ESR
Science for Communities

5 October 2020

[redacted]
By email: [redacted]

Dear [redacted]

Official Information Act Request: PCR testing for COVID-19

On 8 September 2020, you sent a request for information under the Official Information Act 1982 to the Ministry of Health, who transferred your request to ESR on 11 September 2020. Your request was as follows:

"With regard to the PCR viral testing in New Zealand, what is the number of amplification cycles being used for diagnosing COVID-19? If there is not a set amplification cycle number what is the threshold (upper limit) cycle number to which the testing authority with amplify to?"

Our response to your request

The PCR assays used in most NZ diagnostic laboratories is set to cycle for 45 amplification cycles. However, the cut-off for calling a result as positive is equal and below 40 amplification cycles and only when it has also been confirmed by a second target PCR which became positive equal or below 40 cycles. The reason why amplification cycling is continued beyond 40 cycles is so that one is able obtain additional information on the amplification curve which needs to be exponential over the next 5 cycles. If it is not exponential, then the test needs to be repeated from the same sample and if the amplification curve is again not an exponential curve then one would request a repeat sample and call the result inconclusive.

Your right to seek a review

You have the right to seek an investigation and review by the Ombudsman of this decision. Information about how to make a complaint is available at www.ombudsman.parliament.nz or freephone 0800 802 602.

Thank you for your request.

Yours sincerely,

Jill Vintiner
Chief Operations Manager – Health and Environment Group ESR

INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH LIMITED
Kenepuru Science Centre: 34 Kenepuru Drive, Kenepuru, Porirua 5022 | PO Box 50348, Porirua 5240, New Zealand
T: +64 4 914 0700 **F:** +64 4 914 0770
www.esr.cri.nz

MINISTRY OF HEALTH
MANATŪ HAUORA

26 January 2021

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[redacted]

By email: [redacted]
Ref: H202100070

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 11 January 2021 for:

> *"What's the Cycle Threshold (CT) value used to perform the PCR test for COVID19; what changes by date have been made to the (Cycle Threshold (CT)) value per lab for this test (COVID19) since the start of testing in New Zealand."*

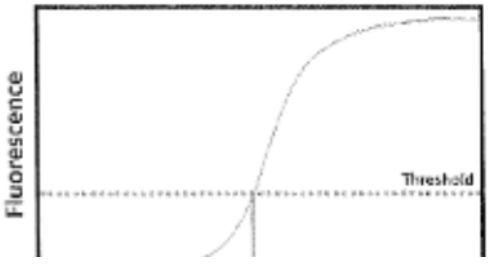
I will respond to your queries in turn.

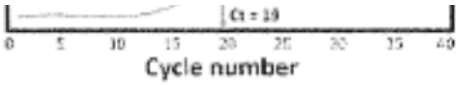
"What's the Cycle Threshold (CT) value used to perform the PCR test for COVID19"

In order to provide context around Cycle Threshold (CT) values and Polymerase Chain Reaction (PCR) cycles, the novel coronavirus is made up of a genetic material called ribonucleic acid (RNA). When the virus enters your cells, it uses RNA to replicate itself. PCR testing detects DNA. This means that the first step in the PCR test process is to convert the viral RNA into DNA using the enzyme 'reverse transcriptase'. Once this is completed, chemicals are used to amplify the DNA so it can be read by the PCR instrument. This is done by reading the fluorescent signal that is emitted from amplified DNA within the sample. This signal is measured as the cycle number at which the target is first detected.

The PCR reaction will continue to run for its full 40 cycles to allow for exponential amplification of the RNA targets using repeated thermal cycling to allow for enough amplified DNA product to be detected by the instrument. The CT value is the cycle number recorded where sufficient amplified product had reached a detectable level.

The graph below represents a full PCR run of 40 cycles with a sample reaching a detectable level of amplified DNA that has crossed the threshold at 19 cycles.




Ct = 19
0
5
10
15
20
25
30
35
40
Cycle number

"what changes by date have been made to the (Cycle Threshold (CT)) value per lab for this test (COVID19) since the start of testing in New Zealand."

