Please accept this response from Pathology Technology Australia. We remain ready to supply further information and data if deemed appropriate for us to participate in any face to face hearing.

Executive Summary

Pathology Technology Australia (PTA) is the peak body representing manufacturers and suppliers of the tests and technology used in pathology laboratories, hospitals, and in primary care. Increasingly pathology technology is being used in the home for self-testing.
Australia imports about 97% of its pathology tests and technology requirements (1). About 30% of these devices travel through the Asia-Pacific region to get to Australia (1). Most of these tests come via airfreight, are very temperature sensitive, and have a relatively short shelf-life (1 to 2 years).
The pandemic introduced Australians to pathology technology and its critical role in detecting and understanding the SARS COV-2 virus, responsible for COVID-19 disease. PCR – polymerase chain reaction – the method for detecting the viral genetic material – its RNA; Genomic Sequencing – determining the virus's RNA subtype for epidemiological information, to inform the production of mRNA vaccines, and evolve detection strategies; and rapid antigen tests (called RATs in Australia) to detect the SARS COV-2 viral antigens.
Members of PTA supplied and maintained over 95% of the PCR and genomic sequencing tests and technology used in public health and patient testing for COVID-19 disease.

It is generally accepted that Australia performed well as a nation managing the pandemic (2), and the tests and technology described above were instrumental in providing critical individual and epidemiological information to drive decisions and support our response. Even so, the human and economic cost was substantial. It's important to understand the barriers to adoption and opportunities in the pathology technology sector that underpin this nation's preparedness for future similar challenges; be they contagion, other biosecurity threat, supply chain disruptions or climate-induced challenges.
In this submission we respectfully summarise some perspectives on behalf of the manufacturers and suppliers of these vital pathology tests – not only for COVID-19, but for all the tests and technology disrupted during the pandemic. In some cases, the pandemic threw up challenges that would have been difficult to prepare for. In other cases, there were some obvious missed opportunities to intervene well in advance.
We would value an opportunity to expand on the learnings and recommendations in any face-to-face hearing that the enquiry holds.

Supporting local pathology technology sector – Sovereign capability

Australia was extremely fortunate to have a good supply of PCR devices installed in laboratories, legacy of several health screening programs, including for HPV (Human Papilloma Virus) testing – the precursor of Cervical Cancer. We also have a diligent and well organised pathology technology supply sector, which immediately took up the challenges of securing supply of vital PCR tests and consumables, even as countries around the world began limiting export and preserving their own inventories.
Despite this excellent working base – Commonwealth and State health purchasing decisions largely ignored the fledgling local pathology test manufacturing sector. This is despite requests (by Government) and, in some cases, grants to local test manufacturers encouraging them to quickly tool up and manufacture COVID-19 tests.
In one example, an Australian company invested $12 million (at Government request) to rapidly convert one of its manufacturing labs to supply a vital component of the PCR test (which was in global short supply). There were subsequently no Government orders.
Another company received substantial Government grant to develop and manufacture a rapid COVID-19 test. The company produced a device that met all specifications in a very short time frame. Again, not a single government order.
A Queensland company developed globally leading technology for rapid detection and monitoring of COVID-19 outbreaks. The company required a modest purchasing commitment from Government and some assistance navigating TGA registration, but instead it has gone into administration in Australia. This

particularly bleak outcome has sent a strong message to manufacturers that they are not welcome in Australia.

Supply Chain Challenges

Securing supply and transport under the specific storage conditions of vital pathology tests and technology was extraordinarily challenging when world freight services were severely disrupted. Temperature sensitive pathology test freight (requiring -20°C shipping and handling in many instances) cannot be held up for more than 24hrs without risking a temperature excursion thus voiding the product.
Suppliers went to extraordinary lengths to secure supply of COVID-19 tests, including persuading their factories in Europe and North America to supply, in the face of home country pressure. For example, the USA Defence Production Act of 1950 was invoked during the pandemic and could have resulted in more than 30% of the world's supply of PCR tests being reserved for US domestic use.

The greatest challenge was the diminished availability of air freight capacity and the huge cost increases. Freight costs escalate to more than 500% of the pre-pandemic level. Freight costs remain 200% or more above the pre-pandemic even today. Suppliers have had to absorb these costs as government purchasing authorities refused to accept increases. This has had the effect of reducing supply confidence in Australia. Supply chain disruptions and global demand for pathology technology, also impacted sourcing of raw materials. Australian-based manufacturers import nearly 100% of the critical oligonucleotide building blocks required to manufacture PCR tests. These same oligonucleotides are required for an RNA manufacturing capability (such as in mRNA vaccines). PTA needs to be more closely involved in any initiatives to bolster local infrastructure and production in this space to ensure the pathology, R&D and manufacturing needs are met.

