

[REDACTED]

By email: [REDACTED]
Ref: H202008534

Dear [REDACTED]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 27 November 2020 for:

"I understand that the current PCR testing protocol in New Zealand involves testing laboratories doing 45 "cycles" of PCR on a Covid-19 test sample. I request copies of any reports, advice or any other documentation that:

- 1) discuss or explain why laboratories in New Zealand are currently completing 45 cycles for each test sample; and*
- 2) discuss or identify the risks (in terms test result accuracy and/or conclusively identifying actual "live" cases of Covid-19) associated with completing this number of "cycles"; and*
- 3) discuss the prevalence or risk of "false positive" PCR testing results in New Zealand."*

Information in response to each part of your request is as follows.

"1) discuss or explain why laboratories in New Zealand are currently completing 45 cycles for each test sample"

All reverse transcription polymerase chain reaction (RT-PCR) assays are validated for the number of polymerase chain reaction (PCR) cycles used for SARS-CoV-2 testing by the laboratories that perform RT-PCR testing. Typically samples are tested over 40 cycles. All testing is performed under ISO 15189 accreditation which includes verification by an external organisation; International Accreditation New Zealand (IANZ). However, the Ministry of Health (the Ministry) is unable to provide copies of reports, advice or documentation for this part of your request as it is the prerogative of each individual laboratory which assay that they validated and implement.

"2) discuss or identify the risks (in terms test result accuracy and/or conclusively identifying actual "live" cases of Covid-19) associated with completing this number of "cycles"

No documents have been identified that discuss or identify risks associated with completing a certain number of cycles. As such, I am unable to provide any information in response to this part of your request under section 18(g) of the Act.

However, you may be interested to know that analytical accuracy of the PCR is very high but clinical accuracy of the PCR is a function of the prevalence of SARS-CoV-2 in the population being tested. The SARS-CoV-2 RT-PCR tests used in New Zealand have very high specificities and the strategy of using a second and/or third SARS-CoV-2 PCR assay with different gene targets increases the specificity of the PCR even further. The combined SARS-CoV-2 PCR testing experience of the New Zealand laboratories is that the false positive rate is extremely low.

“3) discuss the prevalence or risk of “false positive” PCR testing results in New Zealand.”

No documents have been identified that discuss the prevalence or risk of false positive PCR test results in New Zealand. As such, this part of your request is refused under section 18(g) of the Act, as the information is not held by the Ministry.

However, please note that false positive test results have occurred in New Zealand as in any other countries. The Ministry does not have exact figures for how often it has happened, but it is believed to have been no more than a handful of cases. Most of these cases involved handling or sample contamination problems in the laboratories. These cases are usually discovered before reporting, but they may also be discovered after a report was issued. An amended report and corrective actions will ensure that the patient is informed of this erroneous report should the patient already have been informed of a positive result.

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



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