Please note that CT values are standardised across all testing and are not subject to change.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

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

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[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

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

MINISTRY OF HEALTH
HĪKINA WHAKATUTUKI

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[redacted]

By email: [redacted]
Ref: H202009192

Dear [redacted]

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

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

MINISTRY OF HEALTH

26 January 2021

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[redacted]

By email: [redacted]
Ref: H202100070

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 11 January 2021 for:

> *"What's the Cycle Threshold (CT) value used to perform the PCR test for COVID19; what changes by date have been made to the (Cycle Threshold (CT)) value per lab for this test (COVID19) since the start of testing in New Zealand."*

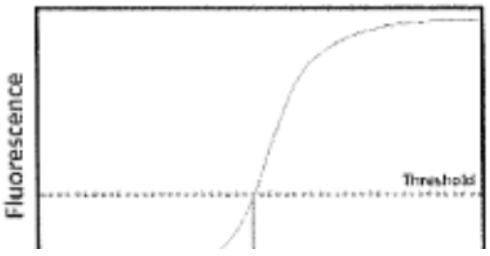
I will respond to your queries in turn.

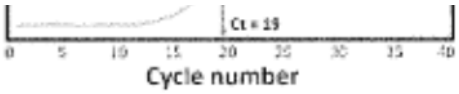
"*What's the Cycle Threshold (CT) value used to perform the PCR test for COVID19*"

In order to provide context around Cycle Threshold (CT) values and Polymerase Chain Reaction (PCR) cycles, the novel coronavirus is made up of a genetic material called ribonucleic acid (RNA). When the virus enters your cells, it uses RNA to replicate itself. PCR testing detects DNA. This means that the first step in the PCR test process is to convert the viral RNA into DNA using the enzyme 'reverse transcriptase'. Once this is completed, chemicals are used to amplify the DNA so it can be read by the PCR instrument. This is done by reading the fluorescent signal that is emitted from amplified DNA within the sample. This signal is measured as the cycle number at which the target is first detected.

The PCR reaction will continue to run for its full 40 cycles to allow for exponential amplification of the RNA targets using repeated thermal cycling to allow for enough amplified DNA product to be detected by the instrument. The CT value is the cycle number recorded where sufficient amplified product had reached a detectable level.

The graph below represents a full PCR run of 40 cycles with a sample reaching a detectable level of amplified DNA that has crossed the threshold at 19 cycles.




Ct = 19
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Cycle number

"what changes by date have been made to the (Cycle Threshold (CT)) value per lab for this test (COVID19) since the start of testing in New Zealand."

Please note that CT values are standardised across all testing and are not subject to change.

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.

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Yours sincerely

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

MINISTRY OF HEALTH
HĪKINA Ō HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

2 February 2021

[redacted]

By email: [redacted]
Ref: H202100145

Dear [redacted]

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 15 January 2021 for:

> *"Can you give me the details of the current test kits also. Also, certain people such as Siouxsie are keen to tell people the testing is highly accurate. So, can you tell me why Dr Bloomfield ordered a repeat test and a serum test for a child who tested positive in Japan, and totally denied the positive result."*

Details regarding the test platforms used in our accredited medical diagnostic laboratories performing SARS-CoV-2 RT-PCR can be found in the following weblinks:

- https://diagnostics.roche.com/global/en/article-listing/general-information-cobas-sars-cov-2-coronavirus-test.html
- https://www.molecular.abbott/us/en/products/infectious-disease/RealTime-SARS-CoV-2-Assay
- https://www.hologic.com/coronavirus-test
- https://www.thermofisher.com/au/en/home/clinical/clinical-genomics/pathogen-detection-solutions/covid-19-sars-cov-2/multiplex.html
- https://www.dnature.co.nz/shop/dnature-kits/human/covid-19-sars-cov-2-multiplex-rt-qpcr-kit-500-reactions/
- https://mirxes.com/

The polymerase chain reaction (PCR) test is accurate for identifying current COVID-19 infections, but it does not determine when an infection occurred. Careful assessment of PCR tests must be taken with people who have already had COVID-19 when they are re-tested as the virus can linger for months in the nose. Serology testing is helpful in determining new from old infections. If someone has a positive swab and a positive serology test it is most likely they are an old or historic case.

are an old or historic case.

The Director-General ordered a PCR test and serology test be performed on the child as there were concerns that it was a 'false positive.' This was because the initial test used in Japan was a rapid saliva test, which is less reliable, and because none of the travel companions had tested

positive. A confirmation test and serology were therefore sought as it was considered that it may be a historical case given the information about the family the Ministry held.

