

Virginia Crawford

By email: fyi-request-14341-1a7c6327@requests.fyi.org.nz
Ref: H202100581

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 1 February 2021.

I will respond to each part of your request in turn.

Could you please direct me to the document that stipulates this (40 Ct), as my understanding is that the number of cycles can be anything from 20 onwards, with a MAXIMUM of 40, not that it SHOULD be 40.

The Ministry does not hold a document that stipulates COVID-19 tests should run for 40 cycles. As a result, this part of your request is refused under section 18(e) of the Act.

I can confirm that PCR assays for all COVID-19 tests run for 40 cycles in IANZ accredited New Zealand laboratories. This is stipulated by the manufacturer instructions who have performed extensive validation and verification of their assay and is built into the analyser software utilised to perform testing

Further to my request above, I would like to draw your attention to the PCR handbook: https://scanmail.trustwave.com/?c=15517&d=7N2M4E37OiflqUaV1imqp5PfDBk_HAM024F4nn1R_w&u=https%3a%2f%2fwww%2egene-quantification%2ede%2freal-time-pcr-handbook-life-technologies-update-flr%2epdf If you look at page 25, you will see at the bottom of the page, the following: "For Research Use Only. Not for use in diagnostic procedures." Should the PCR process be used for testing Covid-19?

The statement "For Research Use Only. Not for use in diagnostic procedures." applies to assays and procedures undergoing development and are used for research purposes only, as the performance characteristics of the assay or product has not yet been established for diagnostic purposes. SARS-CoV-2 RT-PCR testing used in our accredited medical diagnostic laboratories have undergone rigorous validation for specific performance characteristics that include analytical and clinical sensitivity and specificity for the detection of SARS-CoV-2.

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Kel-Wat', is centered on a light yellow rectangular background.

Dr Kelvin Watson
Group Manager, COVID-19 Testing and Supply
COVID-19 Health System Response