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Pathology Technology Australia
Senate Select Committee on COVID-19
May 2020

Executive summary

- Pathology Technology Australia represents the manufacturers and suppliers of more than 90% of the tests and technology required for pathology testing in laboratories, hospitals, community centres and at home.
- As such we hold the only source of critical information about the installed base of technology, the capability of that technology, the supply of tests and knowledge of new tests and technologies being developed.
- Our very broad sector overview enables us to connect resources and expertise in unique ways to solve supply and manufacturing challenges.
- Our members have access to some of the world's best scientific and clinical expertise and can provide valuable input to the strategy for managing challenges such those presented by the COVID-19 pandemic.
- Our recommendation is that Pathology Technology Australia be included in the groups advising government on testing and associated testing technology.
- This should start as soon as practical, so we can provide accurate and up to date insights and advice regarding pathology testing direction and policy.

It should be clearly understood that without the technologies and tests developed, manufactured and supplied by members of Pathology Technology Australia, very little pathology testing would be possible. Research into diseases would be more difficult to achieve and there would be very little personalised medicine or companion diagnostics. We play an indispensable role in the health of all Australians and drive efficiency in our healthcare economy.

Introduction

Pathology Technology Australia, established in 2009, is the peak body representing the manufacturers and suppliers of the technology and tests used in pathology laboratories, hospitals, community clinics and home testing. Our member companies supply more than 90% of the pathology tests and technologies used to diagnose and manage the health of Australians. Our membership ranges from the largest global suppliers to the some of our best local innovators.

Technology supplied by our members is not only used to diagnose and manage health conditions; it is also used in the search for new disease entities, to uncover disease processes and to develop new therapies. An excellent example of this is the development of CAR-T therapy for blood borne cancers. None of this work could have happened without the technology provided by our members.

During the COVID-19 pandemic, Pathology Technology Australia actively participated in multiple areas of Australia's response. These are set out below, along with our suggested list of opportunities for improvement and our final recommendations. On behalf of the manufacturers and suppliers of over 90% of all pathology testing performed in Australia, we stand ready to help in any way we can.

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Manufacturers and suppliers mobilised

Many member companies have a long history of developing the highest quality tests and technology. To their great credit, they rapidly turned their expertise to developing and validating a broad range of tests for COVID-19. Such has been their focus that they have compressed 2 to 3 years of research and development time into 2 to 3 months; delivering high quality COVID-19 nucleic acid tests (most commonly the PCR tests for viral RNA) and antibody tests, often called serology tests.

With the declaration of a pandemic, demand for COVID-19 related testing increased exponentially. Increased demand for the testing technology, test kits and the required consumables (such as liquid chemicals, disposable plastic trays and pipette tips) depleted inventories and stretched supply chains within Australia and around the world. From the raw material suppliers, to finished goods manufacturers, supply chains were challenged.

To their great credit suppliers and manufacturers, up and down the supply chains, ramped up production. In a very short period, companies leveraged their quality processes and manufacturing expertise to increase production by up to 20-fold.

Our member companies were very diligent in managing local supplies and negotiating with their suppliers for inventory to be prioritised for use within Australia.

Local action plan

Pathology Technology Australia and its members quickly reacted to the challenge. Within weeks of the first cases detected in Australia, the test kits were being sourced from suppliers and imported to Australia.

We formed a COVID Executive Cabinet to identify areas of challenge and to find solutions both internally and externally. The Cabinet has met once or twice a week since.

One role Pathology Technology Australia quickly adopted, as the body representing its members, was as the communication conduit to federal, state health, regulatory and funding authorities. We met and communicated on a regular basis with the TGA, the Biosecurity Imports Division at the Department of Agriculture, Water and Environment (DAWE) and with the Medical Benefits Schedule (MBS) Division. We met weekly with the Department of Industry, Science, Energy and Resources (DISER).

Our comprehensive overview of this sector enabled us to link skills, resources and capabilities to areas of need, such as gaps in supply of critical components. We did this multiple times during the COVID-19 challenge.