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

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

MINISTRY OF HEALTH

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

1 March 2021

[redacted]

By email: [redacted]
Ref: H202102074

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 26 February 2021 for:

> *"I would like to know if the SARS-Cov-2 PCR testing being conducted in New Zealand is qualitative or quantitative. Or, if it is some combination of the two, or has differed over time (since PCR testing fro SARS-Cov-2 began in NZ), please elaborate on what the situation is."*

COVID-19 PCR testing conducted in New Zealand is qualitative in that it provides a yes/no result: COVID-19 is either detected (positive test result) or not (negative test result). No changes have been made since testing began in New Zealand.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

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

MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

17 March 2022

s 9(2)(a)

By e-mail: s 9(2)(a)
Ref: H202201617

Tēnā koe s 9(2)(a)

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 17 February 2022, which on 9 March 2022 was refined to:

> *"...information regarding the PCR swab samples after being transported to a lab for analysis what happens to those samples and any gathered data on said samples."*

To be authorised to process PCR test swabs, a lab must be accredited by International Accreditation NZ (IANZ). IANZ's requirements for accreditation include a lab having standards which satisfy IANZ criteria for test swab handling, management and retention timeframes for processing

After PCR swab samples are processed by labs, all negative samples and the majority of positive samples are discarded while a small number of positive samples are forwarded to ESR for whole genome sequencing. Once ESR has completed whole genome sequencing, it then discards these samples. According to ESR's records, of the 362,687 positive cases reported in the EpiSurv database from 12am 14 Dec 2021 to 12am 14 March 2022, 1.5% (5516 cases) have had at least one sample forwarded to ESR for whole genome sequencing.

With regard to data, the number of tests processed, the number of positive and negative results and various demographic data of those tested such as age group, sex, ethnicity and district health board of domicile are forwarded to the Ministry of Health each day to be recorded in the Ministry's COVID testing statistics database and then included in the Ministry's daily updates. For positive results, the data will also include the number of community cases and cases from the border. No identifying details of any person who has been tested are forwarded to the Ministry with this data.

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.

Nāku noa, nā

Jo Pugh
(Acting) Group Manager
COVID-19 Testing and Supply

MINISTRY OF HEALTH
NGĀ MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

21 March 2022

s 9(2)(a)

By e-mail s 9(2)(a)
Ref H202202861

Tēnā koe s 9(2)(a)

RESPONSE TO YOUR REQUEST FOR OFFICIAL INFORMATION

Thank you for your request 22 February 2022 under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) for the information relating to PCR testing and COVID-19 vaccine. Please find a response to each part of your request below.

> *1 - Why is the PCR test being used to diagnose Covid-19? A PCR test is not capable of distinguishing mere contamination from infection. As long as the viruses remain on the mucous membranes and do not enter the cells of the body, a person is only contaminated, but not infected. In this case, the viruses do not replicate and therefore do not pose a risk of infection. Nevertheless, a PCR test will deliver a positive result for such people.*

A PCR test can detect fragments of Reverse-Transcribed Ribonucleic Acid (RT-RNA) from the SARS-CoV-2 virus. This RNA is translated into Deoxyribose Nucleic Acid (DNA) also known as RT-DNA as it has been reverse-transcribed. The RNA sequence for SARS-CoV-2 has unique regions, meaning that the primers used in PCR tests to detect SARS-CoV-2 will amplify only a specific section found only in SARS-Cov-2. This is a definitive and highly-specific test. When this test is used in conjunction with a clinical assessment of patient's symptoms, the diagnosis of COVID-19 is highly robust.

> *2- People are required to self-isolate and are required to quarantine if they have a positive PCR test. Based on the points made above in question 1, that a PCR test can not detect infection, please explain the MOH advice and subsequent legislation that requires people to be quarantined and self isolate based on a positive PCR test result. I would also like to know the justification for previous lockdown measures and current traffic light settings based on "case" numbers rather than people infected?*

Advice from the Ministry to the government about lockdown measures and the current traffic light system is publicly available, and can be found on the *Unite against COVID-19* website: www.covid19.govt.nz/about-our-covid-19-response/proactive-releases/alert-levels-and-restrictions/.

