PANTONIC HEALTH

"A pathology lab the size of a shoe box is giving us the control we need"

Rapid PCR Testing trial (DnaNudge)

Whiddon Glenfield Residential Aged Care

An evaluation
January 2022

Whiddon
Award-winning care

Introduction

Whiddon has been providing exceptional care to older Australians across regional, rural and remote NSW and QLD for more than 70 years. From our philanthropic beginnings, we have grown into a large not-for-profit organisation with more than 1,800 residents, across 20 locations, employing close to 3,000 employees. We are an award-winning aged care provider with residential aged care, community care services and retirement villages across New South Wales and South East Queensland.

In addition to this, Whiddon's Community Care provides care and services to over 800 clients with over 100,000 annual service hours. Services are provided through a variety of funding streams including Home Care Packages, the Commonwealth Home Support Program, the National Disability Insurance Scheme, and private and brokerage services.

Whiddon is passionate about enriching lives, and supporting wellbeing for its residents, clients and employees. We have a strong reputation for innovation and leadership in the industry through our involvement in areas such as relationship-based care, creative ageing, animal wellbeing programs and more recently, health screening technologies such as Rapid Antigen Tests and Rapid PCR.

This report is an evaluation of a trial into Rapid PCR testing within an aged care setting, using equipment and technology developed by DnaNudge. The trial is a collaborative initiative between Whiddon and Pantonic Health, who are the licenced distributors of the DnaNudge Rapid PCR in Australia.

Acknowledgements

- Pantonic Health
- DnaNudge and Regius Prof Christofer Toumazou FRS
- Whiddon Glenfield, Sharon Fletcher and the entire Glenfield team who contributed to the trial under extremely challenging circumstances
- Pandemic Health Solutions

Contents

Executive summary

This report represents Whiddon's findings following the trial of a Rapid PCR testing device, within an aged care setting during the COVID-19, Omicron outbreak in Australia. The trial commenced on 19 November 2021 and utilised a Rapid PCR unit, capable of delivering results within 90 minutes, developed by UK firm DnaNudge and distributed by Pantonic Health.

This report follows Whiddon's pioneering trial into rapid antigen testing within the residential aged care services environment in July 2021, during the COVID-19 Delta outbreak. This trial was supported by the Commonwealth Government and resulted in the widespread use of rapid antigen testing as an important screening tool in residential aged care and other industries.

The trial provided valuable insights into workforce screening, through a single point of entry with high volumes of pedestrian traffic, while also validating the testing regime required to most effectively screen employees working frequently within an aged care environment.

Further, this initial trial led to a secondary effort, aimed at screening the mobile workforce operating in the Home Care environment. This latest Rapid Antigen Trial applied technology, by way of a mobile application, to support off-site screening and ensure that employee results could be efficiently administered to protect employees and clients alike.

Throughout both trials, which were conducted intermittently over a period of approximately six months, PCR testing remained the "gold standard" and was required as a secondary and mandatory verification mechanism. Rapid antigen tests demonstrated their utility and value in both settings and have proven to be an invaluable tool, not only in health settings, but within our communities as a whole. This is evident by the widespread acceptance and use of rapid antigen testing to manage the Omicron outbreak across Australia.

Figure 1. Whiddon and Pantonic Health Employee Screening Trials, July 2021 – November 2022

While the application of Rapid Antigen Tests within Australia has expanded more broadly, following relaxation of regulations requiring clinical supervision requirements, PCR testing continues to act as the key validation instrument.

With this noted, the main hindrance relating to PCR testing in Australia today, remains the time taken to obtain results. This includes the time taken to visit, queue and complete a PCR test, coupled with the waiting time for processing and receipt of results. Where community transmission is at its highest, as has been experienced during the Omicron outbreak, PCR testing can take 72 hours or more to receive a result. At the time of writing this report, NSW Health had placed a notice asking people to "allow up to 5 days" before following up for further support. Even during times of lower community transmission, any lost time within a critical setting (such as health or aged care) can be detrimental and place lives at risk, so accurate, instantaneous testing can only be seen as a positive.

