

██████████
By email: ██████████
Ref: H202009192

Dear ██████████

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 11 December 2020. The responses to each of your questions can be found listed below:

1) SARS-COV-2 and Covid-19

Please give the government's definition of the difference (if any) between Sars-Cov-2 and Covid-19

There is no difference, both naming conventions refer to the same virus. SARS-CoV-2 is the virus that causes the disease. COVID-19 is often referred to as the disease.

2) Test equipment and processes

Please LIST all BRANDS /Brand SUB-TYPES of PCR testing kits authorised (now or previously) in New Zealand for identifying the presence of the "Covid-19" virus in a human being.

Please refer to the answer provided in question 4.

3) For each Brand & Brand sub-type, please include:

- Maker of the test kit, and country of origin

The Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

4) – A link to the maker specifications of each kit

Roche Diagnostics: <https://diagnostics.roche.com/global/en/article-listing/general-information-cobas-sars-cov-2-coronavirus-test.html>

Abbott: <https://www.molecular.abbott/us/en/products/infectious-disease/RealTime-SARS-CoV-2-Assay>

Hologic: <https://www.hologic.com/coronavirus-test>

Thermofisher: <https://www.thermofisher.com/au/en/home/clinical/clinical-genomics/pathogen-detection-solutions/sars-cov-2-covid-19.html>

Dnature: <https://www.dnature.co.nz/>

MiRXES Pte Ltd: <https://mirxes.com/>

5) - *If included by the manufacturer / supplier, the number of cycles recommended for use in assessing the result of each test.*

The Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

6) - *The name / names of the ANALYSING ENTITY (ie laboratory) where each brand of test is processed*

The Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

7) - *If the number of cycles used in processing the tests is determined by the laboratory (rather than in accordance with test manufacturer recommendation), please list the number of cycles used by each laboratory and, if in existence, a link to the laboratory specifications for PCR test processing.*

The Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

8) *Relevant Rules / Guidelines*

Please provide a copy of (or link to) any rules / guidelines provided by the NZ government / regulatory agencies in relation to the taking of samples for and processing of "Covid-19" PCR tests, in particular with regard to the number of cycles (actual or range) that should be used (or not used) to produce a PCR test result which is considered valid.

In regards to the taking of samples this information is available on the Ministry of Health website <https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-information-health-professionals/case-definition-and-testing-guidance-covid-19#instructions>. In regards to the processing of Covid-19 PCR tests, the Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

9) *Changes to number of cycles*

Please state any/all changes to amplification/number of cycles of PCR test since the inception of using the tests in NZ and the dates of any such changes.

The Ministry of Health does not hold this information. This aspect of your request is refused under section 18(g) of the Act.

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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