve a local consumables supplier through subcontracting to offer an integrated solution. The consortium-based approach enhances credibility and assures a reliable supply for government clients.

Avicena Systems' innovative efforts and strategic partnerships position them as a key player in the global diagnostic industry, providing rapid testing solutions with credibility and assurance of supply.

> **It's challenging for an Australian startup with limited capital and lacking approved tender lists or security clearances to pitch to overseas entities like the Ministry of Defence. That's why we are pursuing a consortium approach.**

Priority

Establish Sustainable Sovereign Manufacturing

Building and retaining sustainable manufacturing facilities for diagnostics in Australia is crucial to ensure the necessary equipment and resources are readily available for the production and distribution of diagnostic products. Having a domestic manufacturing capability means greater control over the supply chain, which can improve the security and reliability of diagnostic technologies and ensure critical products are available to the healthcare system when they are needed. Retaining these facilities also provides jobs and stimulates the domestic economy. In recent decades, a major challenge for potential manufacturers has been the high costs of establishing and maintaining local infrastructure, which can be prohibitive for SMEs, particularly if the federal, state and territory governments – the main purchasers of diagnostics – are not procuring them. To ensure this resource and capability is effective, demand signalling from national priorities set by federal, state and territory governments will ensure there is a cohesive and focused approach to manufacturing.

Action 3.1
Enhance the Australian manufacturing workforce

Importance: Driver

Timeframe: 1–2 years

Action 3.2
Provide incentives for entities with local manufacturing infrastructure to rent out facilities to SMEs

Importance: Foundation

Timeframe: 2–4 years

Action 3.3
Provide manufacturing subsidies or rebates

Importance: Foundation

Timeframe: 2–4 years

Australia can take decisive action to encourage the establishment, maintenance and expansion of new and existing facilities for late-stage companies that need to scale up. This will ensure that the necessary equipment and resources are readily available for the production and distribution of critical diagnostic products. To support the growth of domestic manufacturing facilities, Australia must secure skilled professionals with expertise in manufacturing through both domestic and international initiatives. Coupled with incentivising entities with local manufacturing infrastructure to lease their facilities, SMEs will no longer need large capital investment to commercialise and scale up critical diagnostic products. With these measures in place, the necessary equipment and resources will always be readily available for the production and distribution of diagnostic products, even in emergencies, times of uncertainty or high demand.

Action 3.1: Enhance the Australian manufacturing workforce

Enhance, attract, and retain the skills and capabilities of the Australian manufacturing workforce through the following initiatives:

- domestic: Secure the availability of workforce development and training programs with industry backing and funding from the National Diagnostics Development Centre (Action 1.3).
- international: Create further incentives within the visa framework to attract and retain skilled professionals with expertise in areas such as manufacturing, quality management, regulation and reimbursement.

Why is this important?

A common challenge for local diagnostic technology stakeholders exploring the establishment of domestic manufacturing facilities is access to capable personnel. The high-tech nature of the diagnostic manufacturing sector requires a skilled workforce in areas such as manufacturing, quality management, regulation and reimbursement, which stakeholders report is often difficult to access in Australia.

MTPConnect's Researcher Exchange and Development within Industry (REDI) initiative (MTPConnect, 2021) conducted a root-to-branch skills gap analysis, which confirmed that there are four key skills gaps in advanced medical products manufacturing and biosecurity capabilities, including shortages of workers with practical knowledge of Good Manufacturing Practice, technical experts in commercial-scale process design and regulatory requirements, awareness of the range of different skills required for commercialisation, and staff with computational skills for drug and vaccine development.

In addition, five other skills gaps were also identified, such as a lack of expertise in supply chain planning and handling and analysing big data.

Through REDI, MTPConnect is funding new training programs addressing identified gaps, providing industry experiences and skills development for researchers, clinicians, medical technology and pharmaceutical sector professionals and innovators and working to develop an industry-ready workforce with the skills necessary to keep pace with a rapidly changing sector.

While this and other initiatives to build business capability and strengthen the resilience of start-ups are making a difference, additional diagnostic commercialisation training and resources would support Australian companies for ongoing success.

> **Being able to establish manufacturing really comes down to the people. We have found some great people but not enough of them.**
>
> – Australian SME

PRIORITY

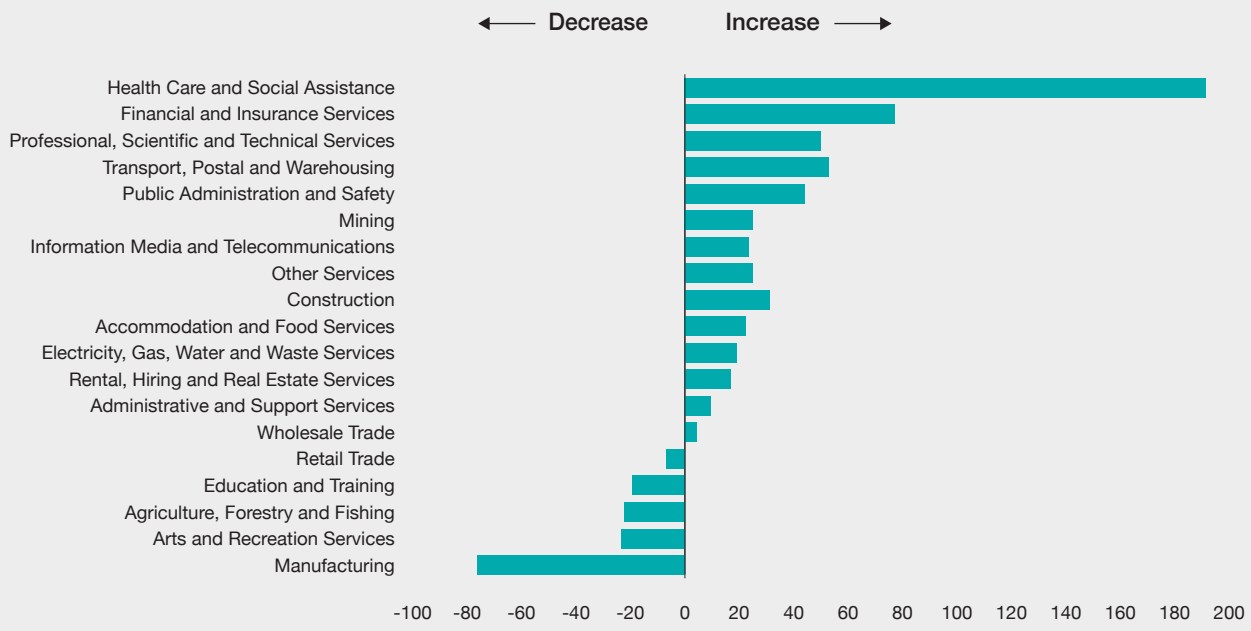
Figure 4: Key skills gaps to support advanced medical manufacturing and biosecurity capabilities

Source: MTPConnect (2021).

Vocational education and training qualifications data also shows a long-term decrease in the number of completions of courses relevant to diagnostic manufacturers (Figure 5). Simultaneously, the manufacturing industry is suffering a shortage of workers driven by the ageing and retirement of its workforce. This workforce is one of the oldest of any sector in Australia with an average age of 42 (based on data from 2018), which is two years older than the average of the overall Australian workforce. Between May 2021 and May 2022, manufacturing saw the largest decrease in employment of any industry in Australia, with a 79,500 decrease in the number of people employed. This creates a challenge for growing subsectors, such as diagnostics manufacturing, to attract and retrain workers exiting the broader manufacturing industry.

Action 3.1: Enhance the Australian manufacturing workforce

Figure 5: Employment growth by industry ('000s persons) – May 2021 to May 2022



Source: National Skills Commission (2022).

How to implement

To foster a sovereign diagnostic manufacturing ecosystem, incentives will be required to reverse these negative trends across the broader manufacturing sector. Courses relevant to long-term growth sectors such as diagnostic manufacturing should be well funded to incentivise individuals to upskill in these areas. Successful, established training programs that address identified skills gaps should continue to be funded.

Additionally, incentives and pathways should be established to encourage individuals from sunset industries, where domestic manufacturing is in decline, to retrain in growth sectors such as diagnostic manufacturing.

Salary subsidies can send a strong demand signal to industry that the federal, state and territory governments are supportive of sovereign manufacturing, while also benefiting the economy more broadly by creating opportunities for on-the-job training and development and reducing the burden of unemployment from people who might otherwise exit industry altogether.

To attract and retain a sustainable manufacturing workforce, Australia's immigration settings should also be optimised to support sovereign diagnostics manufacturing as a strategically important and growing sector. Australia has a nimble skills-based immigration system with the ability to designate priority sectors to meet Australia's short- and long-term requirements. At present, healthcare and teaching occupations are designated as priority categories for new visa applications. However, the specified healthcare subgroups relate to Health Professionals, Health and Welfare Support Workers, Medical Scientists and Medical Technicians (among others). Consideration should be given to the broader manufacturing workforce required to commercialise and scale up sovereign manufacturing of diagnostic technologies in Australia.

With significant Australian Government funding being directed to help scale up sovereign manufacturing capacity in the coming years, including through the NRF, a rapid increase in the available workforce will be required to maximise the full potential output of these facilities. This will necessitate near-term growth in immigration levels of workers with relevant skills and experience in conjunction with longer term education initiatives to upskill domestic workers. Workforce support will also be provided through the digital National Resource (Action 2.1).

> CASE STUDY

RHINOMED

The Impact of the Lack of Procurement and Commitment to Local Manufacturing in Australia

Rhinomed, an Australian-founded and head quartered company, developed a revolutionary new nasal swab for sample collection in upper respiratory disease diagnosis, (Covid, flu, etc). The Rhinoswabs' novel anatomically inspired design is the first real innovation in nasal swabs in decades. It standardises the sample collection process for the first time improving the user experience, while delivering the clinical equivalence to a combined nose and throat swab. The ability for people to self-collect using the Rhinoswab significantly reduces the burden on healthcare workers. The company subsequently extended the Rhinoswab design to create the world's first nasal swab designed purposely for children (aged 4+).

The New South Wales Government was the first customer to buy the adult Rhinoswab for inclusion in their testing programs, including the testing of 15,000+ Year 12 students in 2021. The Victorian Government followed and included the adult Rhinoswab in its testing program roll out. The company is now actively involved in rolling the Rhinoswab range out in Rapid antigen tests for Covid and flu in global markets.