In our experience, the trial and exposure to the DnaNudge unit within an operating environment, has proven to address this critical issue. The DnaNudge has delivered PCR standard results within 90 minutes of which 99.1% have correlated with pathology results taken concurrently.

In deciding to proceed with the DnaNudge device, Whiddon's due diligence included reviewing various comparative studies assessing the diagnostic accuracy of the unit, accessing direct references from public and private entities recommending the product, as well as a meeting with Regius Professor Chris Toumazou to discuss the background, technology and operation of the DnaNudge first-hand. This was followed by a number of live workshops that involved Whiddon clinicians who were able to access and use the unit in a simulated environment.

The DnaNudge Rapid PCR test is not approved for use in Australia as yet, however an application with the Therapeutic Goods Administration (TGA) is underway.

Key Highlights

This trial demonstrated the benefit of having an on-site rapid PCR test which provided comparatively reliable results within 90 minutes. The key highlights of this trial were:

- Of the 116 people tested using the DnaNudge, only 1 of those results differed to the lab-based PCR test. This represents an accuracy level during the trial period of 99.1% against the pathology results
- The DnaNudge test was easy to administer, with the only minor challenge identified relating to establishing connectivity with Wi-Fi
- The early results enabled early intervention to enact Outbreak Management, potentially halting further transmission of the virus

- The impact on the workforce of saving anywhere between 24 hours to 6 days in isolation whilst waiting on a PCR results is significant and would provide much needed relief to a workforce in crisis
- The capability of being able to pool up to 12 specimens within one testing period provides additional efficiencies, both from a timing and cost perspective
- Rapid PCR testing has broad application across residential and community aged care services to provide enhanced management of COVID-19 and potentially other viruses. This is particularly relevant in rural and remote areas where point of care testing provides a much more efficient method of diagnoses compared to laboratory-based testing which may be located several hours from the service.

About the DnaNudge

DnaNudge's COVID Nudge test is a rapid, accurate, portable and lab-free RT-PCR test that delivers results at the point of need and in 90 minutes. The test is authorised by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for clinical use and has subsequently obtained its CE mark. An average sensitivity – compared against numerous the UK's National Health Service (NHS) lab-based tests – is around 95% and specificity around 100%. These results satisfied the MHRA's performance criteria. The test is now being rolled-out UK wide in urgent NHS patient care and elective surgery settings, plus out-of-hospital locations.

The test is currently being used successfully in eight London hospitals – including cancer wards, emergency and maternity departments. The CovidNudge test is now in the process of being deployed across the NHS nationwide, in urgent patient care and elective surgery settings, plus out-

Regius Professor Chris Toumazou, CEO and co-founder of DnaNudge and founder of the Institute of Biomedical Engineering at Imperial College London provided the following statement:

DnaNudge is very excited to be working with Whiddon and Pantonic Health to demonstrate the benefits of our rapid, lab-free RT-PCR test in aged care settings, where the ability to rapidly identify COVID-positive individuals is of absolutely paramount importance, and key to infection control. Our CovidNudge test is a unique, portable true PCR platform that offers a high degree of multiplexing on a single chip, with 72 available wells enabling the simultaneous detection of new and emerging SARS-CoV-2 virus variants such as Delta and Omicron. Our new 'quad cartridge' can detect all variants of COVID and also, crucially, distinguish between Flu A, Flu B and respiratory syncytial virus (RSV), providing a vital tool to help differentiate between common circulating respiratory viruses. We believe that CovidNudge is the only test that goes direct from sample to result, using a true gold-standard thermal cycling PCR technique that delivers results within 90 minutes. The value our solution has delivered across care homes and mental health services within the UK has been immense, with no trade-off whatsoever between speed and accuracy.

of-hospital locations. In addition to COVID-19, the DnaNudge also has the capability of testing for influenza and RSV viruses.