Communicating Critical Information

An effective pandemic response draws on the full diversity of pathology technology including large-scale centralised molecular testing (PCR), cost-effective rapid antigen testing (RATs), targeted rapid molecular testing (point-of-care PCR), and genome sequencing. Lack of communication with PTA, the sector peak body, and piecemeal public communication led to mass confusion as to where, when and what technology to utilise. This led to long queues and delays at PCR testing sites, and public distrust of RAT effectiveness.

There are examples in Australia of where all these technologies were used in seamless partnership to great success. The Grampians Health Services effectively used a combination of Rapid Antigen Tests and PCR to quickly identify and manage COVID-19 outbreaks in the region's aged care facilities. This meant that outbreaks were identified quickly and suppressed within weeks, with remarkably small loss of life.
Had Australia adopted this combination of tests more broadly, educated people properly in the roles and limitations of each test and made rapid antigen tests more generally available sooner, we could have emulated the Grampians Health experience.
The role out of point of care PCR COVID-19 testing in national aboriginal community-controlled health services was pivotal in reducing morbidity and mortality. We were fortunate that there were point of care PCR devices in the field performing a vital study on sexually transmitted infections in first nations communities that could pivot and expand testing for SARS-COV-2.

A further aspect of communication involved demand signalling by the major commonwealth and state health authorities. Haphazard, fractured and sometimes non-existent communication on Australia's testing strategy resulted in the supply sector not being able to plan and forecast effectively. In many cases PCR testing was cloistered within state public health networks who communicated poorly or not at all with the supply sector. Signalling on the demand for RATs was even more compromised, leading to virtual collapse of PCR and RAT testing in the summer of 2021.
The chaos of 2021 could have been avoided if the industry had been more closely included in plans and discussions on testing strategy. PTA could have provided balance to the prevailing opinions on technology, its ideal applications, and the supply considerations. Some good examples of this include the purchase by the

Commonwealth Government of COVID-19 rapid *antibody* tests. Any level of consultation on this purchase would have delivered counsel against it, as these tests are ineffective in detecting infectious cases. Similarly, the current write-offs State and Commonwealth government are experiencing with hundreds of millions of Rapid Antigen Tests might have been avoided with consultation on the limitation of shelf-life and storage conditions.

Impact of the Pandemic on Our Overall Health

It has become apparent that Australia is now facing a secondary pandemic of sorts – the consequences of delayed diagnosis and treatment or follow up of non-COVID-19 related health conditions. This has the most serious consequences for the incidence and severity of chronic diseases and cancers. We are yet to face the full impact of this new challenge.
During the pandemic PTA joined with around 40 health supply, professional and consumer groups to form the Continuity of Care Collaboration (CCC). The sole aim of this group was to highlight the perilous state of non-COVID-19 related healthcare in Australia. One of the tactics of this group was to measure the decline in pathology testing as a surrogate for the decline in patients attending to their acute and chronic health issues. In addition, PTA has collected data on the supply of tests into Australian laboratories and has a continuous data set from 2018 to present. This is probably Australia's most reliable source of testing numbers and could be used to provide better surveillance of testing during times of stress.

Recommendations

Our predominant recommendation is to include and involve the peak body for the manufacturers and suppliers of the tests and technology needed to manage future health challenges. We are currently calling on the Health Minister to create a Diagnostics Expert Advisory Group consisting of healthcare professionals and laboratory service providers, patient advocacy groups, industry bodies, and government representatives. If such an EAG existed, PTA could provide substantial information about the performance and capability of the technology, about testing capacity, manufacturing and supply. We can provide authoritative information on stockpiling, storage, stock rotation.
Government needs to involve the peak body far more in testing strategy and demand management. We can't have a repeat of the situation we faced in the summer of 2021. This could have been avoided or minimised with better management.
PTA represents many of the local test and technology manufacturers and can advise and coordinate local solutions, identify barriers and broker better outcomes.
Indeed, PTA partnered with MTPConnect to obtain a grant from the Commonwealth Department of Industry, Science and Resources, to complete a major study of Australia's sovereign diagnostics manufacturing capability and our supply chain resilience. This study identified and described the barriers to successful manufacturing in Australia and made recommendations on how to remediate the current poor situation. The ADAPT Report (1) and its recommendations forms part of our response to this enquiry. Of relevance is:

- Funding for a centralised concierge service that will guide local innovators through the challenges of commercialisation vital testing technology, thus shoring up local supply of critical tests and technology.
- Recognition within government procurement contracts of economic multipliers for locally manufactured tests and technology

While we recognise the efforts the commonwealth Department of Foreign Affairs and Trade and AusTrade went to in helping to identify air freight space to ship vital tests into Australia, the costs were prohibitive, and the services scant. A key recommendation is that in future supply chain and freight capacity challenges, the Commonwealth must provide reliable and low-cost air freight capacity for life saving medical imports.

(1) ADAPT Report
(2) New COVID data shows how Australia's pandemic strategy compares with other countries - ABC News
(3) Australian Institute of Health and Welfare – multiple references