MEDIA RELEASE **1 APRIL 2020**

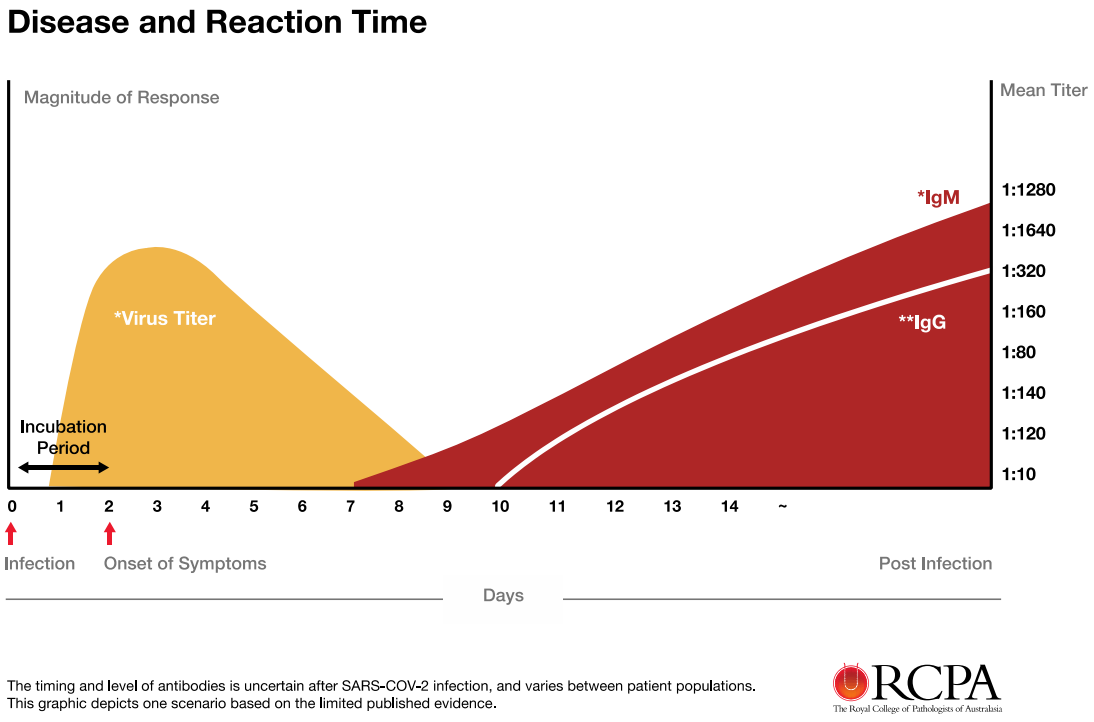
RCPA advises against COVID-19 IgG/IgM rapid tests for the detection of early COVID disease

The Royal College of Pathologists of Australasia (RCPA) supports the use of molecular tests for SARS-COV-2 and advises against the use of serological COVID-19 IgG/IgM rapid tests, such as a pin prick blood test, to detect early COVID disease.

President of the RCPA, Dr Michael Dray said,

"The IgG/IgM tests have a fundamental limitation; they rely on the detection of antibodies made by the patient in response to SARS-COV-2, they do not detect the virus. Patients may only make antibodies to COVID-19 infection a week to 12 days after they first become sick, therefore, if doctors rely on these rapid tests early in the disease, their diagnosis will be wrong."

The graph below demonstrates the difference between the level of IgG and IgM antibodies and the virus titre, in relation to the incubation period for COVID-19.



The RCPA states that:

- Molecular testing on a single throat with deep nasal swab is the current test of choice for the diagnosis of acute COVID 19 infection;

- COVID-19 IgG/IgM rapid tests have no role to play in the acute diagnosis of COVID-19 virus infection, and most importantly;
- COVID-19 IgG/IgM rapid tests will miss patients in the early stages of disease when they are infectious to other people.

"The RCPA therefore recommends that the new IgG/IgM tests are not used to screen for early infection, and that current Polymerase Chain Reaction (PCR) tests remain as the primary testing method for COVID-19. Whilst these new antibody tests may have a place in detecting unrecognised past infection and immunity, that role still needs to be rigorously evaluated.

"Most importantly, from a public health perspective, COVID-19-positive patients are infectious to other people early in infection when the COVID-19 IgG/IgM tests are giving false-negative results. False negatives would have serious risks of incorrectly reassuring people and therefore increasing the spread of infection within the community.

"Furthermore, elderly or immunocompromised patients may take some time to develop anti-SARS-COV-2 antibodies, and some may never develop antibodies. Reliable detection of IgM antibodies early in infection is also problematic due to cross-reactions resulting in false-positive results. In sharp contrast, the basic strength of molecular tests is that they directly detect gene sequences of the virus in the early stages of infection when the patient is infectious," said Dr Dray.

Australia is among the world leaders for the number of SARS-COV-2 molecular tests performed per 100,000 population, with more than 250,000 undertaken in Australia so far. New Zealand pathology laboratories are also performing large numbers of molecular tests, with over 1,770 tests performed per day currently.

The RCPA Quality Assurance Program (QAP) recently introduced one of the first quality assurance programs for SARS-COV-2 in the world. This program will help laboratories optimise their molecular tests that have had to be developed rapidly in response to the COVID-19 pandemic.

In the early days of the pandemic, Australia effectively and rapidly developed and implemented robust national testing capacity through the Public Health Laboratory Network (PHLN). Testing is now broadly available through a range of hospital and private pathology providers, providing additional valuable support to Australia's response to this public health emergency.

"The Therapeutics Goods Administration (TGA) requires that all SARS-COV-2 tests kits, both molecular and antibody-based, are subject to an effective evaluation process in Australia, this is especially important during this the COVID-19 emergency where the risk to the community of a false negative test is very high.

"It is encouraging that further review and assessment of the antibody tests has been commissioned by the TGA. The RCPA and its Fellows look forward to working with the TGA and other stakeholders to determine the best use of these COVID-19 IgG/IgM rapid tests in the Australian setting. By doing this, we will be able to safeguard Australia's world-class

testing capability for COVID-19 and ensure that the highest quality testing technology is available to support the Australian community. The College also looks forward to providing similar assistance to the authorities in New Zealand," said Dr Dray.

To view the RCPA's position statement on COVID-19 IgG/IgM rapid tests visit:

https://www.rcpa.edu.au/getattachment/bf9c7996-6467-44e6-81f2-e2e0cd71a4c7/COVID19-IgG-IgM-RAPID-POCT-TESTS.aspx

To download the graph visit:

https://www.dropbox.com/sh/zv69ebrgzcn2dkx/AADZO7S31itC4Wj8SxNBx0zza?dl=0

For further information on the RCPA, please visit www.rcpa.edu.au or see our updates on Facebook - @PathologyRCPA, Twitter - @RCPAPresident, @PathologyRCPA, or Instagram - @the_rcpa #RCPA #pathology #MedicineIsPathology.

ENDS

About the Royal College of Pathologists of Australasia:

The RCPA is the leading professional organisation representing pathologists, medical specialists and scientists who provide pathology testing in Australasia. Its mission is to train and support pathologists and to improve the use of pathology testing to achieve better healthcare.

Media enquiries:

Dr Debra Graves
Chief Executive Officer
The Royal College of Pathologists of Australasia
+61 2 8356 5858
Debrag@rcpa.edu.au

Linsey Brown
Managing Director
The Public Relations Agency
+61 425 514 005
Linsey@thepublicrelationsagency.com.au