(DnaNudge, www.dnanudge.com)

The problem

PCR testing has long been recognised as the "gold standard" for COVID-19 diagnosis. However, as community transmission of COVID-19 significantly increased in NSW, the pathology-based PCR testing failed to adequately support aged care operations and other operating environments, due to delays created by the volume of tests. It was reported that test results were taking up to six days to be returned, thus losing the critical time for early intervention to stop further transmission of the virus.

Within an aged care setting, delays in receiving the result of a COVID-19 diagnosis are detrimental to care delivery on a number of fronts. In regard to residents, it increases the isolation period that individuals are exposed to, which impacts the wellbeing of the care recipient and their families alike. A delayed diagnosis may also delay any necessary medical interventions required. Further, in regard to employees, delays in receiving COVID-19 diagnosis have resulted in many employees furloughing and remaining in isolation unnecessarily as their samples have eventually returned negative results. This has occurred during unprecedented pressure on the workforce, due to the pandemic, a characteristic of COVID-19 not restricted to Aged Care.

The objectives of the trial

The overarching aim of the trial was to gain more control in protecting residents, clients and employees and their families from contracting the COVID-19 virus, through earlier detection of COVID-19. Directly, it was anticipated that early intervention would provide improved health management and infection control measure for residents, while indirectly, the objective was to understand whether this could be achieved by increasing the capacity of the workforce through early detection and reduced furloughing measures.

To achieve this, it required reducing dependency on external third parties providing COVID-19 diagnosis support, which carried with it risk, and operational inefficiency in the midst of a crisis. In addition to this, the trial sought to assess the utility and application of a mobile, PCR-testing unit available on-site, within a busy and dynamic operating environment, to aid the early management and control of COVID-19 transmission.

Setting up the trial

Timing and scope of the trial

The trial was implemented at Whiddon Easton Park, a 488 residential aged care campus employing over 700 employees. The trial commenced in November 2021 and continued through to January 2022.

Education and training

Education on how to use the Nudge Box was provided by Pandemic Health Solutions in Australia and DnaNudge in the UK, applying train the trainer methodology. Further training was then provided to the end-users by the internally endorsed trainers.

The training consisted of:

- Setting up the Nudge Box and iPad
- Testing protocols
- Using the Nudge Box for both individual and pooled samples
- Interpreting the results
- Clinical practices.

Guidelines and instructions were customised and provided to the end-users. It should also be noted that a level of ICT support was required to assist with network configuration and the necessary WIFI and security access that the PCR Nudge Requires.

In addition to this, the two key testing methodologies and related protocols had to be clearly understood by Whiddon's DnaNudge operators. Specifically, this related to "pooling tests" versus single tests. The DnaNudge unit has the capability to test up to 12 samples at a time, generating a result for the pooled sample. This is ideal in a residential aged care setting, where wings within a building can accommodate over twenty residents.

With this said, and in reference to the pooling of tests, care must be taken to accurately record and track the residents tested, in the event that a positive test is generated. As the pooled testing process cannot track the individual or individuals who have tested positive, where a positive result is detected, the pooled group must then be tested again, individually. However, this early test allows for the impacted wing to be isolated (rather than the whole floor or building) until the individual tests are received.

Process and testing protocols

Testing protocols were developed to ensure clear understanding of the process and follow-up required. The protocols were reviewed and approved by the consultants involved in managing the trial.

Rapid PCR testing was completed on the following people:

1. Employees and residents who returned a positive rapid antigen test
2. Residents and/or staff who were exhibiting COVID-like symptoms
3. Residents that returned to the facility after visiting a hotspot location or high-risk areas such as hospital visit
4. Residents and employees who were deemed close or casual contacts where there is an exposure risk to others
5. Visitors who have been deemed close or casual contacts following a visit and who consent to the dual testing.