Contribution made by Pathology Technology Australia members

Pathology Technology Australia and its members are extremely proud of the part we have played in responding to the pandemic within Australia. Our members very quickly delivered nucleic acid tests for detecting COVID-19 RNA. Within a few weeks of the first cases being detected in Australia our members were supplying tests to pathology laboratories. In addition, our members have

worked tirelessly to secure supply of products against an increasing global demand. Manufacturers have escalated manufacturing volumes to meet demand.
During the weeks following detection of our first case we:

- Interacted multiple times with Dr Gary Lum, Principal Medical Adviser in the federal Department of Health.
- Worked with DISER on a weekly basis to provide critical supply information.
- Worked with TGA to have an accelerated assessment in place for COVID-19 test kits. TGA decided to go with an exemption strategy. We then worked with TGA to modify the wording of the exemption to include commercial pathology providers doing the tests.
- Worked with the DoH to have the wording of the COVID-19 PCR MBS item changed to remove the need for 2 tests. The original item descriptor mandated testing for other respiratory viruses and for COVID-19. This placed unnecessary strain on the already stretched supply chain for testing consumables.
- Communicated with the Biological Imports Division at DAWE to enable accelerated entry for critical COVID-19 testing products. At the time, we suggested that DAWE should prepare for many import permit applications. Our work with the Biologicals Division at DAWE continues.

Member companies of Pathology Technology Australia worked very quickly to provide a comprehensive audit of the installed base of COVID-19 related testing platforms for;

- Nucleic acid tests, including RNA extraction systems and detection systems.
- Lab-based serology testing.

The audit demonstrated that the installed base of nucleic acid test technology was substantial and could enable increased testing within the existing accredited pathology laboratory framework. However, supply of some critical components required to complete testing did not meet demand in some cases. To address this, suppliers ramped up production and import of technologies and consumables.

The gaps in supply have led to a push for both a local manufacturing capability and for increased diversity in supply of consumables from outside Australia. Once again Pathology Technology Australia was able to leverage our network to advise DISER on resources within Australia that could provide local manufacturing and supply. Key to this were some of our Australian based members, who quickly stepped in and filled some of the supply gaps.

While some local manufacturing capability is likely to play a role in future challenges, it is highly likely such supply can provide only a small part of our requirements.

The audit also demonstrated that within the accredited pathology laboratory infrastructure there is enough capacity to significantly increase COVID-19 serology testing. Member companies have worked extremely hard to develop and manufacture the highest quality antibody tests for COVID-19 and are making these available for our accredited labs to run on high-volume, automated testing analysers. These serology tests are very similar in format and performance to the tests we use to detect antibodies for hepatitis, HIV and other infectious diseases.

Pathology Technology Australia is a major funder of the Know Pathology Know Healthcare program (run by Pathology Awareness Australia). It is through this program that we participate in a coalition of more than 20 healthcare related groups to form the Continuity of Care Coalition. This group has been responsible for raising awareness of the importance for people to continue looking after their health.

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Pathology Technology Australia published 3 position papers during the pandemic:

- *COVID-19 Avoiding the second Tsunami of Healthcare Challenges*. This paper was first published on 2nd April and outlined the concerns we had for people not following up on their healthcare needs outside of COVID-19.
- *National Testing Strategy for COVID-19 Recovery*. First published on 22nd April and recommended a testing strategy based on published data demonstrating that nucleic acid tests and serology testing together have greater diagnostic accuracy than either test done separately. Our recommendations suggested that serology testing has a role in our testing strategy as we emerge from the initial stages of this pandemic. It is important for our understanding of individual and population immunity and it is important for certain groups within our population, such as healthcare workers, teachers and first responders.
- *Making sense of a national testing stockpile*. First published on 4th May, this paper points out the challenges we face in developing a national stockpile of testing kits. It also highlights challenges we will face in maintaining local manufacturing capability at levels enough to supply our needs in a pandemic. Tests are not the same as PPE. They often have a very short shelf life and require exacting storage conditions. Our best suggestion for managing a short-term supply challenge is to fund supply companies to hold an extra 2- or 3-month's inventory in their local warehouses and have them manage the storage and turn-over of the stock accordingly.

Lessons Learnt

1. We were surprised when the government announced the acquisition of 1.5 million rapid antibody tests for COVID-19. As far as we know, there was no consultation with the industry or the professional groups such as RCPA. This decision was seriously flawed on several fronts:
   - The tests were not sourced from or through pathology test suppliers with a track record of reliability in Australia.
   - There was a lack of transparency and consultation.
   - There seemed to be no understanding of the limitations of these tests and of setting the right expectation about how these are best used and interpreted.

   An additional challenge with some of these products is that the results are not easily captured or tracked in a database and therefore become difficult to manage or use in a constructive manner.

   These kinds of products do have a role in healthcare, but the way in which they were acquired and then proven to be of low quality, erodes confidence in the available high-quality tests and technology.