In response to both local and global demand Rhinomed invested in the development of an initial prototype manufacturing site in Keysborough, Victoria. The company followed this investment on with the scoping of an $8.9 million local full-scale manufacturing plant, which had the potential of employing upwards of 70 people, would allow the onshoring of manufacturing, build sovereign capability, and strengthen Australia's health security. This project received strong support from the Victorian Government's Department of Jobs Precincts and Regional Development, and Rhinomed was offered $1.8 million of support (20 percent of the project).

However, the company made it clear that the project was dependent not on the receipt of grants but rather on either the federal or state Government committing to purchase the swabs that the facility would manufacture. Sadly, despite the Victorian Department of Health acknowledging multiple benefits, superiority, and significant health economic savings of the Rhinomed swabs, there was no appetite from either Federal or State Governments to buy or support these locally made products. Today millions of nasal swabs continue to be procured from foreign companies, manufacturing offshore.

As a result, the company has now set up manufacturing of the Rhinoswabs in offshore outsourced manufacturing facilities. While there is an opportunity to onshore manufacturing in the future, the economic incentives available offshore make investment close to global markets compelling.

This scenario highlights a clear disconnect between Government investment and policy in innovation through the R&D tax benefit and innovation grants and the actual procurement choices the Australian Government(s) make. If Government chooses to invest in innovation and the development of solutions to clear unmet clinical needs, it would make sense that the first customer to benefit from this innovation should be the Australian taxpayer.

Action 3.2: Provide incentives for entities with local manufacturing infrastructure to rent out facilities to SMEs

Build a National Network Alliance that incentivises companies and universities with local manufacturing infrastructure to lease out their facilities/laboratories/equipment to support early-stage companies (with guarantees of security and provision of own QMS). This will reduce the investment and resources required for companies to commercialise and scale up their technologies, as well as foster synergy and collaboration (Action 2.1).

Why is this important?

Many stakeholders see a need for alternative manufacturing solutions to help the scale-up period, bridging the gap between ideation and market entry. The capital requirements to establish large, stand-alone facilities dedicated to a new product can sometimes be insurmountable for SMEs prior to demand and order flow being validated.

Stakeholders are supportive of shared manufacturing hubs akin to the Manufacturing Technology Centre (Manufacturing Technology Centre [MTC], 2022) in the UK, a publicly funded manufacturing facility designed for promising SMEs looking to establish early-stage production capacity. While such solutions have worked well elsewhere, stakeholders raised concerns that it may be difficult to provide equitable access to these facilities in Australia given the wide geographic spread of Australia's diagnostic technology sector.

> **For the type of company that we are, we needed laboratory space that wasn't tied into a university or a medical research institute... can we get into that precinct? Is there anyone that's got a lab that's renting out? There's nothing.**
>
> – Australian SME

How to implement

A way to provide a decentralised alternative to these manufacturing hubs is by allocating equivalent funding towards incentives for owners of existing manufacturing infrastructure to share facilities with SMEs instead. Many laboratories and manufacturing facilities have spare capacity but limited incentive today to ensure this is utilised by SMEs that may benefit from it. Governments can help ensure these facilities are opened up to SMEs working on diagnostic technologies by providing both security where an SME seeks to lease third party facilities and subsidies towards ongoing lease costs of these facilities.

BENEFITS

- Improves access for SMEs to manufacturing facilities, equipment, and expertise that they may not be able to fund independently
- Improves utilisation and return on investment for existing manufacturers
- Increases collaboration between SMEs and manufacturing partners fostering the development of new ideas and products
- Sends a strong demand signal to investors to encourage funding of future diagnostic manufacturing infrastructure

During times of emergency, such as pandemics, the Australian Government can also leverage this alliance by utilising the spare capacity present in existing manufacturing infrastructure.

It is important to note that this approach of sharing manufacturing infrastructure with SMEs can only be successful if universities and other owners of such facilities are incentivised to offer their facilities at a competitive rate that start-ups can afford. Without such incentives, start-ups may not be able to utilise the spare capacity in existing facilities, and the benefits of decentralisation may not be fully realised.

This initiative should be the responsibility of the National Diagnostics Development Centre (Action 1.3).

> **Those opportunities would be really good if there's a hub established that you can lease for just a couple of days in a month to do some of those pilot production runs from.**
>
> – Australian SME

Action 3.3: Provide manufacturing subsidies or rebates

Implement manufacturing subsidies or rebates covering:

- establishing, maintaining and expanding new and existing facilities for late-stage companies that need to scale up
- environmentally sustainable manufacturing facilities and processes
- manufacturing of critical raw materials, components and products, as identified by the Nationwide Diagnostics Policy (Action 1.1).

Why is this important?

Given the capital requirements to establish large, standalone facilities can sometimes be insurmountable for SMEs as well as multinationals, prior to demand and order flow being validated, stakeholders raised the need to have subsidies or rebates for later-stage companies to establish, maintain and expand new and existing facilities.

> **We do apply for the R&D Tax Incentive. [...], but there are hardly any manufacturing incentives.**
>
> – Australian SME

How to implement

Various funding initiatives have been established to support medical manufacturing in Australia, such as the NRF. With support from the Western Australian Government, MTPConnect deployed a medical products manufacturing voucher program, which saw more than $1 million injected into Western Australia's medical products sector.

Administered effectively, these programs and others have the potential to transform Australia's diagnostic manufacturing sector and establish the foundations of a sustainable and resilient sovereign supply chain.

While the NRF is still being established and will be administered by an independent board making independent investment decisions, it is noted that priority areas for the $15 billion initiative include medical science and advanced manufacturing.

There are likely to be opportunities to structure investments made under the NRF as public-private partnerships, with the Australian Government being a cornerstone investor in large-scale manufacturing facilities alongside private capital partners and industry participants. As part of these agreements, strategic priorities of Australian Government can be upheld for times of crisis while preserving sound commercial prioritisation during business as usual periods. For example, the Australian Government can preserve the right to utilise facilities (on commercial terms) for the production of critical diagnostics products during emergency periods (e.g. pandemics). This is an important benefit of the diagnostic manufacturing sector as a platform technology that can be rapidly adapted and repurposed for different diseases and conditions.

In general, funding programs should be tailored to ensure accessibility across all segments of the industry, particularly companies in the later stages of commercialisation and early stages of scaling up. Without specific provisions in place to ensure portions of funding pools are allocated to scaling businesses, there is potential that most funding will be received by larger, established players with greater resources to invest in application processes. This may skew funding away from areas where it may have the greatest impact.

Tax incentives similar to those observed overseas (see Figure 6) could be considered to encourage establishment of sovereign manufacturing capacity. Industry stakeholders noted the success of the patent box regime in the UK, which incentivises research and development by applying a lower tax rate to profits derived from IP developed within the country, provided that manufacturing of the ultimate product is retained within the country. It is noted that legislation to establish a patent box initiative in Australia was introduced in 2022 but has since lapsed.

Action 3.3: Provide manufacturing subsidies or rebates

Figure 6: Examples of overseas manufacturing subsidies or rebates

IRELAND

R&D credit
A 25 percent credit on qualifying R&D expenditures; total effective tax deduction of 37.5 percent.

IP regime
Tax deduction for capital expenditure incurred by a company, which is carrying on a trade, on the acquisition of qualifying IP assets.

Exemption for new start-up companies
A corporation tax holiday applies to certain start-up companies that commence to trade between 2009 and 2026.

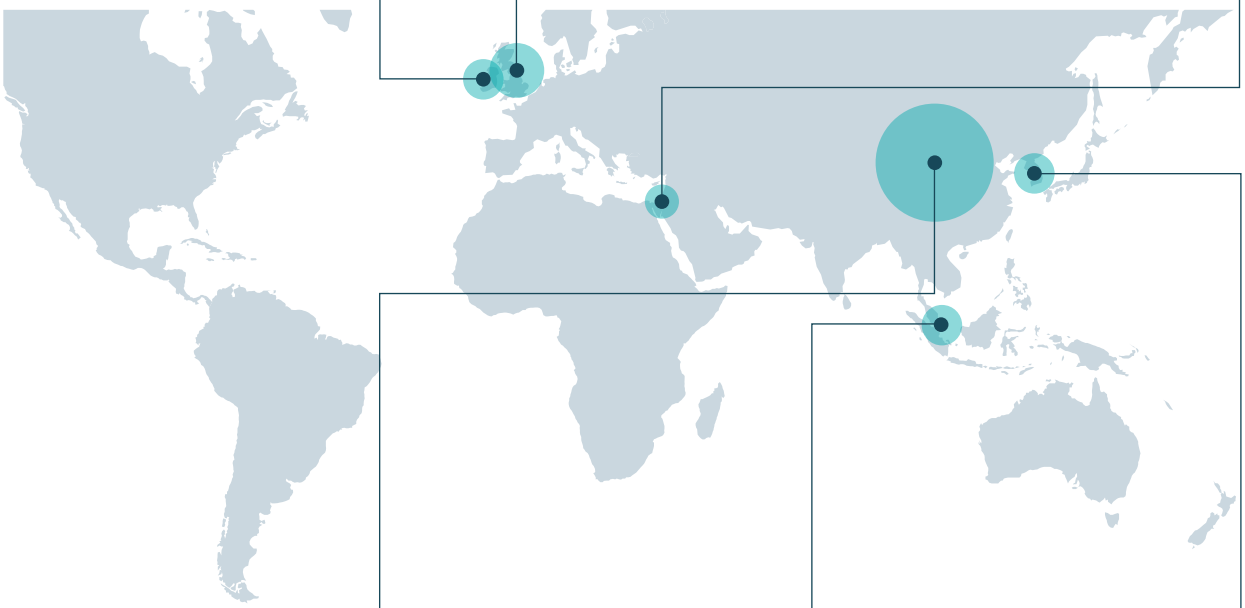
UNITED KINGDOM

Capital allowances
Allow commercial property owners to claim tax relief on capital expenditure (e.g. 'plant and machinery' and immovable items embedded in the property).

Patent box
Manufacturers apply a lower rate of 10 percent corporation tax to profits earned from their patented inventions.

ISRAEL

Encouragement of capital investments law
Provides tax benefits to encourage capital investment and economic entrepreneurship which involve technological innovation and manufacturing activities.



CHINA

Free or reduced cost of land
Local governments offer industrial land for free or at reduced prices to support manufacturing.

SINGAPORE

Investment allowance
Allowance (on top of normal capital) on a percentage of approved fixed capital expenditure.

Integrated investment allowance
Allowance (on top of normal capital allowance) on a percentage of approved fixed capital expenditure to be incurred on productive equipment or any second-hand productive equipment.

Land intensification allowance
Initial allowance of 25 percent and annual allowance of 5 percent on qualifying capital expenditure incurred for the construction or renovation/extension on a qualifying building or structure.

