

23 February 2021

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Sovereign Sharna

By email: [fyi-request-14542-90bec223@requests.fyi.org.nz](mailto:fyi-request-14542-90bec223@requests.fyi.org.nz)  
Ref: H202100399

Dear Sovereign Sharna

### Response to your request for official information

Thank you for your four requests under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 26 January 2021 regarding COVID-19 testing, laboratories and vaccines, which has been consolidated into one request in accordance with section 18(A) of the Act.

The Ministry's response to each part of your request is as follows.

*"The names, addresses and email addresses of each of the Covid 19 testing laboratories which are responsible for the processing of PCR cycle threshold part of the testing cycle. I require the details for all labs processing all tests for all pillars under the test and trace scheme."*

A list of the accredited COVID-19 testing medical laboratories is publicly available:  
[assets.website-files.com/5e447d8550a99c8326ee5ae6/5fda668b7011309493f1afef\\_COVID-19%20Accredited%20Testing%20Laboratories.pdf](https://assets.website-files.com/5e447d8550a99c8326ee5ae6/5fda668b7011309493f1afef_COVID-19%20Accredited%20Testing%20Laboratories.pdf).

*"Names of the companies that have produced the SARS-COV2 testing kits in NZ."  
"Copies of the instructions and/or guidelines included in one or more (preferably all) of these SARS-COV2 testing kits that are in use in the NZ and any labelling or recommendations that accompany the kits."  
"Copies of pages which show how the results of these tests are interpreted."*

A list of the companies that supply COVID-19 PCR testing kits in New Zealand is listed below, including publicly available information on each company's testing kit:

- Roche Diagnostics: [diagnostics.roche.com/global/en/products/params/cobas-sars-cov-2-test.html](https://diagnostics.roche.com/global/en/products/params/cobas-sars-cov-2-test.html)
- Abbott: [www.molecular.abbott/us/en/products/infectious-disease/RealTime-SARS-CoV-2-Assay](https://www.molecular.abbott/us/en/products/infectious-disease/RealTime-SARS-CoV-2-Assay)
- Hologic: [www.hologic.com/coronavirus-test](https://www.hologic.com/coronavirus-test)
- ThermoFisher: [www.thermofisher.com/au/en/home/clinical/clinical-genomics/pathogen-detection-solutions/sars-cov-2-covid-19.html](https://www.thermofisher.com/au/en/home/clinical/clinical-genomics/pathogen-detection-solutions/sars-cov-2-covid-19.html)
- dnature: [www.dnature.co.nz/](https://www.dnature.co.nz/)
- MiRXES Pte Ltd: <https://mirxes.com/>

*“For the tests to occur in NZ were maori iwi/hapu consulted or is/was maori iwi consent needed in each iwi area the tests will occur in?”*

Nasopharyngeal swabbing for COVID-19 may be accessed on a voluntary basis by members of our communities. The availability of this swabbing actively supports New Zealand’s approach of elimination by helping to quickly locate and manage any identified cases of COVID-19.

District health boards (DHBs) are responsible for providing or funding the provision of health services in their respective districts. DHBs are expected to provide services that meet the needs of their communities and must ensure services are accessible and culturally appropriate. For example, DHBs in the Auckland region have developed their COVID-19 testing approaches with Māori, Pacific and Middle Eastern/Latin American/African communities and health leaders.

Further information is also publicly available on the Ministry website in the *Updated COVID-19 Māori Response Action Plan*: [www.health.govt.nz/publication/updated-covid-19-maori-response-action-plan](http://www.health.govt.nz/publication/updated-covid-19-maori-response-action-plan).

*“Please could you tell me which organisation decides how many times the PCR (polymerase chain reaction) tests are amplified?”*

The Ministry does not hold this information, the cycle threshold (Ct) and cycling parameters are determined by the test manufacturer. Therefore, this part of your request is refused under section 18(g) of the Act.

*“How many times are the PCR tests are amplified in NZ?”*

A sampled processed for PCR testing typically runs for 40 cycles.

*“How many and which laboratories are the tests sent to?”*

As mentioned above, a list of the accredited COVID-19 testing medical laboratories is publicly available: [assets.website-files.com/5e447d8550a99c8326ee5ae6/5fda668b7011309493f1afef\\_COVID-19%20Accredited%20Testing%20Laboratories.pdf](https://assets.website-files.com/5e447d8550a99c8326ee5ae6/5fda668b7011309493f1afef_COVID-19%20Accredited%20Testing%20Laboratories.pdf).

*“What is the total number of tests completed from the date started out to the date of this request?”*

*“What is the positive rate percentage of the tests to date?”*

COVID-19 testing information is publicly available: [www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/testing-covid-19](http://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/testing-covid-19).

*“What is the positive rate percentage of the antibody tests to date, and what total number of tests?”*

The Ministry does not have access to this information. For this reason, this part of your request is refused under section 18(g) of the Act.

*“What is the sequence that the PCR tests are testing for?”*

The Ministry does not hold this information, please refer to publicly available research: [www.ncbi.nlm.nih.gov/search/all/?term=sars-cov-2](http://www.ncbi.nlm.nih.gov/search/all/?term=sars-cov-2).