2. The acquisition of tests and associated platforms by the Minderoo Foundation has also caught many in the sector by surprise. Whilst we fully support increasing product diversity and supply chain certainty, we are again concerned about the lack of transparency and consultation. In this case, it might also be that the federal DoH was caught by surprise. All-the-same, some discussion with the sector would have been welcome and may have helped with a much smoother implementation.

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3. When Australia locked down there were some serious unforeseen consequences related to people not continuing to attend to their ongoing health related issues. Visits to the GP and other healthcare professionals dropped between 40 and 80% in some cases. This was best seen through the pathology test numbers, which dropped by 40 to 60% across both the public health and commercial pathology laboratories. The effect of this is that people were not following up on cancer, diabetes and heart disease care, amongst many other conditions. There is now a serious concern that the human and health economic cost of the failure to manage non-COVID healthcare will far exceed that of COVID-19 itself.

4. There is an understandable but misguided push for local manufacturing to fill supply gaps for critical pathology tests. While there are some outstanding local manufacturers, their efforts cannot fill the supply gaps. It is important to understand that most testing devices require dedicated proprietary consumables. In some cases, 3rd party consumables can be adapted, but there is a substantial validation and quality verification overhead required to ensure the quality of these results. It is not practical to produce most pathology tests and consumables locally at short notice. Such short-term challenges might better be dealt with by funding suppliers to increase local inventory. We strongly endorse long term funding focused on nurturing local innovation to find new and exciting technologies to apply to future challenges.

5. Our member companies provide technical service specialists to install, train, service and repair vital testing technology. When national and state borders closed, and as airline schedules were cancelled, movement of these essential personnel across the country became extremely difficult. Each state established a different process for approving access to their state. The consequence of this complexity was delayed service, potentially impacting the availability of vital pathology testing. We need a standardised process across all states for the efficient movement of essential personnel.

6. Global air freight space became progressively harder to source, more unstable and more expensive. Members have noted long delays in uplift of testing products from overseas manufacturers, disruption to shipments in transit and freight rates increasing up to 10 times the pre-COVID price. We were grateful to Austrade for finding solutions to these challenges; however, these contingencies were not in put in place until mid-May.

7. Point of Care testing technology is available for testing in GP offices, community clinics and in rural and remote settings. Pathology Technology Australia has, for 5 years, been promoting the establishment of a funded Point of Care Testing infrastructure and capability in Australia. In our view, Point of Care Testing is critical and can provide accessible, affordable and high-quality testing for all Australians. During COVID-19, our members provided tests and technology for use in the Point of Care Testing environment. However, no funding for such testing exists today, and this will limit the benefits only to those who are willing to pay. To better manage the healthcare for all Australians, we need a policy of funding for Point of Care Testing across a range of healthcare management issues, such as infection, heart disease and diabetes.

Recommendations

It is clear from this experience that suppliers hold important information and resources that can better inform policy and strategy, and as such we have the following recommendations:

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- Pathology Technology Australia stands ready to provide critical information on testing capability, supply and innovation. We recommend that a methodology be established to enable Pathology Technology Australia to provide relevant and timely information directly to the groups managing healthcare policy and pandemics. We are the only group that holds the consolidated information on testing capabilities, supply chain stability and the innovation pipeline, and are therefore an integral part of the pathology testing ecosystem.
- Greater transparency and consultation ahead of any substantial purchase of test kits, when not sourced from suppliers with a track record of reliable supply in Australia.
- Early establishment of a clear and well communicated plan for people to continue managing their healthcare outside the challenges of the pandemic.
- A standardised and coordinated process for facilitating movement of essential personnel across state borders.
- Establish international air freight contingencies for essential products early in a pandemic.
- Consultation with Pathology Technology Australia on initiatives for increasing a national inventory of critical tests.
- TGA to consider the capability of sponsors to provide technical support and training as part of any accelerated product registration or temporary exemption.
- Manufacturers and suppliers have access to some of the most experienced and knowledgeable scientists and clinical experts in the world. We should use them.

In conclusion, as the peak body representing manufacturers and suppliers of pathology testing for all Australians, and the reasons outlined above, our recommendation is that Pathology Technology Australia be included in the groups advising government on testing and associated testing technology.

About Pathology Technology Australia

Pathology Technology Australia Ltd is the peak industry body representing manufacturers and suppliers of technologies, vital to testing patient samples in the clinical laboratory, in hospitals and in the community. Our members supply more than 90% of all pathology tests and associated technology used to diagnose and manage the health of Australians.

This technology enables more than 500 million tests to be performed in Australia every year. With an aging population and increasing disease chronicity, pathology testing technology will play an increasingly important role in providing high quality, accessible and affordable healthcare services in Australia's future.