It is worth noting that not all employees who returned positive rapid antigen tests during this period participated in the trial. Circumstances and timing resulted in some employees attending the lab-based PCR tests only.

- Confirmation of the test result against the lab-processed PCR test was to occur as soon as possible
- Until the result was confirmed from the laboratory, the person was considered COVID-19 positive until proven otherwise
- The COVID-19 Outbreak Management Plan was implemented
- Ongoing management of this person was as per the advice from NSW Health.

Collection of data

A mixed methods approach was applied to gathering data and feedback throughout the trial. Measures included:

1. The number of tests completed within the period
2. The number of positive tests and their correlation against the lab-based PCR test
3. Surveying of the personnel who operated the Nudge Box to identify ease of use and any other key findings when testing
4. Surveying key personnel to understand their experience of using the Rapid PCR testing
5. An analysis of the impact that lab-based PCR test result processing time has on the workforce.

Findings

Data measures

Number of tests completed

The trial commenced on 19 November 2021 and for the purpose of this report, was finalised on 14 January 2022. During this period, there were 62 tests processed of which 9 were aborted due to error. Of the 53 tests completed, 7 of these were pooled samples resulting in 116 tests being completed in total.

From the 116 tests completed:

- 18 tests returned a positive result including one pooled test
- Following the positive pooled test, individual samples were taken which identified two positive cases
- All but one of the positive test results aligned with the lab-based test results demonstrating a 99.1% sensitivity
- The one test that tested negative on the Nudge Box, that did not correlate with the positive lab-based PCR test, was from an asymptomatic person who did not experience any symptoms for the duration of the infection.

Surveys

Two surveys were conducted with:

1. The employees who operated the Nudge Box, and
2. The senior managers of the campus.

Key themes emerging from the operators were as below (n=4).

Did you find the Nudge Box easy to use?	Were there any difficulties when using the Nudge Box?	Did you find the pooled sample functionality useful?	Were there any concerns raised by any of the people tested using the Nudge?
The main difficulty experienced with the Nudge Box was connecting the box to the Wi Fi network. Once this was resolved, general feedback indicated that the box is easy to operate.	Generally only Wi Fi connectivity. The quick reference guide was beneficial for trouble-shooting problems. The iPad was on UK time and this created some confusion and at times, it displayed the results from tests which were conducted elsewhere. The team would also like to further understand the reasons for the aborted tests.	Feedback indicated that the pooled samples were beneficial, especially for saving time and working to assess the COVID-19 status of wings or hubs of residents. Some concerns were raised about conducting this in a safe environment due to the increased risk of exposure when working with multiple samples.	Generally no, other than residents becoming sample weary due to the length of the COVID-19 pandemic.

Key themes emerging from the senior managers were as below (n=8).

What benefits did you experience in having the Rapid PCR test available on-site?	Did having access to the Rapid PCR make COVID management easier	What role do you see the Rapid PCR testing have going forward?
• Timely diagnosis, enabling a rapid response especially as the lab-based PCR test results have often been delayed • Pooled samples enabled quick containment of the area • The Rapid PCR testing could potentially lead to better resident outcomes due to early identification and intervention • Provides peace of mind to residents, families and staff to get a rapid response.	• **Rapid results mean rapid action!** • Enables swift activation of Outbreak Management Plan and therefore reduce risk • Beneficial for employees who tested RAT positive as they will able to have their PCR test completed and return to work if it negative • Really useful for symptomatic residents to get a swift response • The changing rules around rapid antigen tests does impact the relevance of the Rapid PCR in the current high transmission environment.	• The changes allowing RATs as evidence for COVID-19 may impact upon the use of the machine in high community transmission areas. However, as there can be a higher level of false positive in rapid antigen tests, the Rapid PCR could be used to test these staff and potentially assist with the workforce shortages if the RAT provides to be a false positive • In times of high community transmission and when a service is in outbreak management, there is less reliance on the Rapid PCR. However, during periods of lower community transmission, the Rapid PCR must form part of the clinical assessment for symptomatic residents and staff • Rural areas often have extended delays for PCR results so having a Nudge Box on-site will enable timely diagnosis • The Nudge Box has the ability to screen for other viral illness and this too would be of benefit to manage outbreaks.

