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RCPA
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Position Statement

Subject:	**COVID19 IgG/IgM RAPID POCT TESTS**
Approval Date:	March 2020
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Reviewed By:	Microbiology Advisory Committee
Number:	1/2020

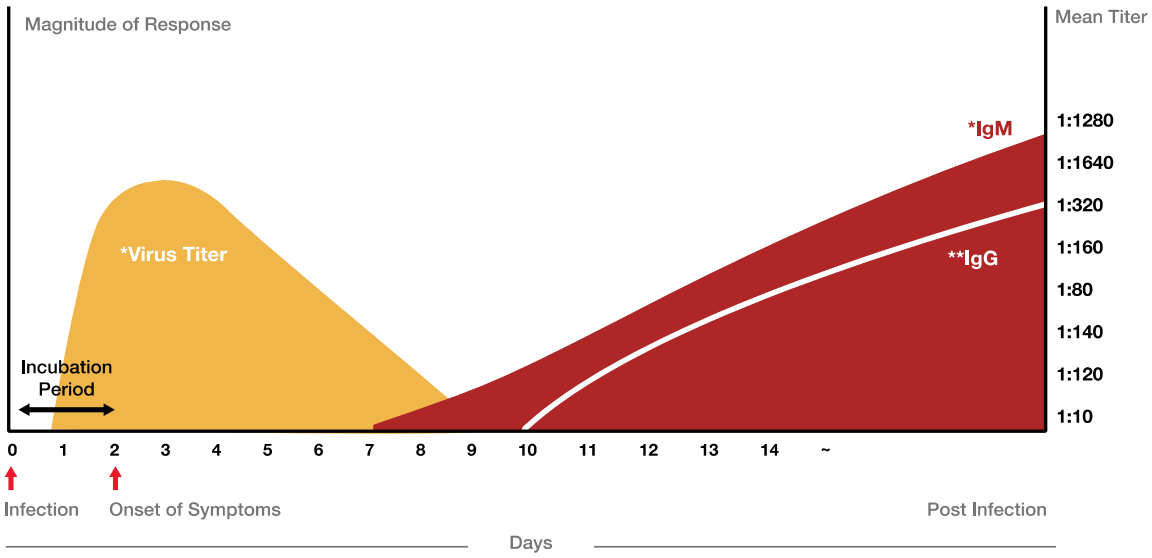
The Royal College of Pathologists of Australasia (RCPA) states that:

- 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.

One COVID-19 IgG/IgM rapid test received extensive media publicity around Australia and New Zealand recently. These IgG/IgM tests have a fundamental limitation. They rely on the detection of antibodies made by the patient in response to SARS-COV-2, the virus that causes COVID-19 disease, they do not detect the virus and thus must not be used to screen for early infection.

Patients may only make antibodies to COVID-19 infection a week to 12 days after they first become sick (see diagram below). If doctors rely on these COVID-19 IgG/IgM rapid tests early in the disease, their diagnosis will be wrong. Furthermore, elderly or immunocompromised patients may never (or only much later) develop anti-SARS-COV-2 antibodies. Reliable detection of IgM antibodies early in infection is also problematic due to cross-reactions resulting in false-positive results. Most importantly from a public health perspective, COVID-positive patients are infectious to other people early in infection when the COVID-19 IgG/IgM tests are giving false-negative results. Australia's public health response will be compromised by the use of these tests in the early stages of COVID disease.

Disease and Reaction Time



The timing and level of antibodies is uncertain after SARS-COV-2 infection, and varies between patient populations. This graphic depicts one scenario based on the limited published evidence.

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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. More than 230,000 SARS-COV-2 tests have been undertaken in Australia so far. In fact, Australia is among the world leaders for the number of SARS-COV-2 molecular tests performed per million population. New Zealand pathology laboratories are also performing large numbers of tests with over 1700 tests performed per day currently. No laboratory test is perfect. Molecular tests can miss COVID-infections if a poor sample is collected or if the patient carries a low level of virus. A well collected single throat with deep nasal swab are the optimal sample for PCR. Limited data is available on the presence/ duration of viraemia, (virus in the blood) and therefore on the performance of PCR's on blood samples.

RCPAQAP has just run one of the first quality assurance programs (QAP) 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.

For the detection of early COVID disease, RCPA therefore supports the use of molecular tests for SARS-COV-2 and strongly opposes the introduction of COVID-19 IgG/IgM rapid tests for this purpose. The excellent laboratory response to the COVID-19 pandemic in Australia would be jeopardised by inappropriate widespread use of COVID-19 IgG/IgM rapid tests.

These antibody tests may have a place in detecting unrecognised past infection and immunity however that role needs to be rigorously evaluated. The RCPA is aware that further review and assessment of these tests has been commissioned by the Therapeutics Goods Administration (TGA) and the College 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.

Finally, 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 COVID-19 emergency where the risk to our community of a false negative test is very high.