Information about self-isolation requirements is publicly available, and set out in the COVID-19 Public Health Response (Self-isolation Requirements and Permitted Work) Order 2022: www.legislation.govt.nz/regulation/public/2022/0046/latest/whole.html#LMS647742.

3 - Why is the PCR test being run at 40 cycles when it is known that 40 cycles increases false positives which in turn effectively "creates cases"?

If the test system only begins detection after a large number of replication cycles, the viral load is so low that active infection is ruled out. Studies show that a patient is considered "less infectious" above 25 cycles. In fact, the authors of a Canadian study failed to identify any replicable virus beyond 24 cycles .

The maximum number of PCR cycles is set by commercial assay manufacturers (in most cases, it is set to 40 cycles, at which point a reactive result would be called). Extensive specificity testing (testing of non-COVID-19-infected samples to look for false positives) has been performed by the manufacturers to guard against non-specific amplification at high cycle numbers before applying for certification. Additionally, each diagnostic laboratory also verified their assays' specificity before use to make sure that no false-positive test results are produced by testing SARS-CoV-2 negative samples repeatedly.

4 - Based on points 1,2 and 3 it has to be asked - Is the MOH purposely trying to create cases for the government to maintain the emergency status and therefore allow the roll out of the vaccine to continue and retain the restrictions and controls in place? Every positive test is included in the statistics as an alleged "new infection" and thus is the very metric on which political decisions are based. Case numbers therefore have significant impacts on all facets of society, including the mental, physical, emotional and financial well being of all individuals.

While the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information, compile information they do not hold, or provide/prove an opinion to respond to a request made under the Act. Your questions and supporting statements appear designed to engage in a debate about the government's COVID-19 vaccination programme rather than be a request for official information. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information. This question is therefore refused under Section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

5 - Given the Covid 19 vaccine does not have full safety approval, please explain how it is allowed that 64 of 147 deaths reported to CARM post vaccination can not be assessed due to insufficient information as at 31 January 2022? Every single death recorded post inoculation with a vaccine without full approval should be assessed. This is particularly vital given that the vaccine is called "safe and effective" and 90%+ of the population over 12 was required to take this vaccine if we were to move out of lockdowns and into the traffic light system.

Medicines are approved based on the expected benefits outweighing the risks of side effects. They are not given a safety approval. Provisional consent allows conditions to be imposed on the vaccine, restricting its use by healthcare professionals according to the data available at the time of approval. Provisional consent was included in the *Medicines Act 1981* to allow early access to medicines for New Zealand patients with a significant unmet clinical need. The process for investigating reports with a fatal outcome is published on the Medsafe website and can be found on www.medsafe.govt.nz/COVID-19/q-and-a-vaccine-safety.asp.

6 - Given the Covid-19 vaccine does not have full safety approval and has been rolled out to the entire population in NZ aged 5+, please explain and justify the decision to make injuries and deaths post vaccination only "encouraged" to be reported, rather than mandatory. It seems bizarre to make masks mandatory in public places to protect peoples

health, but not the reporting of adverse reactions and deaths after a new vaccine that does not have full safety approval.

To make reporting mandatory, it would have to be included in legislation, and there would need to be a process to enforce reporting. Given that it cannot be proven that someone failed to recognise an adverse reaction, mandatory reporting cannot be enforced.

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 e-mail info@ombudsman.parliament.nz or by calling 0800 802 602.

Nāku noa, nā

Darryl Carpenter
Group Manager Testing and Supply
COVID-19 Health System Response

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

23 March 2021

[redacted]

By email: [redacted]
Ref: H202102134

Dear [redacted]

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 March 2021 for information regarding PCR tests in New Zealand.

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

> *"1. I am hereby making a request for an OIA with regards to full public disclosure of the detailed components of the materials used in the composition of the swabs that are being utilised in New Zealand for the purpose of the PCR tests that are being undertaken in New Zealand."*

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.

