

**Press Release – False COVID-19 Test Results
Pathology Technology Australia
June 4, 2020**

In reference to the comments by Dr Norman Swan in the media yesterday:
<https://www.abc.net.au/news/2020-06-03/coronavirus-queensland-how-is-a-false-positiive-possible/12308076>

Pathology Technology Australia would like to provide more clarity around the comments by Dr Swan on false COVID-19 test results.

Dr Swan stated, "The genetic tests came into practice in January without the normal evaluations and checks and balances that would happen with a pathology test just to get it into service."

The article led readers to understand that there is a very high false result rate for COVID-19 testing in Australia and that this was due to rushed product introduction. This is not accurate. As Dr Ian Mackay mentioned in the article, no test is perfect. In fact, tests conducted in Australia are of the highest quality and perform extremely well.

The first point of clarification; almost all the first COVID-19 PCR tests performed in Australia were carried out using in-house assays and performed in Public Health Laboratory Network (PHLN) facilities, which are recognised as the experts in this field. These tests were validated by the PHLNs themselves.

Secondly; commercial PCR test kits became available in Australia during late February and early March. These kits are produced by some of the world's most experienced and high-quality manufacturers, using their well-established quality and process frameworks. To suggest that quality has been compromised for the sake of getting a test to market is just not true and hinders the overall context of fighting this pandemic.

There is a false negative rate in all gene amplification testing. While the amplification of the viral RNA can occasionally be problematic, variation in results are mostly due to sampling; either the swab did not make sufficient contact with the back of the nose or throat, the virus has moved further down the respiratory tract or sampling occurs too late in the infection to detect virus particles.

With the very large number of tests performed in Australia our sample collectors have become very proficient at obtaining an adequate sample, our pathology labs are proficient at performing the detections and our pathologists and clinicians are proficient at interpreting results.

The performance of these tests is well understood, and clinicians interpret them extremely well.

It is important we understand that testing is of the highest quality and people should be confident in the suppliers, who have worked night and day over the past 3 months to ensure we have adequate supplies of these tests. This puts Australia amongst the leaders in the world for testing and the management of the COVID-19 pandemic.

Pathology Technology Australia represents the companies that manufacture and supply about 85% of all COVID-19 test kits. Our member companies adhere to the highest standards of test development and validation. These companies are audited frequently to ensure they adhere to their quality and process standards. Once these kits are deployed in our accredited pathology laboratories, further quality processes are employed to ensure test results are sound.

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