Hon Yvette D'Ath MP
Minister for Health and Ambulance Services
Leader of the House

Queensland Government

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Mr Neil Laurie
Clerk of the Parliament
Queensland Parliament
George Street
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13 OCT 2021

Dear Mr Laurie Neil

I write in response to your letter regarding petition number 3589-21, tabled in Parliament on 14 September 2021 in relation to 'Evidence required by the people of Queensland from the Queensland Government about the efficacy of PCR tests'.

In relation to the queries presented, please see below response:

The cycle threshold of PCR test in Queensland
The endpoint cycle number used in SARS-CoV-2 real-time RT-PCRs depends on the method, validation, kit and platform used. It may range from 35 to 45 cycles. The threshold cycle (CT) is not a fixed value. It is the result returned after real-time RT-PCR of a patient sample's nucleic acid extract and falls in a range between approximately 15-35 cycles. It may fall beyond that upper limit, and such results would be further investigated - as are all positive results - in collaboration with clinical microbiologists, epidemiologists and public health experts and further sampling and testing. Accredited Queensland laboratories aim to provide the most accurate results as quickly as possible.

The irrefutable evidence used to justify the use of PCR test and its threshold
Laboratorians, scientists, microbiologists, epidemiologists and those with public health expertise agree that the sensitivity of RT-PCR requires interpretation. A sample from a person which generates a value suggestive of a lower viral load does not by itself explain that patient's status. They could be early in their infection, heavily infected but the sample was poorly collected, or they could be late in their infection. All of those still indicate the person was at some point infectious, and this knowledge is essential for contact tracing and quarantine of contacts. This process has been extremely successful in Queensland, so we currently have many more freedoms than other jurisdictions in Australia or other nations. True false positives are almost entirely avoided when RT-PCR is conducted in a quality framework and in collaboration with clinical microbiologists, epidemiologists and public health experts.

PCR-based tests that are developed by an expert accredited pathology laboratory in Australia must undergo a rigorous optimisation and TGA validation process during which the threshold is defined based on experience with that test. Different tests, even for the same virus or virus gene, can behave differently, therefore, this optimisation and validation process, which is then reviewed in detail by National Association Testing Authority (NATA), is an essential part of producing quality testing results.

Kary Mullis had no hand in developing real-time PCR and did not have experience in a pathology laboratory setting. However, he did co-author a scientific paper that supported the use of very early PCR methods for virus detection, concluding PCR would be useful to detect viruses, including cytomegalovirus, hepatitis B virus, Epstein-Barr virus and human immunodeficiency virus. Mullis's comment is often used out of context. PCR cannot by itself detect "disease" as a disease is a

collection of signs and symptoms noted by an experienced clinician and the sufferer. In this pandemic, PCR-based tools identify the infectious pathogen (SARS-CoV-2) which causes the disease (COVID-19), and they do that very specifically and sensitively.

The future of PCR test in Queensland, given the CDC announcement:
Queensland will continue the use of PCR testing for the SARS-CoV-2 virus. The Centre for Disease Control's 21 July 2021 announcement states that the CDC will withdraw the request to the U.S. FDA for emergency use authorization of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel first introduced in February 2020. This was one of 117 distinct RT-PCR tests for detecting SARS-CoV-2 listed on the FDA webpage for which there was sensitive data provided. It is important to note that there is no single "PCR" to detect this virus and its variants. The U.S. CDC also recommended that laboratories consider replacing a SARS-CoV-2 test with one capable of detecting both SARS-CoV-2 and influenza viruses as the latter may emerge at any time after travel begins again.

The decision to use PCR has been influenced by such things as; expert availability to very quickly develop tests without the need for the infectious virus to be in the country (Queensland was a world-leader in providing its citizens optimized and validated real-time RT-PCR based SARS-CoV-2 testing); the impacts of a slow commercial test development processes which would have seen Australia overwhelmed by COVID-19 well before testing was available; the high sensitivity of real-time RT-PCR which was essential when nothing was known about this new pandemic pathogen; results being returned to patients within 6-48 hours; and the quality of the collaborative laboratory network which already exists within Australia to perform PCR-based testing.

I trust this information is of assistance to the petitioners.

Yours sincerely

Yvette D'Ath

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