Approved foreign loan incentive
Reduced or nil withholding tax rates on interest payments on loans taken to purchase productive equipment.

SOUTH KOREA

Special tax exemptions for SMEs
A tax deduction of up to 30 percent for SMEs engaged in a qualified business.

Patent box
A 25 percent tax credit for income derived by SMEs and medium-scale companies from the leasing of patents or utility model rights.

Source: Deloitte (2021), Access2Funding (2022), PricewaterhouseCoopers (2023b), PricewaterhouseCoopers (2023a)

Priority

Enhance regulatory and reimbursement support for diagnostics

The TGA is one of the most well-respected regulators of diagnostic tests, medical devices and medicines in the world. While the approval processes maximise the safety and efficacy of products, they also create a barrier for domestic and international manufacturers, who necessarily have to meet stringent criteria early in the product life cycle. Challenges, as reported by stakeholders in the industry, include the lack of regulatory expertise in Australia, inadequate specific regulatory guidance, as well as the high cost of obtaining support from specialised consultants. Additionally, while Australia has a fully funded pathology testing ecosystem and some diagnostics are covered by Medicare, few point-of-care tests are reimbursed or the reimbursement subsidies are often untenably low, with funding directed towards laboratories rather than manufacturers or suppliers. These low reimbursement subsidies have proven to hinder the uptake and adoption of diagnostic tests that could significantly improve population health outcomes. With the current levels of support available to companies, it is difficult to navigate the local regulatory and reimbursement pathways, driving local manufacturers overseas. In turn, this drives companies to focus on building manufacturing capabilities in overseas markets, closer to their primary customers. As key milestones for market access of diagnostic technology, regulation and reimbursement processes require continual review to ensure that they are fit for purpose and improve in future-focused, new technology areas.

Action 4.1
Provide a sustainable funding model for the TGA

Importance: Driver

Timeframe: 1–2 years

Action 4.2
Provide funding for regulatory support

Importance: Foundation

Timeframe: 2–4 years

Action 4.3
Improve reimbursement pathways for diagnostic technologies

Importance: Foundation

Timeframe: 2–4 years

A sustainable funding model for the TGA is essential for maintaining world-class regulatory processes and supporting the diagnostic manufacturing sector. By restructuring the funding model to rely less on fee-for-service applications and increasing government bulk funding, the TGA can better support companies during the application process. Adequate reimbursement pathways for Australian-made diagnostic technologies are also crucial for sector growth. A reformed reimbursement model focusing on value will strengthen the diagnostic market and promote preventative healthcare. By improving reimbursement processes and providing conditional funding for priority diagnostics, Australia can bolster its diagnostic industry and enhance public health outcomes.

Action 4.1: Provide a sustainable funding model for the TGA

The Australian Government should provide a sustainable funding model for the TGA to retain its leadership position in the region and build its expertise and resources to continue to meet future-focused technologies and trends.

Why is this important?

The TGA is required to recover its costs for all activities that fall within the scope of the *Therapeutic Goods Act 1989*. As a result, the TGA currently generates its own funding via a fee-for-service model as well as annual charges imposed on companies with ARTG-listed products. As a result, approximately 92 percent of the costs of the TGA are currently borne by industry rather than government. Although the TGA provides guidance and support where they can, given their resource availability, it is not always possible to meet the needs of stakeholders. Stakeholders report that this is a significant barrier to the TGA being able to operate to its full potential.

Despite average revenue per application increasing from $1,795 to $1,922 over June 2018 to 2021 (Figure 7), the TGA reports increasing difficulties funding its operating costs. This is in part due to recent cost increases as a result of services provided beyond regulatory assessments, which are cross-subsidised through application fees. Public health programs now represent approximately one-third of the TGA's work, but only eight percent of the TGA's funding comes from the public sector.

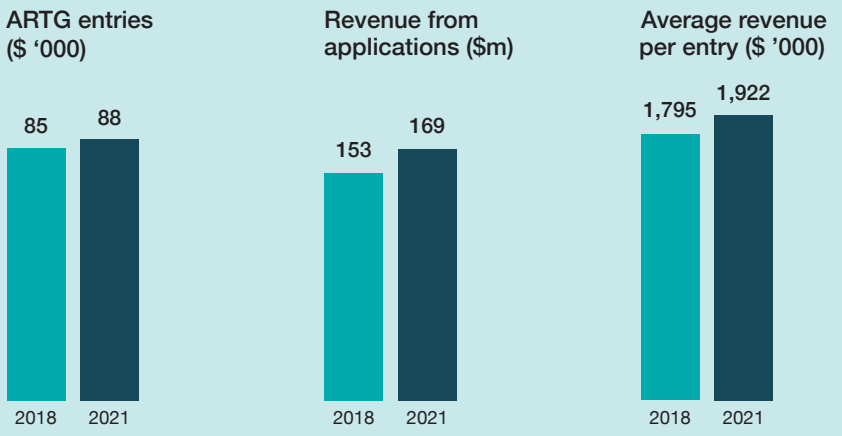
As a result of the limited funding available to the TGA, industry stakeholders also report experiencing lengthy delays in receiving approval and a lack of direct regulatory support both pre-submission and throughout the process.

To address these challenges, Australian Government is proposing to substantially increase TGA application fees for industry, but this will increase costs also for SMEs, creating a further headwind to new product development within Australia.

> **An agile regulator is the enabler of an entire system.**
>
> – International adviser

The scope of services provided by the TGA will continue to evolve over the coming years and, without a structural shift in the TGA's funding model, it will remain challenging for the organisation to uphold its world-class regulatory assessment processes while also avoiding additional costs and delays for applicants.

Figure 7: TGA entries and revenue for all submissions and industry sectors



Sources: Therapeutic Goods Administration (TGA) (2022) and Therapeutic Goods Administration. (2021).

How to implement

Given the public interest in maintaining Australia's world-leading TGA regulatory processes, and its critical role in the medical products ecosystem, the TGA should be funded more sustainably. The funding model should be restructured to significantly reduce the share of funding generated from fee-for-service applications.

The Australian Government should increase the level of guaranteed bulk funding to the TGA, in alignment with other public sector agency funding models and comparable international regulatory agencies, such as the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA). This shift will increase funding certainty for the TGA, enabling greater project-specific funding for initiatives to improve the quality of the submission process for applicants (Action 4.2). By adopting a more sustainable and predictable funding model driven by government rather than industry, the TGA will be empowered to focus more directly on its core regulatory functions rather than on optimising its commercial model.

Establishing a model that supports a more streamlined approval process will increase the ease of doing business in Australia's diagnostic manufacturing sector and foster a more rapid commercialisation cycle, including for future-focused and innovative diagnostic technologies.

Action 4.2: Provide funding for regulatory support

The TGA should allocate a portion of the additional funding received through Action 4.1 to provide additional regulatory support to Australian SMEs. This could be further supported by the National Diagnostics Development Centre (Action 1.3) and the Diagnostics Manufacturing Fund (Action 2.5).

Why is this important?

The TGA's approvals processes are challenging to navigate for researchers and companies seeking ARTG listing, particularly when the necessary guidance and support are lacking. For SME manufacturers with limited funding, the time and financial investment required to apply to the TGA can be challenging. Some may apply in a suboptimal manner, resulting in rejection, delays and costly rework.

The complexity of the application process often necessitates the engagement of private regulatory consultants, which can be prohibitively expensive and create a barrier to applying. To address these challenges, the TGA has established the SME Assist program to assist SMEs, start-ups and researchers in understanding their regulatory obligations. However, this program's scope is relatively limited due to the lack of dedicated funding.

To enhance engagement and communication and provide a suite of resources for Australian SMEs, the TGA could offer more user-friendly content, tailored advice on building technical files and navigating the regulatory process. The TGA could also play a more educative role, giving them the capability to work with, and engage with, industry to provide more comprehensive support for SMEs seeking regulatory approval.

The TGA's work to better engage with industry could be supported by the National Diagnostics Development Centre (Action 1.3) and activities under the Diagnostics Manufacturing Fund (Action 2.5).

> **The system is set up to fail until the technology is deeply valued.**
>
> – Australian SME

How to implement

Funding should be provided by Australian Government (Action 4.1) to enable the TGA to expand its support services. Increasing regulatory support and communication for companies was the most commonly proposed solution among stakeholders when discussing how to improve market access for diagnostic manufacturers. Broader regulatory training support will also be provided through the digital National Resource (Action 2.1).

The TGA should allocate a proportion of the additional funding received through Action 4.1 to increase its pre-submission engagement with companies and provide tailored and actionable advice to help diagnostic manufacturers navigate the ARTG process. For example, it should be easy for applicants to schedule a meeting with a TGA representative and receive advice on matters such as the preferred type of clinical trials and data required. Providing access to such technical advice would streamline the application process, increasing speed to market, deeper transparency and clarity, along with a reduction of cost to market for all parties involved.

The TGA should also consider appointing dedicated Case Managers, whose role would be to provide an interface between the applicant and assessment functions within the TGA. This too would help demystify the application process, particularly for SMEs. These initiatives could be established as standalone programs or alternatively form part of an expanded next phase of the existing SME Assist program.

> **If it's the first time something is going to be made in Australia, having someone from the TGA help you project manage, provide a set of documents to fill in, and provide a quick review of them before you submit them to try and make sure that your application goes through in an expedient fashion – that would be a massive assistance.**
>
> – Australian SME

Action 4.3: Improve reimbursement pathways for diagnostic technologies

The current Australian Government Review of Health Technology Assessment (HTA) should:

- consider streamlined, harmonised and transparent pathways to ensure reimbursement of diagnostics is commensurate with the overall cost of manufacturing diagnostic products
- consider short-to-medium term conditional funding for diagnostics viewed as national priorities (Action 1.1) or funded by the Diagnostics Manufacturing Fund (Action 2.5), to conduct post-market surveillance of value and performance.

Why is this important?

The MSAC is responsible for evaluating medical technologies and services and providing advice to the Australian Government on whether these should be funded under the Medicare Benefits Scheme (MBS).

MSAC was identified as one of the most significant roadblocks to access for many stakeholders, including SMEs, multinationals and researchers. This is concerning, as obtaining adequate reimbursement is key to encouraging development and commercialisation of diagnostic technology creating a sustainable diagnostic market, facilitating a preventative healthcare model, and attracting companies to manufacture in Australia.

> **Australia is falling behind the rest of the world without access to these tests.**
>
> – Multinational

Key issues raised by these stakeholders include:

- the current reimbursement model is outdated and does not always support innovations, due to a focus placed on price rather than value in the assessment
- for reimbursed diagnostic technologies, particularly point-of-care tests, the fee generally does not provide an adequate return on the investment required to manufacture them
- MSAC has onerous application requirements that are resource and time intensive. This often leads to manufacturers not able to submit in the first place.