Cost of the trial

Unit cost of the testing

- The commercial arrangement applied to the DnaNudge provides the unit at no direct cost, rather the test cartridges are purchased for a nominal amount (at the time of this report $99 per unit or $125 for pooled or multiplex cartridges). For clarity, this is comparable to the manner in which many home printers are sold
- The set-up costs of the trial for an 80-bed residential aged care service, incorporating RN education and ICT set-up expenses is approximately $2,000 (6 RNs trained for 2 hours each plus a generous 8 hours of ICT support)
- The single cartridges retail for approximately $99 for individual tests and $125 for pooled tests (up to 12 tests)
- Registered Nurse time to run the test is approximately 15 minutes which equates to approximately $14 per test
- Therefore, the unit cost per individual test (excluding the initial set-up and education costs) is approximately $113
- The unit cost per pooled test (n= 12 and assumption that all tests are negative and nil further testing is required), incorporating an additional 30 minutes of RN time for specimen collection, is approximately $38 per person.

Test costs and results:

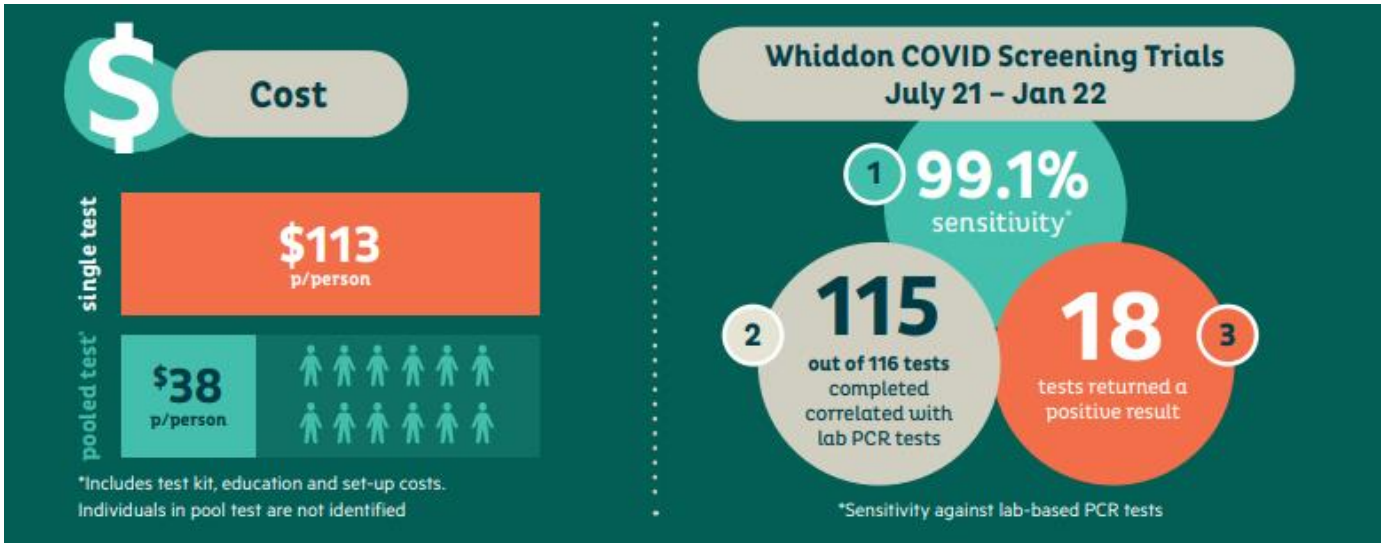

Figure 2. Whiddon PCR trial costs and results

Cost comparison against the lab-based PCR test

- A lab-based PCR test result has taken up to 6 days to return
- A conservative estimate of a 48-hour return timeframe will result in personal leave payments for employees required to isolate until they receive their test results (average wage costs plus loading):
    - Assistant in Nursing (AIN) = $534
    - Registered Nurse (RN) = $920
- These savings are in addition to the savings that could be made if agency staff are not required to replace unnecessarily furloughed employees (as detailed below).

