

Chief scientist warns against serology for identifying past COVID infection

No good for diagnosis, now concerns about the accuracy of the blood tests suggest their use is limited even for identifying antibodies, says Professor Alan Finkel

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There are no serology tests accurate enough to detect an individual's immunity to COVID-19 or identify the disease's true prevalence, Australia's Chief Scientist is warning.



Some 1.5 million of the tests have been ordered by the Federal Government and their approval for use fast-tracked by the TGA.

But concerns about their value continue.

A review by Professor Alan Finkel has concluded that the global evidence on the current crop of serology tests shows they are not even adequate for retrospectively tracking the spread of the virus.

“For as long as the prevalence of COVID-19 is low in Australia and available serological tests are not approaching 100% specificity, serological testing to measure the prevalence of COVID-19 will not be meaningful,” his review, released last week, says.

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The TGA has so far approved more than 20 different serology tests for use in Australia after a fast-tracked, less rigorous assessment process of their safety and efficacy.

But it has also asked the Doherty Institute for Infection and Immunity to confirm their sensitivity and specificity - work that is still ongoing.

It remains unclear which tests have been purchased by Australian Government, which it originally said would be for use by GPs.

Nor have the promised details on the protocols for their use been published.

The UK Government reportedly spent more than AUD\$30 million on two million serology tests earlier this year, with Prime Minister Boris Johnson saying they had “the potential to be a total game changer”.

But Professor Finkel, in his review, cites research from Oxford University on the nine most promising serology tests considered for potential use in the UK.

None of the tests reached the target of 98% specificity, which researchers said was essential to avoid putting people at unnecessary risk if they were wrongly declared immune to COVID-19.

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In Australia, given case numbers are still low, the minimum expectations for the accuracy of the tests should be even higher, Professor Finkel said.

“For example, if a test is 99% accurate (sensitivity and specificity are each 99%) but the disease prevalence is only 1% of the population, then the false positive rate will be 50%.

“This creates a significant challenge in identifying immunity within populations in a country with a low rate of infection.”

He added that serology tests also relied on “a clear understanding of the full immune response to SARS-CoV-2” but that understanding was still lacking.

He referred to one preprint study suggesting antibody concentrations might start to wane just eight weeks after symptom onset.

Concerns about false positives rates has already led WA and SA to ban GPs from using serology for diagnosis.

Those ignoring the rules face fines of up to \$20,000.

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So far, the main use of the tests in Australia has been in specific contact tracing cases.

Two weeks ago, Queensland health officials investigated two COVID-19 cases in workers at a pathology lab in Cairns.

Initially, they struggled to understand why the workers had been infected because they were not close contacts, said Chief Health Officer Dr Jeanette Young.

However, serology tests identified three more workers who had been infected then recovered — the missing links in the chain.

Professor Finkel's report stressed there was evidence from the UK suggesting some laboratory-based serology tests could be more accurate than point-of-care versions.

"If highly accurate serological techniques operating in some academic labs are validated against national standards, they could offer a means for predicting prevalence at the population level."

However, he said no lab-based serology tests have been approved by the TGA for use in Australia.

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We have compiled a list of resources to help GPs combat coronavirus, which can be read here. Or click here to read the rest of our coronavirus coverage.

Current Australian coronavirus statistics - 5 May

Total: 6825 confirmed cases, including 95 deaths:

- 107 in ACT
- 3033 in NSW
- 29 in NT
- 1038 in Queensland
- 438 in SA
- 223 in Tasmania
- 1406 in Victoria
- 551 in WA

Source: Department of Health, Coronavirus health alert