> **Australian communities don't have the same access to tests that they do in other countries like Canada, like the US, European countries because of the funding barrier.**
>
> – Multinational

A wave of groundbreaking advancements in diagnostic technology is rapidly approaching. This innovation encompasses not only physical testing methods but also the accompanying software. A key trend in these developments is decentralising traditional healthcare models and bringing the laboratory closer to the patient or community, empowering greater consumer control and more integrated care models. As personalised treatments become increasingly important, novel diagnostic products will emerge as the standard, entering the market at an accelerated pace. To ensure the prompt availability, relevance and currency of these tests, it is crucial to establish adaptable and efficient regulatory approval and reimbursement pathways. This will enable Australian patients to benefit from the best domestic and international innovations in diagnostics.

Action 4.3: Improve reimbursement pathways for diagnostic technologies

How to implement

At the time of writing, the Australian Government is reviewing its HTA processes, including MSAC, to improve methods and policy. Key aims of this review include reducing time to access for medical products and services, and ensuring Australia's HTA system evolves with advancements in medical technologies (Department of Health and Aged Care, 2023).

As part of this process, focus should be placed on reforming the MSAC process to include a clear fit-for-purpose pathway for diagnostic technologies, including those that are underpinned by software such as artificial intelligence. This will facilitate earlier adoption of innovation into the clinical workflow.

Skilled, independent experts from industry should be included in the process to advise and evaluate technologies and to build skills and knowledge to inform MSAC on future trends and advancements in the sector.

For the diagnostic technologies identified as critical to Australia's national interest (Action 1.1) or supported by the Diagnostics Manufacturing Fund (Action 2.5), the provision of short-to-medium term conditional funding should be considered, for companies to conduct post-market surveillance and validation. This will not only provide companies with the opportunity to collect more accurate and real-life data, but it will reduce the time within which Australians can access diagnostic technologies in the event of an emergency or periods of high demand.

> **Rebates haven't changed for decades even under inflation – it always comes down to cost.**
>
> – Multinational

Priority

Implement sustainable procurement practices

Government procurement is one of the most effective levers to broaden and democratise access to diagnostics and retain manufacturing capabilities in Australia. Government procurement and demand signalling via national priorities represent a significant component of the Australian market's attractiveness for companies making decisions about research or manufacturing investment. The central role played by the federal, state and territory governments in our local market for diagnostics shape industrial outcomes and build resilience across the supply chain.

Action 5.1
Conduct an economic evaluation to assess the broader benefits of Australian-made diagnostics

Importance: Foundation

Timeframe: 2–4 years

Action 5.2
Improve state and territory government procurement

Importance: Foundation

Timeframe: 2–4 years

Action 5.3
Encourage the Australian Government to be involved in product development

Importance: Driver

Timeframe: 2–4 years

Harnessing government purchasing power to prioritise local diagnostic products in tender and procurement exercises will help stimulate domestic manufacturing, increase job opportunities and promote a more robust local economy. It will also strengthen Australia's position in the global market. By fostering a supportive environment for local manufacturers, the country can become a leader in diagnostic technology development and commercialisation.

The implementation of prioritised and emergency procurement orders for strategic diagnostic products will also enhance the nation's public health preparedness and response capabilities. These initiatives will help ensure access to critical diagnostic technologies in times of crisis or disrupted global supply chains and reinforce the country's ability to address public health challenges effectively.

Conducting an economic evaluation of Australian-made diagnostics and adopting appropriate 'Buy Australian' procurement policies, in line with the Buy Australia Plan, is an important first step towards much-needed procurement reform.

Action 5.1: Conduct an economic evaluation to assess the broader benefits of Australian-made diagnostics

The Australian Government should conduct and disseminate an economic evaluation to assess the broader benefits and impacts of Australian-made diagnostics. The results should guide state and territory government procurement (Action 5.2) as well as the HTA review (Action 4.3).

Why is this important?

Australian manufacturers are at a structural cost disadvantage due to Australia's higher labour costs and more comprehensive regulatory frameworks compared to international competitors. Additionally, early-stage Australian manufacturers developing cutting-edge products will often be at a scale disadvantage relative to more established global peers. This means on a pure unit cost basis, Australian-made diagnostic products can often struggle to compete with international competitors.

Stakeholders cited a lack of local demand for Australian-made diagnostic products as one of the primary barriers to establishing Australian manufacturing facilities. Without confidence in state and/or federal government bodies as a cornerstone client, investors and researchers struggle to develop the necessary business case to support significant capital investment onshore. However, there is strong evidence that a thriving domestic manufacturing ecosystem can offer an array of broader economic benefits.

> **If you want local capacity, you have to legislate it or incentivise in some way so that local companies are brought into the process.**
>
> – Australian SME

For example, evidence suggests the existence of a 'multiplier effect' whereby investment in local manufacturing creates additional downstream economic benefits including local employment, demand for other locally produced raw materials and inputs, and additional tax revenue (see examples on right of page). While these studies provide clear evidence of likely benefits, they are often generalised across sectors, or relate to other sectors and geographies.

How to implement

An economic evaluation focused specifically on the diagnostic technology sector would confirm the existence and extent of these benefits and provide more actionable insights to inform policy and procurement practices. For example, this may include insights regarding the benefits of a more proximate and resilient supply chain for Australia's health sector. This is critical to enabling government bodies to adopt evidence-based policies and determine the appropriate level of investment to support Australia's local diagnostic manufacturing capability. This may also assist government procurement bodies to justify individual procurement decisions made in favour of Australian manufacturers on the basis of non-price factors (see Action 5.2).

> EXAMPLE

The return on $1 for manufacturing

The US National Association of Manufacturers states: 'With every US $1.00 spent in manufacturing, an additional US $2.74 is added to the economy.' Based on Grant Thornton Manufacturing Benchmarking report data: '… for every Government (federal, state, or local) dollar spent, there's 30 cents worth of additional revenue generated over that original dollar. So if Government spends $1 on an Australian product, as opposed to importing a product, there's a 30% premium that can be paid, because the benefit comes back to the community. In addition, our lower, more conservative multiplier says that Government could spend $1.90 locally, and it's the same as spending $1 on offshore procurement.'

Source: Grant Thornton (2020).

Action 5.2: Improve state and territory government procurement

State and territory government procurement orders should incorporate:

- 'Buy Australian' procurement criteria as determined in Action 5.1
- priority procurement orders for Australian-made diagnostics considered national priorities (Action 1.1) or funded by the Diagnostics Manufacturing Fund (Action 2.5)
- emergency procurement orders for Australian-made diagnostics, with the guarantee of purchase. This procurement order should be used during crises and in periods of uncertainty and high demand.

Why is this important?

While it is acknowledged that some states and the Australian Government have a Buy Australian policy, it is critical for Australia to adopt a future-focused, consistent and united practice towards procurement of diagnostics. This includes moving away from a simple unit cost comparison to a wider awareness of sustainable procurement practices, supply line resilience and domestic manufacturing capability. State and territory governments should consider the broader economic, social and environmental benefits that accrue from local manufacturing when comparing suppliers and making procurement decisions. The lack of this results in diagnostic device companies with Australian manufacturing facilities often losing out on large government contracts because of price.

Many stakeholders highlight that their ability to secure third-party investment for local manufacturing facilities would be improved with a mechanism for state and territory governments to preference local diagnostic manufacturers wherever viable. Without it, the appeal for third-party investors of a lower-cost offshore manufacturer able to undercut on price to secure key government contracts is significant. As such, the decision is often made to instead establish these facilities in countries with a more cost-competitive environment.

In addition, Australian diagnostic SMEs researching strategically important diagnostic technologies often face a 'chicken and egg' dilemma: the company lacks manufacturing capacity to bid for government contracts, but at the same time investors lack conviction to fund scaling-up of manufacturing capacity without clear line of sight to government orders. As such, a framework should be established to enable government buyers to issue advanced or prioritised procurement orders to overcome this challenge.

> EXAMPLE

The Kentucky Procurement Code Model

In 2010, the Kentucky General Assembly in the US passed Senate Bill 45, which requires public agencies to provide a preference to Kentucky resident businesses when bidding against a non-resident bidder from any state that itself has a local preference law in place. In the 10 years following, Kentucky's manufacturing output has increased from US$28.2 billion to US$38.3 billion (+36 percent).

Source: The National Association of Manufacturers (2021).

> **What it allowed us to do, by having the government as the first purchaser was springboard into an export market... The government purchasing it (diagnostic products) gives you that commercial validation to go and secure other customers.**
>
> – Australian SME

PRIORITY

Action 5.2: Improve state and territory government procurement

How to implement

Introducing a mandate for both federal and state/territory public sector buyers of health products to consider the country of manufacture would level this playing field and provide an advanced signal to investors that government is willing to support locally made diagnostic products. This could be aligned with the Australian Government's Buy Australian Plan (Australian Government Department of Finance, 2023), and should also include a framework for calculating and incorporating downstream economic benefits from local procurement as part of bid assessment processes.

An emergency procurement order would enable buyers to agree contracts with local suppliers in advance of production capacity being built for certain categories of diagnostic products. This could include:

- early-stage diagnostic products with high-potential impact
- strategically important diagnostic products in high demand due to abnormal conditions (such as a pandemic)
- strategically important diagnostic products in low supply due to disrupted global supply chains.

This would provide certainty and underpin the business case for rapid scaling-up of critical manufacturing infrastructure during periods of abnormal demand for, or unstable supply of, important diagnostic technologies.

A prioritised procurement order would involve a commitment from government to order a specified quantity or proportion of diagnostic products identified as national priorities (in line with Action 1.1) from local manufacturers. Research and development funding is often directed towards priority areas. But the focus on price as a primary criteria in procurement results in manufacturing of technologies moving offshore once commercialised. Prioritised procurement orders would increase Australia's return on investment from such R&D initiatives and increase surety of supply for strategically important products.

> EXAMPLE

Victoria's advanced ventilator procurement orders

During the COVID-19 pandemic, the Victorian Government combined a grant with a commitment to order a minimum quantity of ventilators from local manufacturer Grey Innovation. This provided the local business with the certainty required to secure a licence from an overseas ventilator patent owner and invest in the necessary capacity to manufacture the devices locally. As a result, the state was able to work with the private sector to rapidly increase the resilience of its supply of ventilators during the fight against COVID-19.