> *"I would like to make a request for this and the details of the manufacturer of the swabs that are used in PCR tests in New Zealand."*

Below is a list of swab manufacturers that are used for PCR testing in New Zealand:

- Copan Diagnostics Inc
- Huizhou Flygene Technology
- Citotest Scientific Co Ltd
- Noble Biosciences Inc.
- Yocon Biology Technology Company

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

Darryl Carpenter
Group Manager COVID-19 Immunisation, Testing and Supply
COVID-19 health System Response

ESR
Science for Communities

14 December 2021

Ron Law
By email: juderon@gmail.com

Dear Ron

Official Information Act Request: SARS-CoV-2 testing

On 4 February 2021 you sent a request for information under the Official Information Act 1982 (Act) to ESR as follows:

"Can I have the following details on all SARS-CoV-2 PCR tests you have on Episurv? Date of test, CT, method used, interpretation ([weak]Positive/Negative/equivocal, etc), and genome if done."

Our response to your request:

On 6 April 2021 we advised you that we were withholding Ct values. The Ombudsman has since ruled that Ct values must be released, therefore, please see the *attached* spreadsheet for a list of all Ct values available to ESR for COVID-19 cases as of 8 December 2021. Ct values are not available for all cases as it is dependent on the PCR testing platform used and how the laboratory reports the results. No standardisation for Ct values exists across RT-PCR platforms, making it difficult to compare results among diffe[illegible]tests. Different PCR assays will record different Ct values for the same sample. Also, the [illegible]e infection cycle when the sample was taken as well as the sample quality (how rigorous the nasopharyngeal swab was taken) influence the result.

On 6 April 2021 we also advised you that we would provide genome information if we were to provide Ct values. Please see below the genome sequencing information of all COVID-19 cases in New Zealand that have undergone genome sequencing as at 9am, 6 December 2021.

INSTITUTE OF ENVIRONMENTAL SCIENCE AND RESEARCH LIMITED
Kenepuru Science Centre: 34 Kenepuru Drive, Kenepuru, Porirua 5022 : PO Box 50348, Porirua 5240, New Zealand
T: +64 4 914 0700 F: +64 4 914 0770

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SARS-COV-2 VARIANTS SUMMARY

(Source: Microreact 'covid genomic analysis' project 09.00 am, 06 December 2021)

WHO nomenclature	Pango lineage	Confirmed cases	Report date of last confirmed case
VARIANTS OF CONCERN (VOC)			
Alpha	B.1.1.7	178	06 Aug 2021
Beta	B.1.351	33	27 Jun 2021
Gamma	P.1	8	01 Jun 2021
Delta	B.1.617.2 (and AY sublineages, excluding AY.4.2*)	4085	02 Dec 2021
Omicron	B.1.1.529	0	-
VARIANTS UNDER INVESTIGATION (VUI)			
Delta*	AY.4.2*	5	04 Nov 2021
Eta	B.1.525	8	08 Jun 2021
Theta	P.3	3	20 Mar 2021
Kappa	B.1.617.1	5	09 Apr 2021
-	B.1.617.3	4	11 Apr 2021
-	C.36.3	4	12 Jun 2021
Lambda	C.37	0	-
Mu	B.1.621**	1	19 Jun 2021

* AY.4.2 is a sub-lineage within Delta that has been assigned as a distinct VUI.
** The case of the Mu variant detected in New Zealand was lineage B.1.621.1, a sublineage of B.1.621 which has all the key spike mutations of concern found in lineage B.1.621.

Definitions for variants of concern (VOC) and variants under investigation (VUI) are detailed in Public Health England Technical Briefing 8. United Kingdom (UK) Health Security Agency Technical Briefing 30 (Last updated 26 November 2021) provides the most up-to-

date analyses contributing to variant risk assessments and designation of new VOC and VUI.

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Kenepuru Science Centre: 34 Kenepuru Drive, Kenepuru, Porirua 5022 | PO Box 50348, Porirua 5240, New Zealand
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Epsilon (Lineages B.1.427 and B.1.429; last detected in a case reported in New Zealand on 29 Dec 2020), Zeta (Lineage P.2; last detected in a case reported New Zealand in on 05 Mar 2021), and Iota (Lineage B.1.526; never detected in a case reported in New Zealand), variants are no longer considered VUI by WHO.

Your right to seek a review

You have the right to seek an investigation and review by the Ombudsman of this decision. Information about how to make a complaint is available at www.ombudsman.parliament.nz or freephone 0800 802 602.

Thank you for your request.

Yours sincerely

Jill Vintiner
Joint General Manager Health and Environment Group – Health
ESR

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