The pooling of tests is obviously far more efficient from a cost perspective as only one test cartridge is utilised, thereby allocating the unit cost ($125) across the number of individuals tested.

In our experience, Whiddon found that it was more financially viable to test using the pooled approach. Essentially, this meant that of the 6 pooled tests that were conducted at Whiddon Glenfield across 63 people, only 1 generated a positive result. Had Whiddon tested each resident individually in this example, the cost would have arrived at $7,119 rather than $1,320. This latter figure takes into account retesting 10 people individually to determine the positive tests. This demonstrates a saving of around $5,800 through the use of pooling. This method is most applicable with cohorts where the probability of infection is low.

Of course, this result is totally dependent on the environment and the level of transmission. During the entire period that these pooled tests were conducted, and while community transmission was peaking, Whiddon only had 4% of residents test positive. However, as the Omicron peak neared, up to 24% of employees were tested as positive using rapid antigen tests, generally at the screening point, prior to entry to the homes. At this point, the pooled testing method was less useful. Where high levels of transmission are occurring within the home, our view is that it is optimal to test individually, although the trial did not assess at which point the effectiveness of pooled testing diminishes. Combining the screening of employees with a mixed model, utilising RAT's and Rapid PCR can reduce costs further and provides a more efficient operating model based on current cost structures.

Valuable Care Hours Lost Due to Employees Self Isolating

To illustrate the impact that delays in testing have on the workforce, a review of COVID-19 confirmed and suspected employees was conducted across the entire Whiddon group of services. During the period between 1 December 2021 and 31 December 2021, Whiddon recorded 40 employees who were COVID-19 positive from a cohort of 236 suspected COVID-19 positive employees. This illustrates, of the 236 lab-based PCR tests conducted, only 40 tests (17%) delivered a positive result (incidentally, this result is closely aligned to the 16% positive test result identified in this trial).

Using this 17% positive test rate, the impact on the workforce, who are enforced to isolate whilst awaiting PCR results, can be further extrapolated. Specifically, 196 (83%) of the 236 employees tested PCR negative and in compliance with best practice and public health orders, all employees were required to self-isolate until pathology results were obtained. In the absence of a Rapid PCR unit and applying a conservative 48 hours waiting period, this will result in 708 hours per week lost from the roster as these employees will eventually deliver negative results. This equates to over 18.6 full time equivalent employees over the course of a week, that could be redirected towards critical care management during the peak of the pandemic. The chart below provides a graphic illustration of the potential hours lost unnecessarily due to the delays in PCR testing (i.e. 83% of the employees tested were negative).

In terms of cost to the organisation and should suitably qualified staff be available, it is anticipated that these additional 708 hours paid at agency rates for Assistants in Nursing ($47/hour) will amount to approximately $33,282 in additional wages to cover furloughed employees, over the week alone and $147,392 for the month. This cost will increase if the furloughed staff are registered nurses.