> **The best way to create sovereign manufacturing is to have sovereign demand**
>
> – Australian SME

CASE STUDY

Ellume's Pivot to the US Market: Lessons Learned

Ellume was founded in Brisbane in 2010 by a clinician who saw a need for rapid at-home diagnostic solutions during the 2009 H1N1 (swine flu) pandemic. After a decade of research and development and a $5 million funding round from private investors in 2019, the company was well placed to help meet the need for at-home diagnostic testing during the COVID-19 pandemic. Ellume had developed home flu-testing kits as well as a smartphone app to help users interpret their results.

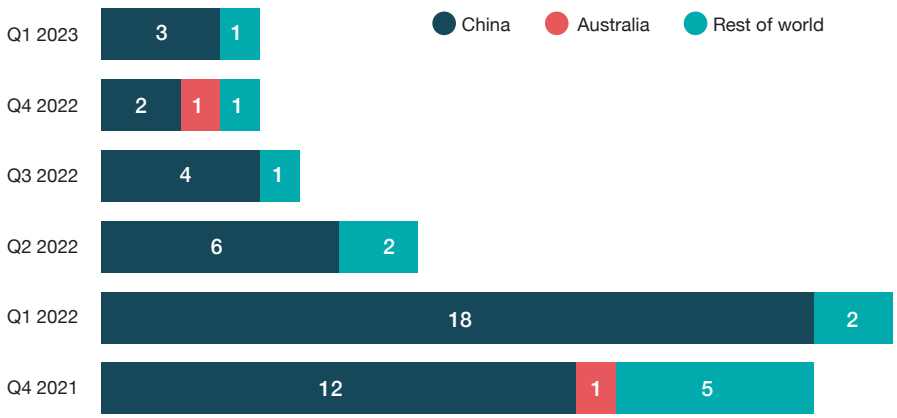
With the capability to produce up to 10 million tests per month (with lower volumes for higher-quality testing products), Ellume's domestic manufacturing capacity had the potential to help relieve strain on Australia's laboratory testing system during the COVID-19 pandemic in 2020 and 2021. However, authorisation from the TGA for at-home COVID-19 self-tests was required before Ellume could begin supplying its tests in Australia. The assessment process meant TGA authorisation was not provided for any COVID-19 at-home self-tests until November 2021, with the majority of early approvals provided to China-based manufacturers (see figure below).

By contrast and in parallel, Ellume was receiving significant support from the US Government and regulatory authorities to rapidly scale up its US production capacity. In November 2020, the FDA issued an Emergency Use Authorization (EUA) for its first at-home self-test kits, with an EUA being issued for Ellume as the first over-the-counter test less than a month later. By February 2021, Ellume had received a $304 million order from the US Department of Defense to supply 8.5 million test kits to the US Government. The US Government also expressed enthusiasm for Ellume to build a large onshore manufacturing facility with capacity of 500,000+ tests per day. Ellume received a grant of around $80 million to support this, resulting in the business's focus pivoting to its US operations where manufacturing capacity has been rapidly scaled up.

Due to difficulties in the Australian market as well as challenges arising from a product recall over concerns of false positive results, Ellume placed its Australian arm into voluntary administration in September 2022. The business's focus pivoted to its US operations; however, in December 2022 both the Australian operations and the US subsidiary were acquired by a Brisbane-based competitor, Hough Consolidated.

> **We knew the FDA pretty well. Indeed, they'd kind of co-designed the product with us by virtue of their requirements settings. On the back of that, we ended up being the first home COVID test being approved in the USA and in the middle of the pandemic they expressed their significant enthusiasm for making a big investment in Ellume to scale out manufacturing in the US.**

No. of TGA approvals of COVID-19 rapid antigen self-tests per quarter by country of manufacturer



Source: Therapeutic Goods Administration (TGA) (2023).

Action 5.3: Encourage the Australian Government to be involved in product development

Federal, state and territory governments should provide leadership on product development for diagnostics considered national priorities (Action 1.1) and are Australian made through a collaborative process to ensure the products are fit for purpose and more attractive to procure.

Why is this important?

The structure of Australia's healthcare system means that government agencies at federal and state/territory level are commonly the largest customers for local diagnostic technology companies. In this context, stakeholders are enthusiastic about greater involvement from these agencies throughout the product development life cycle. By having clear channels to communicate with the ultimate buyers of new diagnostic technologies, manufacturers are better able to understand the specific needs of their customer and design products that are tailored to these needs and well positioned to navigate the regulatory and funding approval processes at the point of commercialisation.

How to implement

Government agencies responsible for procuring diagnostic technologies should have ongoing, open dialogue with industry to build awareness and bridge the gap between available and emerging technology, and the unique healthcare needs of the Australian population. Increased transparency regarding the needs of the ultimate product buyer can influence early-stage research and product development decisions significantly. Closer engagement between governments and industry will see departments receiving more fit-for-purpose Australian-made products and companies avoiding costly redesign and reapplication processes.

> **The intersection of academia, industry, and government is where magic happens.**
>
> – Multinational

PRIORITY

Priority

Increase resilience, responsiveness, and preparedness

The development of a strong local diagnostic industry as a strategic arm of health security in Australia cannot be viewed in isolation from the development of a robust diagnostics supply chain. Recently, Australia was faced with the challenge of building diagnostic infrastructure capable of handling the population-scale testing required to respond to the COVID-19 pandemic. In response, industry leaders, governments and health departments came together to rapidly expand diagnostic capabilities. This drove positive outcomes during that time. However, it is crucial that we take a strategic approach to ensure that these new capabilities are not only temporary, but a lasting legacy. To ensure this, the system needs to be made more resilient and responsive to future needs through strong demand signalling to guide where efforts should be made to prepare and respond.

Action 6.1
Streamline and simplify import regulations

Importance: Driver

Timeframe: 2–4 years

Action 6.2
Form collaborative partnerships with global companies

Importance: Foundation

Timeframe: 2–4 years

Action 6.3
Provide subsidies on freight during emergencies

Importance: Driver

Timeframe: 2–4 years

Action 6.4
Strengthen export partnerships

Importance: Driver

Timeframe: 2–4 years

Australia's heavy reliance on imported diagnostic raw materials, components and products can be addressed by establishing strategic initiatives that aim to mitigate supply chain risk and improve Australia's future preparedness. The Australian Government can support this goal by simplifying import regulations as well as providing subsidies on freight during emergencies, for Australian companies that manufacture diagnostic technologies. These key initiatives are intended to ensure Australian manufacturers are equipped to respond to future health crises.

Australia has the potential to become a diagnostic centre of excellence; however, some essential items will continue to be imported while the ecosystem develops. The Australian Government can strengthen supply chain resilience by forming collaborative partnerships with global companies to guarantee a steady supply of essential raw materials, components and products. Furthermore, expanding export partnerships with the Indo- and Asia-Pacific regions will create new economic opportunities and contribute to regional prosperity. Pursuing these solutions will not only build greater resilience but it will also result in downstream benefits beyond the healthcare sector. It is crucial that the Australian Government and companies conduct supply chain stress tests on a recurring basis, to identify vulnerabilities.

Action 6.1: Streamline and simplify import regulations

Streamline and simplify the import process by revising the Australian Biosecurity Import Conditions (BICON) system for diagnostic manufacturers.

Why is this important?

Australia's BICON system plays a crucial role in safeguarding the country's unique environment and agricultural system, and preventing the emergence of diseases, such as COVID-19 and SARS (Department of Agriculture, Fisheries and Forestry 2023). The system consists of strict guidelines and protocols necessary to protect the health and security of the overall population including animal health.

Nevertheless, stakeholders including researchers, SMEs, multinationals and state governments reported the need to simplify and make import regulations more favourable for domestic manufacturing. These stakeholders have faced several challenges, including:

- the duplication of efforts and administrative burden associated with regular importation of essential raw materials and components
- a lack of transparency with regard to updates to import regulations and processes, requiring documentation to be resubmitted.

Together these challenges can lead to unnecessary disruptions in the importation of raw materials and components, increasing the probability of inventory expiration, financial setbacks and production delays.

> **The majority of diagnostic products contain biological content... The documentation that you have to produce every single time you bring content into the country is not particularly conducive for companies to set up manufacturing here.**
>
> – Multinational

Considering Australia's geographic distance and extended wait times that local manufacturers already contend with, import regulations should be streamlined and simplified, particularly for low-risk raw materials and components, including those that have been previously imported. Doing so would minimise delays, alleviate some of the burdens currently faced by domestic manufacturers, and make Australia a more attractive place to establish manufacturing – particularly for multinationals.

How to implement

The Department of Agriculture, Fisheries and Forestry (DAFF) should explore options for establishing or enhancing measures that facilitate the streamlining and simplification of importing diagnostic raw materials, components and products. Stakeholders have suggested the following to achieve this goal:

- improve advice and support services, including new documentation requirements
- recognise previously imported materials and components to allow for the reduction of permit efforts and reduce duplication
- establish a two-tiered system that fast-tracks items deemed low risk (such as small particles of biological materials) through customs while maintaining the assessment of other items according to existing rules and regulations. DAFF would be required to identify and classify raw materials, components and products that present no risk to Australia's biosecurity
- educate couriers about the vital storage and handling requirements for diagnostic raw materials and products (e.g. temperature conditions)
- consider establishing specialised freight couriers for medical devices, raw materials and components.

The implementation of these measures can facilitate the importation of these essential items and help retain sovereign manufacturing while maintaining strict adherence to biosecurity measures.

> **Every company is spending hours and hours every day to bring simple products into the country. In comparison, Europe and countries such as the US, France and wherever else in the world, can bring in items without any major issues.**
>
> – Australian SME

PRIORITY

Action 6.2: Form collaborative partnerships with global companies

Form collaborative partnerships with global companies to guarantee a steady supply of essential raw materials, components and finished products for diagnostics to mitigate risk and enhance supply chain security.

Why is this important?

The vulnerability of Australia's diagnostic system became apparent during the COVID-19 pandemic, when there was a shortage of PCR tests and rapid antigen tests – the main form of testing used to adequately respond to outbreaks. According to the Australian Bureau of Statistics, Australia experienced record high imports of these products during this time (Australian Bureau of Statistics, 2022). Although the acute phase of the pandemic is behind us, this magnifies Australia's vulnerability for being able to adequately respond to emerging disease threats as identified by Australian and international defence and national security agencies.

The results of the supply chain resilience survey (p24–28) demonstrate that in the event of another major supply chain disruption, Australia does not have the capability to be self-sufficient. Only 7 percent of participating companies manufacture in Australia, 67 percent manufacture offshore and 26 percent manufacture both onshore and offshore.

