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Ref: H202102835

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Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 12 March 2021 relating to COVID-19 testing protocols. I shall respond to each part of your request below:

> *"I would like to sight MOH's Covid19 testing PCR rate*
> *We want to sight:*
> *PCR amplification rates for 'all' Covid19 tests.*

PCR tests used in accredited laboratories typically run for 40 cycles. All diagnostic laboratories are aware of the possibility that non-specific off-target amplification can occur beyond 37 cycles and generate non-specific amplification curves. Therefore, all Ct values above 30 are viewed with caution and the test repeated from sample using another RT-PCR to exclude any contamination or off-target binding issues.

> *Calibration protocols.*

The Ministry does not hold the calibration protocols for each COVID-19 test in use across the laboratory network. This part of your request is refused under section 18(g) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act. Details of the calibration protocols for an assay would need to be sought from the manufacturers. For further information is are available at:

- 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/

> *That is Total Amplification*

As noted above, PCR tests used in our accredited laboratories typically run for 40 cycles.

Also validation of assay

When using a validated commercial assay a New Zealand laboratory does not have to perform a full validation of the assay (e.g., determining lower limit of detection, specificity, accuracy and repeatability) as this has already been performed by the manufacturer and submitted and granted approval from the Food and Drug Administration in the United States or Therapeutic Goods Administration in Australia. Details of how the manufacturer validates an assay would need to be sought from them.

Laboratories using a validated commercial assay within New Zealand would typically perform a smaller scale verification study to test known positive and negative clinical samples to demonstrate the assay performs as stated in its information for use package insert. This is the data they submit to International Accreditation New Zealand (IANZ) for International Organization for Standardization (ISO) 15189 accreditation. If IANZ is satisfied with the rigour of the verification, it grants approval for the laboratory to state the test has IANZ accreditation. All laboratories performing COVID-19 testing as part of the public health response are IANZ accredited to ISO 15189.

Where can we sight the data for all tests without identifying subjects

For daily testing information please refer to the following link to the Ministry website: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/testing-covid-19.

Development of a Covid19 specific Ab titer assay
Discussion of Ab titer as an immunity marker
Discussion of T cell assay as an immunity marker

The Ministry holds no information on these points, therefore this part of your request is refused under section 18(g) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act. While this is a topic that may be considered in the future, the Ministry does not currently have a scientific stance on it. There is limited scientific literature on this topic, but the Ministry will continue to monitor research as it emerges.

Information relating to individual testing or laboratory data is refused under section 18(f) as the information requested cannot be made available without substantial collation or research.

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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COVID-19 Health System Response