Workforce impacts:

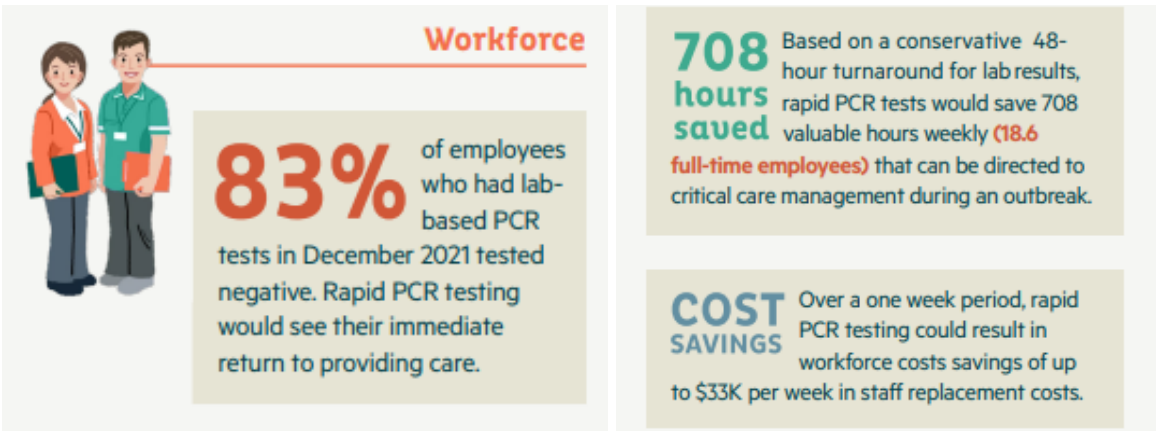

Figure 3. Potential impacts on the Aged Care workforce of rapid PCR testing

Discussion

Giving Providers Control, Minimising Risk and Optimising Care Delivery

In addition to the significant impact a rapid PCR unit has on workforce management, frontline managers involved in the trial noted the control it offered operators, thereby reducing exposure to risk. Operational managers noted that by having access to self-managed PCR technology that returns results within 90 minutes, decision making in regards to both workforce outcomes and resident care, becomes more effective and efficient whilst removing operational risk.

In terms of employee management this is achieved by:

- The ability to manage rosters more effectively
- Reducing employee anxiety by the reporting of results instantaneously
- Less stress on workforce management strategies and supporting staff
- Reducing workforce demands as a result of increased resident isolation practices
- Reducing reactive management practices among service managers and supervisors (critical during a crisis)
- Reducing additional cost (i.e. agency and additional support costs).

In regards to resident care, this is achieved by:

- Improving wellbeing outcomes for residents as a result of shortened isolation periods
- Allowing early health care management intervention as a result of early identification
- Improving infection control as a result of early intervention
- Reducing stress and anxiety on family members and loved ones alike.

Early Intervention Health Strategies
On 6 February 2022, the Federal Government announced that a new oral anti-viral treatment for COVID-19 (Lagevrio (molnupiravir)) will be deployed to all residential aged care services throughout Australia. The advice received specifies that the Lagevrio treatment has been provisionally approved for use:

- in COVID-19 positive adults who do not require supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death
- when prescribed by a GP with discussion on treatment options and consent from the aged care resident
- taken every 12 hours for 5 days, within 5 days of symptom onset (treatment after the initial 5 days of symptoms is unlikely to benefit or be prescribed).

(Source: Department of Health Update / Provider email 06/02/22)

Access to new and emerging COVID-19 treatment strategies (such as Lagevrio), that require early identification of the virus, places even more emphasis on the ability to deploy rapid PCR technology within the active operating environment. This is further amplified within the aged care setting, given the level of acuity among residents, who will directly benefit from these early intervention measures. This is further compounded when we consider those services that reside in regional locations, who can dramatically improve outcomes by accessing results quickly and efficiently.

Other areas worth noting:

- Access to the rapid PCR removes the reliance on the Public Health Network and Pathology Labs in times of increased cases experience delays in workflow, communication and general support
- Removes uncertainty and inefficiency from the crisis management process, which is critical in delivering successful outcomes.