At the time of writing, no strategic agreements have been established for the procurement of critical raw materials, components and diagnostic products. As a consequence, Australia would find itself exposed in the event of a future supply chain disruption. Having sovereign manufacturing is only one way to strengthen supply chains. Although this is important, supply chains can also be strengthened by having diversified suppliers. This can be achieved by forming strong and collaborative partnerships with multinationals from a range of regions to guarantee a steady supply of critical raw materials, components and products.

These strategic efforts must be made in parallel with creating an attractive environment for Australian companies to set up manufacturing and remain in Australia.

> **The Government looks at industry as vendors, not as partners.**
>
> – Multinational

How to implement

To secure a diversified and sustainable supply of diagnostic items critical to Australia's security (through demand signalling in Action 1.1), the Australian Government should seek to partner with global companies (multinationals or SMEs, including Australian organisations), to ensure Australia has a secure supply of essential diagnostic raw materials, components and products.

The Australian Government could secure a commitment from these companies to allocate a portion of their manufacturing to Australia. This is achievable, as demonstrated by the recent partnership agreement between Moderna and the Victorian and Australian governments to build an mRNA vaccine manufacturing facility in Melbourne.

There is also potential for the Australian Government to establish mutual cooperation agreements covering the health sector (and diagnostics specifically) with international partners or to incorporate provisions into established treaties (such as free trade agreements) as they are updated.

This would create a platform for Australian diagnostics businesses to come together with international counterparts and suppliers to more easily form supply partnerships, with support from governments on both sides.

This could be supported by embedding supply chain officers in Australia's embassies, high commissions, consulates and international trade offices, who are primarily responsible for building relationships with suppliers of essential items to help ensure Australia has sufficient access to such items in times of need or high demand.

> **Unfortunately, Australia does not have the capability for economies of scale. But in anticipation of future supply chain issues, we could be better prepared by having affiliations lined up.**
>
> – Government department

> EXAMPLE

Moderna mRNA manufacturing facility

The mRNA vaccine facility in Melbourne is due to be operational in 2024. The facility is expected to help protect Australians against future pandemics as well as reduce Australia's dependence on sourcing mRNA vaccines from other countries.

Having Moderna based in Melbourne will have significant benefits for Australia's pharmaceutical manufacturing ecosystem by creating job opportunities, promoting knowledge transfer, and ultimately enhancing the overall competitiveness and capability of the Australian pharmaceutical industry.

Source: Australian Government (2022a).

Action 6.3: Provide subsidies on freight during emergencies

Provide subsidies or rebates on freight during emergencies, periods of uncertainty or high demand for raw materials, components and diagnostic products. This could be coordinated and supported by the Diagnostics Advisory Council (Action 1.2).

Why is this important?

Australian diagnostic companies must have access to a reliable, economical and secure supply of raw materials, components and products that are not available in Australia, during emergencies, periods of uncertainty or times of high demand.

According to the supply chain resilience survey (p24–28), the majority of companies experienced a significant increase (400 percent) in air and sea freight prices during the COVID-19 pandemic. This had a detrimental impact on their ability to manufacture and deliver high-quality products, thereby impeding their capacity to meet the high demand.

> **The 400 percent increase in COVID-19 logistic costs really killed us. Now all of our profits are gone.**
>
> – Multinational

Although this situation was not unique to the diagnostic industry, if Australia does not have secure access to the raw materials and components required for the development and production of diagnostic technologies in the event of future crises, Australia will be at significant risk of not being able to effectively and appropriately manage future disease outbreaks. This will not only have negative consequences for the wellbeing of Australians, but it will further threaten the sustainability and longevity of Australian diagnostic manufacturers.

Between 2020 and 2022, the Australian Government created the International Freight Assistance Mechanism (IFAM), with the key purpose of enabling the import of items critical to Australia's national interest such as medical supplies and equipment (Australian Trade and Investment Commission, 2023). Nonetheless, both SMEs and multinationals still reported being impacted by the cost of freight, which increased as a result of the pandemic.

How to implement

To boost freight and supply chain security for periods of crisis, the Australian Government should prepare emergency mechanisms such as air and sea freight subsidies or rebates for Australian manufacturers. The Diagnostics Advisory Council (Action 1.2) could be utilised to help implement and manage this initiative.

Given the intention for these subsidies to be implemented in emergencies, careful planning should occur now to create a framework for activation and utilisation of the subsidies. Criteria should be established to determine the following:

- What constitutes an emergency for the purpose of the subsidy program?
- Who is eligible to receive the subsidy?
- Which goods are eligible to be carried under the subsidy?

During emergency circumstances involving lockdowns, the Australian Government should also consider establishing a coordinated program for directly funding the operation of flights by Australian airlines – when commercial options are not available or viable – to ensure air freight capacity is maintained.

> **We would have much preferred to pay the millions or tens of millions of dollars that we were paying for air freight to Qantas to keep Australian jobs.**
>
> – Australian SME

Action 6.4: Strengthen export partnerships

Build strategic alliances to foster export partnerships by becoming the main supplier of diagnostic technologies in the Indo-Pacific and Asia-Pacific markets. This should support regional healthcare systems through an increased supply of Australian-made diagnostic technologies.

Why is this important?

With our world-class healthcare system and expertise in research and development, Australia is well positioned to become the main supplier of diagnostic tests to emerging markets in the Indo-Pacific and Asia-Pacific regions that have poor manufacturing infrastructure and, in some cases, a reduced ability to produce quality diagnostic products on a large scale.

Strengthening international partnerships will also de-risk the challenging procurement process faced by Australian diagnostic manufacturers, who are often forced to target offshore markets as a result of inadequate local adoption and the small Australian market.

Worldwide, countries are increasingly recognising the importance of international coordination for security of supply, not only for diagnostic technologies. For example, the US initiated a Minerals Security Partnership (MSP) with many countries including Australia in 2022; the European Union formed a Strategic Partnership on Raw Materials with Canada in 2021, and Canada established a Joint Action Plan on Critical Minerals Collaboration with the US in 2020 (International Energy Agency [IEA], 2022).

How to implement

The Australian Government should strengthen the efforts to build regional resilience with emerging countries in the Indo-Pacific and Asia-Pacific regions, which are often in need of improved access to quality-assured diagnostic tests. This recommendation is based on stakeholder feedback that Asia represents one of the most attractive markets in terms of population size, but also that it may be more challenging for Australian manufacturers to enter established markets in countries such as China, South Korea and Singapore, which have strong manufacturing capabilities and supply chains.

> **Australia has a good opportunity to become really competitive in the Asia-Pacific region, as we have one-third of the world's population within a six-hour flight.**
>
> – Australian SME

PRIORITY

Action 6.4: Strengthen export partnerships

Further work should take place to identify what barriers exist to Australian diagnostic SMEs looking to export to major and emerging Indo-Pacific and Asia-Pacific nations, and strategies should be formed to help address these at the government-to-government level.

The National Diagnostics Development Centre (Action 1.3) would be well placed to lead this work, working with Austrade and international partners. This could involve informal support navigating complex public sector procurement processes as well as much broader reform via free trade agreements and other formal economic cooperation agreements.

For example, Australia is currently negotiating the Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA) with a view to use this as a foundation to resume negotiations on the more ambitious Australia-India Comprehensive Economic Cooperation Agreement (AI-CECA) (Department of Foreign Affairs and Trade, 2022). These agreements are designed to liberalise and deepen bilateral trade between the two nations but will inevitably include a range of sector-specific trade liberalisation measures. Australia should consider the medical technology and pharmaceutical sector, and diagnostics sector specifically, as one of these sector priority areas.

It is also common for existing free trade agreements to be updated and amended. A key agenda item during amendment negotiation periods should be the potential for increased supply chain resilience in the diagnostics sector. This will ensure that any remaining barriers to Australian companies exporting to Indo-Pacific and Asia-Pacific nations that we have existing free trade agreements with can be reduced.

The Australian Government should also seek to build upon existing initiatives such as the Supply Chain Resilience Initiative, a collaboration between Australia, India and Japan to promote best-practice national supply chain policy and principles between the three nations, as well as foster interconnectedness of businesses from each nation. The medtech and diagnostics sectors should be considered as key agenda items for future meetings under this initiative, and Australia should also consider adopting a similar approach with other fast-growing nations throughout the region (e.g. Indonesia, Philippines, Malaysia, Vietnam).

The Department of Foreign Affairs and Trade (DFAT) should also take a proactive role in promoting trade in the diagnostics sector by facilitating introductions (alongside its Indo-Pacific and Asia-Pacific counterparts) to major diagnostics product buyers (e.g. public health authorities, hospitals, distributors) for Australian manufacturers. For example, in 2018, DFAT developed the report, *An India Economic Strategy to 2035*. This Action Plan recommends increasing Australia's economic engagement with India and aims to turn India into one of Australia's top three export markets by 2035 (Department of Foreign Affairs and Trade, 2018). To further strengthen Australia's strategic partnership and supply chains with India, DFAT should consider extending its recommendations to actively promote Australian-made diagnostic products and services.

"The Australian Government should also seek to build upon existing initiatives... The medtech and diagnostics sectors should be considered as key agenda items for future meetings under this initiative."

The Road Ahead: a Call to Action

The Road Ahead: a Call to Action

The importance of diagnostics products to Australia's health and security is becoming ever more apparent, and the global market for these products continues to grow. As a result, Australia faces an immense opportunity. We can build upon our world-class research platform and develop a powerful diagnostics industry that supports the growth of new companies, spurs job creation and healthier communities.

If this opportunity is not leveraged, the vulnerabilities exposed by the COVID-19 pandemic will become more acute.

- Our diagnostics supply chain is almost entirely reliant on offshore suppliers.
- Our local innovators are forced offshore in the face of a lack of local procurement by public health bodies.
- Innovative emerging diagnostics technologies too often stagnate at the research phase due to a lack of commercialisation support.
- Australian diagnostics companies that do attempt to scale up local manufacturing are hampered by skilled labour shortages, local cost structures, funding constraints and complex regulatory systems.

But if these constraints can be released and the right funding and policy settings are put in place, Australia can unleash the potential of its world-leading diagnostics research and technical capabilities. There is real potential to create a thriving sovereign diagnostics manufacturing hub.

If this vision is realised, the benefits will be far-reaching. These benefits include:

- sustainable job creation and economic growth
- increased geopolitical independence
- a more resilient health system capable of responding to crises
- more equitable access to high-quality healthcare for rural and remote communities.

With improved sovereign diagnostic manufacturing capability, Australia can become a producer and early adopter of life-saving technologies. And our ability to detect, diagnose and monitor illnesses and diseases among our population will be improved.

We can establish a platform that increases Australia's preparedness for the next pandemic or health crisis. We can begin to produce products onshore that our companies ultimately export to the rest of the world. And we can improve Australia's ability to attract top global talent and capital in a virtuous cycle.

As this opportunity sits before us, the Australian Government is commencing a generational investment in sovereign manufacturing via the establishment of the $15 billion NRF, with $1.5 billion allocated to medical manufacturing and $1 billion to advanced manufacturing.

However, harnessing this opportunity requires more than just capital investment in manufacturing facilities themselves. Investment must be coordinated with policy reform across all segments of the sovereign diagnostics manufacturing ecosystem.

Incentives must be put in place to encourage commercialisation and product design. Infrastructure must be established to support a resilient supply chain and logistics services. It must be feasible and attractive to scale production domestically rather than offshoring to lower-cost offshore markets. Regulatory and market access programs must be accessible and streamlined. The ultimate buyers of diagnostic products must have a mandate to consider the broader benefits of 'Buy Australian'.

Creating the right settings in each of these areas will require investment and coordination across government as well as the diagnostics industry. This investment will lead to tangible returns through economic growth, control over supply chains, reduced dependence on imports and a healthier society.

And several non-tangible benefits will be realised including improvements in national security, technology innovation and self-sufficiency – ultimately underpinning our national pride and identity.

1 – 2 YEARS

FOUNDATIONS

- Build a coordinated Nationwide Diagnostics Policy
- Establish and legislate a Diagnostics Advisory Council
- Establish a National Diagnostics Development Centre

DRIVERS

- Enhance the Australian manufacturing workforce
- Provide a sustainable funding model for the TGA

2 – 4 YEARS

FOUNDATIONS

- Establish a Diagnostics Manufacturing Fund to support commercialisation and manufacturing
- Provide incentives for entities with local manufacturing infrastructure to rent out facilities to SMEs
- Provide manufacturing subsidies or rebates
- Provide funding for regulatory support
- Improve reimbursement pathways for diagnostic technologies
- Conduct an economic evaluation to assess the broader benefits of Australian-made diagnostics
- Improve state and territory government procurement
- Form collaborative partnerships with global companies

DRIVERS

- Create a digital National Resource
- Consider more financial incentives to attract investment
- Reform commercialisation and manufacturing grants
- Ensure equitable access to biological materials
- Encourage the Australian Government to be involved in product development
- Streamline and simplify import regulations
- Provide subsidies on freight during emergencies
- Strengthen export partnerships

4 YEARS

Acknowledgements

Acknowledgements

We would like to thank all those who generously contributed their time to assist in developing this Action Plan.

External Advisory Group members:

AdAlta	Dr Paul MacLeman, Chairman AdAlta
ellume	Dr Sean Parsons, Founder Ellume
Bellberry Limited supporting research and ethics	Kylie Sproston, CEO Bellberry
CATAPULT Medicines Discovery	Professor Chris Molloy, CEO Medicines Discovery Catapult
CHF Consumers Health Forum of Australia	Jo Root, Policy Director Consumers Health Forum

Participating stakeholders:

3DMEDiTech	3DMEDiTEch
biosensis Make sense of your research!	Biosensis
Abbott	Abbott
biotome	Biotome Pty Ltd
Abbott	Abbott Rapid Diagnostics Pty Ltd
Cepheid A better way.	Cepheid
AdAlta	AdAlta
CHF Consumers Health Forum of Australia	Consumers Health Forum of Australia
aim Lab Automation Technologies	Aim Lab Automation Technologies
Cr Consulting Pty Ltd	CR Consulting Pty Ltd
Alcolizer technology	Alcolizer Technology
CSIRO	CSIRO Health and Biosecurity
AM Diagnostics MEDICAL DIAGNOSTICS MADE EASY	AM Diagnostics
Queensland Government	Department of Environment and Science
ANFF NSW Node	Australian National Fabrication Facility
GOVERNMENT OF WESTERN AUSTRALIA	Department of Jobs, Tourism, Science and Innovation

Acknowledgements

AnteoTech

Artrya Ltd

Atomo Diagnostics

AusDiagnostics

Australian Centre for the Prevention of Cervical Cancer

Australian Genome Research Facility

Avicena Systems

Baymatob

Bellberry Limited

bioMérieux

Immulab

Industry Development and Participation Branch, Jobs, Innovation & Business Engagement group

INOVIQ Limited

Department for Trade and Investment

Diag-Nose Medical

Diagnostic Technology Pty Ltd

DMTC Limited

Ellume

Envision Sciences

Garvan Institute of Medical Research

Genetic Signatures Ltd

GenieUs Genomics

Illumina

Proteomics International

Radiometer

ResMed

KD&A	
LBT Innovations	
Life Sciences Queensland	
Lumos Diagnostics	
Med2Mark	
Medical Technology Association of Australia	
Medicines Discovery Catapult	
Minomic International Ltd	
Murdoch Children's Research Institute	
National Measurement Institute	
NSW Health Pathology	
Nutromics	
Office of Health and Medical Research (New South Wales)	
Office of the Queensland Chief Scientist at Department of Environment & Science	
Pathology Queensland	
Rhinomed	
Roche	
SA Pathology	
Siemens Healthineers	
Sonic Healthcare Australia, Pathology	
SourceCertain	
SpeeDx	
SynGenis Pty Ltd	
Tenmile	
Therapeutic Goods Administration	
Thermo Fisher Scientific	
Three Stripes Health Consultancy	
Trajan Scientific and Medical	
Universal Biosensors	
University of South Australia Clinical & Health Services	

Acknowledgements

PathWest	PathWest
Peter Mac	Peter MacCallum Cancer Centre
Pharmaceutical Society of Australia	Pharmaceutical Society of Australia
The Pharmacy Guild of Australia	The Pharmacy Guild of Australia
The University of Western Australia	The University of Western Australia – School of Medicine
VitalTrace	VitalTrace
XING Technologies	XING Technologies
ZiP Diagnostics	ZiP Diagnostics

Working Group

MTPConnect

MTPConnect is an independent, not-for-profit organisation focused on growing Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect forges stronger connections between research and industry and maximises opportunities for Australians to make scientific and technological breakthroughs that are successfully translated and commercialised.

MTPConnect works to increase collaboration and commercialisation, improve management and workforce skills, optimise the regulatory and policy environment and improve access to global supply chains and international markets.

In this way, MTPConnect is building a more resilient and competitive medical products sector.

Pathology Technology Australia

PTA is the peak body representing manufacturers and suppliers of about 95 percent of all tests and technology used in pathology laboratories, hospitals, general practice and for self-testing.

PTA members develop and manufacture tests and testing technology and conduct clinical trials and validation testing to meet the requirements for inclusion on TGA's ARTG; they also train doctors and scientists in the use of this technology, provide technical support to maintain devices operating at their optimum and maintain the supply chain – all of which make pathology possible. The member companies of PTA strive to provide tests and testing technology that deliver the highest quality, accessible and affordable healthcare services to all Australians.

HTANALYSTS

HTANALYSTS has been providing boutique impact measurement and communication services for 20 years. It strives to make a powerful impact on society by driving human-centric outcomes. Its purpose is to have a powerful impact on the health of society by connecting people with the best treatments in the fastest amount of time.

Originally founded in 2002, **HT**ANALYSTS has grown to become a leader in healthcare and impact assessment consulting, providing services to the healthcare industry. In recent years, its scientific rigour has proven valuable for those outside the traditional pharmaceutical world, and this has seen the company grow its capabilities to include expertise in social impact measurement, government services, healthy ageing and disability.

HTANALYSTS has extensive experience working with numerous stakeholder groups to develop a comprehensive understanding of complex topics.This includes diverse topics such as health technology assessments, genomics, climate change and unintended pregnancies.

Email: diagnostics@mtpconnect.org.au

Website: www.mtpconnect.org.au/programs/diagnostics

References

1. Access2Funding. (2022). Tax relief for the Manufacturing Industry. Retrieved from https://www.access2funding.co.uk/manufacturing-grants-funding
2. AusDiagnostics. (2020). AusDiagnostics opens state-of-the-art production facility and launches new extraction kit product line to target SARS-CoV-2 and infections beyond the pandemic. Retrieved from https://www.ausdiagnostics.com/content/uploads/2020/09/ausdiagnostics_press_release_-_september_2020_final.pdf
3. Australian Bureau of Statistics. (2022). Impact of COVID-19 on selected medical and associated imports. Retrieved from https://www.abs.gov.au/articles/impact-covid-19-selected-medical-and-associated-imports
4. Australian Government. (2021). Offset your R&D costs to help innovate and grow your business. Retrieved from https://business.gov.au/grants-and-programs/research-and-development-tax-incentive/overview-of-rd-tax-incentive
5. Australian Government. (2022a). Government and business partner to establish mRNA production in Australia. Retrieved from https://www.industry.gov.au/news/government-and-business-partner-establish-mrna-production-australia
6. Australian Government. (2022b). National Reconstruction Fund: diversifying and transforming Australia's industry and economy. Retrieved from https://www.industry.gov.au/news/national-reconstruction-fund-diversifying-and-transforming-australias-industry-and-economy
7. Australian Government. (n.d.). National Freight & Supply Chain Strategy. Retrieved from https://www.infrastructure.gov.au/infrastructure-transport-vehicles/transport-strategy-policy/freight-supply-chains/national-freight-supply-chain-strategy
8. Australian Government Department of Finance. (2023). Buy Australian Plan. Retrieved from https://www.finance.gov.au/business/buyaustralianplan
9. Australian Institute of Health and Welfare. (2021). Older Australians. Retrieved from https://www.aihw.gov.au/reports/older-people/older-australians
10. Australian Trade and Investment Commission. (2021). New A$206m patent box to boost biotech and medtech innovation. Retrieved from https://www.austrade.gov.au/international/invest/investor-updates/2021/new-a206m-patent-box-to-boost-biotech-and-medtech-innovation
11. Australian Trade and Investment Commission. (2023). International Freight Assistance Mechanism. Retrieved from https://www.austrade.gov.au/news/news/international-freight-assistance-mechanism
12. Boaz, A., Hanney, S., Borst, R., O'Shea, A., & Kok, M. (2018). How to engage stakeholders in research: design principles to support improvement. *Health Research Policy and Systems, 16*(1). doi:10.1186/s12961-018-0337-6
13. CSIRO. (n.d.). Australian Health Biobank. Retrieved from https://www.csiro.au/en/work-with-us/industries/health/australian-health-biobank
14. CSIRO Futures. (2022). *Strengthening Australia's Pandemic Preparedness: Science and technology-enabled solutions*. Retrieved from https://www.csiro.au/en/work-with-us/services/consultancy-strategic-advice-services/csiro-futures/health-and-biosecurity/strengthening-australias-pandemic-preparedness
15. Deloitte. (2021). Investments and incentives in Singapore. Retrieved from https://www2.deloitte.com/content/dam/Deloitte/sg/Documents/tax/sg-tax-applying-for-gov-incentives-brochure-02-dec-2021.pdf
16. Department for Business Innovation and Skills. (2011). *Strategy for UK Life Sciences*. Retrieved from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf
17. Department of Agriculture, Fisheries and Forestry (2023). Biosecurity Import Conditions system (BICON). Retrieved from https://www.agriculture.gov.au/biosecurity-trade/import/online-services/bicon
18. Department of Foreign Affairs and Trade. (2018). *An India Economic Strategy* to 2035. Retrieved from https://www.dfat.gov.au/publications/trade-and-investment/india-economic-strategy/ies/introduction.html#:~:text=This%20report%20recommends%20that%20we,as%20close%20as%20any%20in
19. Department of Foreign Affairs and Trade. (2022). Australia-India Economic Cooperation and Trade Agreement (ECTA). Retrieved from https://www.dfat.gov.au/trade/agreements/in-force/australia-india-ecta
20. Department of Health and Aged Care. (2023). Health Technology Assessment reforms and reviews. Retrieved from https://www.health.gov.au/topics/health-technologies-and-digital-health/health-technology-assessments/reviews
21. Government of Western Australia. (2023). New Industries Fund. Retrieved from https://www.wa.gov.au/organisation/department-of-jobs-tourism-science-and-innovation/new-industries-fund
22. Grant Thornton. (2020). *Federal Budget: a 10 year retrospective*. Retrieved from https://www.grantthornton.com.au/globalassets/1.-member-firms/australian-website/mid-size-business/pdfs/gtal_2020_federal_budget_10year_retrospective_report.pdf
23. Hedlund, M., Keijser, P., Floris, A. (2019). *A world of opportunity for IVD innovation*. Retrieved from https://www.bench.com/hubfs/Benchmark%20Collateral/White-Papers/Benchmark%20IVD%20Market%20Study.pdf
24. International Energy Agency (IEA). (2022). Ensuring supply reliability and resiliency. Retrieved from https://www.iea.org/reports/critical-minerals-policy-tracker/ensuring-supply-reliability-and-resiliency
25. Manufacturing Technology Centre (MTC). (2022). All about us. Retrieved from https://www.the-mtc.org/about-us/ our-story/
26. McRae, M. P., Rajsri, K. S., Alcorn, T. M., & McDevitt, J. T. (2022). Smart Diagnostics: Combining Artificial Intelligence and In Vitro Diagnostics. *Sensors, 22*(17), 6355.