Lab PCR tests vs rapid PCR tests:

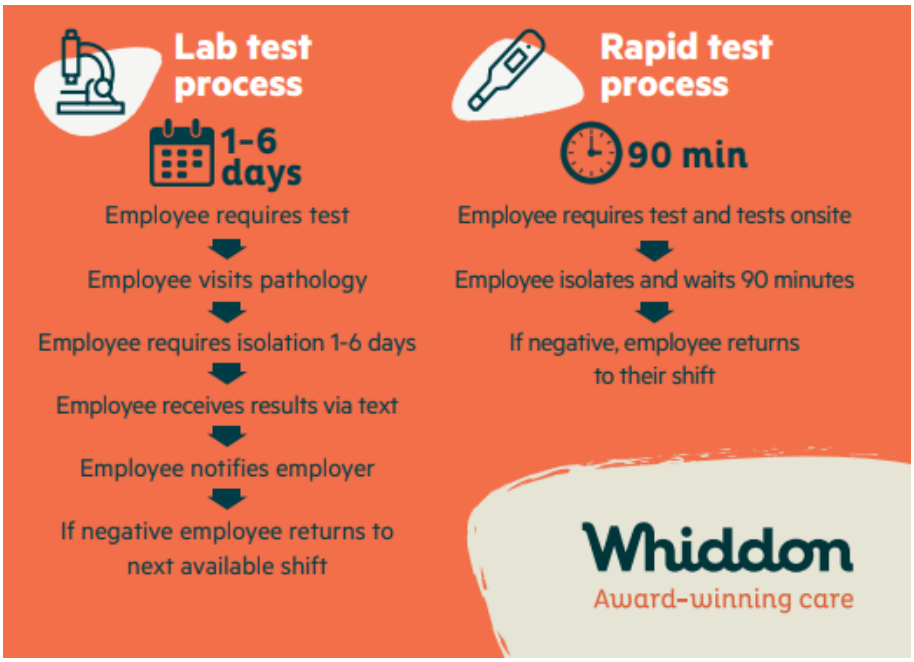

Figure 3. Comparison of timing of lab-processed and rapid-PCR testing

Conclusion

Access to a Rapid PCR testing device, that is portable and returns a result within 90 minutes, has been described as a "game changer". At an operational level, the DnaNudge has the ability to maximise resident care and safety, while also minimising the disruption to the workforce. This is achieved by providing autonomy and control to frontline team members and aged care operators alike.

While the various phases of the pandemic have seen the wait time of PCR test results fluctuate when conducted offsite by third parties, the DnaNudge removes the delays and unpredictability and therefore the risk, as community transmission begins to escalate. This is amplified in regional communities, where PCR test samples are sometimes flown to larger centres for processing.

As such, it is not only the speed at which the unit generates PCR quality results, it is the level of control that the unit brings with it, and therefore the ability for operators to much more closely and effectively manage risk and the safety of their care recipients and employees.

The trial has demonstrated the significant impact that a rapid PCR unit can have on resident care and our critical health workforce. Regardless of the fluctuating levels of community transmission and with the unit's ability to also detect strains of influenza, rapid PCR provides a valuable proactive and cost effective measure in the battle against infectious disease.

While the business model to acquire the unit appears quite reasonable, particularly where a pooled approach is applied, current aged care funding does not support their widespread application. Much as we have seen the Commonwealth subsidise Rapid Antigen Testing in aged care, rapid PCR units should also be subsidised across all aged care homes in Australia, with priority given to regional centres.

The use of this technology will essentially reduce the burden on commercial pathology labs which receive Commonwealth funding for current COVID-19 PCR testing. Through a government subsidised model, this will likely result in a cash neutral reallocation of funding from the Federal budget to the Aged Care Sector (i.e. supporting direct PCR testing), utilising funds that will have normally been directed to pathology labs, thus minimising the burden to taxpayers. In addition, it will also provide pathology labs with greater capacity to support the broader community.

As a country, we continue to learn to live with COVID-19 and improve our collective response to the virus. Just as Rapid Antigen Tests and protective personal equipment (PPE) have become the norm within health and aged care, rapid PCR units should follow suit.