27. MTPConnect. (2020a). *Collaborating in the Public Interest: How Australia's Medical Technology Sector joined with Government to fight COVID-19*. Retrieved from https://www.mtpconnect.org.au/images/V3_MTPConnect%20MTAA%20Taskforce%20Ministerial%20Briefing%20Paper%20(Web%20version).pdf
28. MTPConnect. (2020b). *Fighting Superbugs*. Retrieved from https://www.mtpconnect.org.au/images/mtpc_fighting_superbugs_web_230920.pdf
29. MTPConnect. (2021). *MTPConnect REDI Initiative Skills Gap Analysis Third Report*. Retrieved from https://www.mtpconnect.org.au/reports/redi-skills-gap
30. National Skills Commission. (2022). Australian Labour Market Overview—September 2022. Retrieved from https://labourmarketinsights.gov.au/media/ka0ep1vj/australian-labour-market-overview-september-2022-pdf.pdf
31. Naughtin, C., Hajkowicz, S., Schleiger, E., Bratanova, A., Cameron, A., Zamin, T., & Dutta, A. (2022). *Our Future World: Global megatrends impacting the way we live over coming decades*.
32. NSW Government. (2023). Modern Manufacturing in NSW. Retrieved from https://www.investment.nsw.gov.au/living-working-and-business/modern-manufacturing/
33. Pathology Technology Australia. (2018). *Submission to the 2018 Consultation on R&D Tax Incentive Legislative Amendments on behalf of the IVD Industry in Australia*. Retrieved from https://treasury.gov.au/sites/default/files/2020-01/ivd_australia.pdf
34. PricewaterhouseCoopers (PWC). (2023a). Ireland: Corporate - Tax credits and incentives. Retrieved from https://taxsummaries.pwc.com/ireland/corporate/tax-credits-and-incentives
35. PricewaterhouseCoopers (PWC). (2023b). Taiwan: Corporate - Tax credits and incentives. Retrieved from https://taxsummaries.pwc.com/taiwan/corporate/tax-credits-and-incentives
36. PricewaterhouseCoopers (PWC). (2021). *In Vitro Diagnotics (IVD) Market trends - overview*. Retrieved from https://www.pwc.com/it/it/publications/assets/docs/pwc-IVD-market-trends-overview.pdf
37. Queensland Government. (2022). Made in Queensland. Retrieved from https://www.rdmw.qld.gov.au/manufacturing/manufacturing-assistance-programs/made-in-queensland#:~:text=Made%20in%20Queensland%20(MIQ)%20is,skilled%20jobs%20for%20the%20future
38. Rohr, U.-P., Binder, C., Dieterle, T., Giusti, F., Messina, C. G. M., Toerien, E., Schäfer, H. H. (2016). The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. *PLOS ONE, 11*(3), e0149856. doi:10.1371/journal.pone.0149856
39. Stanford, J. (2020). A Fair Share for Australian Manufacturing: Manufacturing Renewal for the Post-COVID Economy. Retrieved from https://futurework.org.au/report/a-fair-share-for-australian-manufacturing/
40. The National Association of Manufacturers. (2021). 2021 Kentucky Manufacturing Facts. Retrieved from https://www.nam.org/state-manufacturing-data/2021-kentucky-manufacturing-facts/
41. The Treasury. (2016). Tax incentives for early stage investors. Retrieved from https://treasury.gov.au/national-innovation-and-science-agenda/tax-incentives-for-early-stage-investors
42. The University of Queensland. (2006). UQ scientist honoured for developing the world's first cancer vaccine. Retrieved from https://www.uq.edu.au/news/article/2006/01/uq-scientist-honoured-developing-worlds-first-cancer-vaccine
43 Therapeutic Goods Administration. (2021). Financial and non-financial performance. https://www.tga.gov.au/resources/publication/publications/cost-recovery-implementation-statement/financial-and-non-financial-performance
44. Therapeutic Goods Administration (TGA). (2022). *Fees and charges proposal 2022-23: Consultation paper.* Retrieved from https://consultations.tga.gov.au/regulatory-practice-section/consultation-paper-fees-and-charges-proposal-fy2/supporting_documents/Consultation%20paper%20%20Fees%20and%20charges%20proposal%20FY202223.pdf
45. Therapeutic Goods Administration (TGA). (2023). COVID-19 rapid antigen self-tests that are approved in Australia. Retrieved from https://www.tga.gov.au/products/covid-19/covid-19-tests/covid-19-rapid-antigen-self-tests-home-use/covid-19-rapid-antigen-self-tests-are-approved-australia
46. Therapeutic Goods Administration (TGA). (2010). IVD medical devices: Definitions & links. Retrieved from https://www.tga.gov.au/resources/resource/guidance/ivd-medical-devices-definitions-links
47. Uren, D. (2020). Southeast Asia will take a major economic hit if shipping is blocked in the South China Sea.
48. Victoria State Government. (2023). Made in Victoria. Retrieved from https://djsir.vic.gov.au/made-in-victoria/manufacturing-connections
49. Wong, H. Y., Marcu, L. G., Bezak, E., & Parange, N. A. (2020). Review of Health Economics of Point-of-Care Testing Worldwide and Its Efficacy of Implementation in the Primary Health Care Setting in Remote Australia. *Risk Manage Health Policy, 13*, 379-386. doi:10.2147/rmhp.S247774
50. World Health Organization (WHO). (2021). *The selection and use of essential in vitro diagnostics: Report of the third meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2020 (including the third WHO model list of essential in vitro diagnostics)*. Retrieved from https://www.who.int/publications/i/item/9789240019102
51. Worrall, L., Gamble, H., Spoehr, J., & & Hordacre, A. (2021). *Australian Sovereign Capability and Supply Chain Resilience*. Retrieved from https://researchnow-admin.flinders.edu.au/ws/portalfiles/portal/48141864/Australian_sovereign_capability_and_supply_chain_resilience_perspectives_and_options_AITI_2021_.pdf
52. Zero Childhood Cancer. (2020). Retrieved from https://www.zerochildhoodcancer.org.au/blog/openingtheblackboxofchildhoodcancer

Abbreviations

ACDC	Australian Centre for Disease Control
AHB	Australian Health Biobank
ARTG	Australian Register of Therapeutic Goods
BICON	Australian Biosecurity Import Conditions
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department of Agriculture, Fisheries and Forestry
DISR	Department of Industry, Science and Resources
DOH	Department of Health
EAG	External Advisory Group
HTA	Health Technology Assessment
HTANALYSTS	Health Technology Analysts
IFAM	International Freight Assistance Mechanism
IVD	In vitro diagnostic
LSIMF	Life Sciences Innovative Manufacturing Fund
MBS	Medicare Benefits Schedule
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
NRF	National Reconstruction Fund
PCR	Polymerase chain reaction
PTA	Pathology Technology Australia
PoCT	Point-of-care test
QMS	Quality Management System
RAT	Rapid antigen test
R&D	Research and development
SMEs	Small and medium-sized enterprises
SCRI	Supply Chain Resilience Initiative
TGA	Therapeutic Goods Administration
VC	Venture capital

Glossary

Consumables
Supplies required for the manufacturing process that do not form part of an end product.

End-to-end
Production process that takes a product from its beginning (R&D) to its end (service) – that is, across the manufacturing smile curve.

In vitro diagnostic (IVD)
A reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use (Therapeutic Goods Administration, 2010).

Manufacturing
Process of turning raw materials into finished goods through the use of tools, human labour, machinery and chemical processing.

Manufacturing smile curve
Includes R&D, logistics, production, market access and distribution, as well as sales and services.

Raw materials
Inputs that are used in the manufacturing, transformation or assembly process of an end product.

SMEs
Includes start-up companies as well as small and medium-sized enterprises.

Sovereign capability
Relates to ensuring a degree of self-sufficiency and security for a nation, reducing vulnerability due to external dependency in key areas of national interest (Worrall et al., 2021).

Stakeholder
A stakeholder is any government, organisation, medical, researcher group or person that has a direct interest in the process and outcome.

Value chain
Involves the various business activities and processes needed along the manufacturing smile curve to create a product or service.