*“How were the pfizer vaccines refrigerated whilst en route from their country of origin to NZ - please provide an answer for each different type of transportation ie plane, sea, land?”*

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. Pfizer is responsible for the transportation of vaccines to New Zealand.

*“Which company / corporation designed and built the refrigerator or refrigeration systems for the Pfizer vaccines? Can you Please provide the patent for this?”*

Your request for this information is withheld under section 9(2)(b)(ii) of the Act, where its release would likely unreasonably prejudice the commercial position of the person who supplied the information. Freezers used to store the vaccine in New Zealand have been procured by a reputable ultra-low-temperature (ULT) freezer European manufacturer, set and validated in New Zealand by ULT freezer experts.

*“Does the Pfizer vaccine become unsafe or fatal to humans if at any stage the refrigeration is not set to the required temperature?”*

Any product that is exposed to temperatures outside the ranges prescribed for storage and/or transport would be discarded and cannot be used in vaccination.

*“Do you have emergency steps and procedures in place for the pfizer vaccine ie in case of any refrigeration / temperature malfunctions, please state how you are equipped to ensure the safety and temperature requirements of the pfizer vaccine are met at all times?”*

Please refer to the response provided above; the Ministry does not hold this information. The freezers are operated as per manufacturer recommendations and do not pose any additional risk to standard freezers other than operators handling ULT freezers. All operators handling ULT freezers have received training and are supplied with PPE.

*“What resource consents are required internationally, locally, regionally / nationwide for the importation and transportation of the Pfizer vaccine for NZ?”*

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. Pfizer arranges all documentation, licences and approvals. Initial transportation in New Zealand will be standard cold chain management.

*“Does the pfizer vaccine have a hazardous substance or chemical / pharmaceutical registration number, if yes then please provide this information and the name of the agency or authority whom oversees and issued it.”*

The Environmental Protection Authority issues consents for substances and this information is publicly available: [www.epa.govt.nz/news-and-alerts/latest-news/determination-on-pfizer-covid-19-vaccine/](http://www.epa.govt.nz/news-and-alerts/latest-news/determination-on-pfizer-covid-19-vaccine/).

*“Can you please advice as to why it is necessary for the Pfizer vaccine to be stored at such a freezing temperature, and also what is the life span and also the half life of the Pfizer vaccine if kept in its required temperature storage?”*

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. Storage conditions and product expiry are determined by the supplier, Pfizer. Expiry in ULT freezers for the Pfizer vaccine is six months from the manufacturing date.

*“What licences have to be held by ALL or ANY transportation staff for the pfizer vaccine - PLEASE REPLY FOR EACH TYPE OF TRANSPORTATION ie plane, sea, land etc and can you also please advise as to what work safe requirements are to be adhered to and also if there are any work safe licences which are required to be held by ALL or ANY transportation staff whom are involved in the transportation of the pfizer vaccine - please provide an answer for each transport ie plane, sea, land.”*

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. Pfizer is responsible and arranges all documentation, licences and approvals. Initial transportation in New Zealand will be standard cold chain management that does not require any approvals.

*“How long does the Pfizer vaccine live or remain safe and stable once it is outside of its required temperature and refrigeration storage unit? Please also advise half life?”*

The Pfizer vaccine remains stable five days in cold chain, two hours at room temperature and six hours after dilution. Your request for the half-life of the Pfizer vaccine is refused under section 18(g) of the Act, as this information is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act

*“Due to the fact that no vaccine for coronavirus has ever been deployed in a public vaccination program, can you answer What happens if somebody is vaccinated but contracts COVID anyway? Would they suffer an even worse case of illness, a phenomenon known as antibody-dependent enhancement? Or in a less dramatic scenario, what if the vaccines prevent immunized individuals from falling ill but do not prevent them from infecting others? The latter could actually worsen the pandemic if vaccinated individuals think they are safe and become asymptomatic carriers.”*

Coronavirus vaccines are being used in public health programmes worldwide. Please refer to publicly available information on the European Medicines Agency website for different vaccines, for example Comirnaty: [www.ema.europa.eu/en/medicines/human/EPAR/comirnaty](http://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty). The approved indication for Comirnaty is “active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 16 years of age and older”. No claim is being made that the vaccine prevents transmission.

*“And finally, can you please answer and reassure the NZ public on how you are upholding and adhering to the public's most fundamental right, "the right to life". How can you guarantee the public's safety and that of the lives of the public? Can you guarantee that the lives of the public will not be put at risk of sickness or fatality once they are administered with the Pfizer vaccine?”*

*“Logically, due to no long term study or data been held or been able to be already done on the long term affects of the pfizer vaccine then isn't the NZ government and ministry of health taking a huge risk and in fact taking a gamble on the lives of the NZ public? Isn't this then, the complete opposite of protecting the public's most fundamental right - the right to life??!!*

*Surely, Any percentage of risk of fatality is not adhering to our fundamental right to life!!”*

These two parts of your request does not constitute a request for official information.

The development of a safe and effective vaccine is a crucial tool in New Zealand’s ongoing response to COVID-19. New Zealand’s COVID-19 Vaccine Strategy aims to ensure access to a

safe and effective vaccine in order to implement our preferred immunisation programme at the earliest possible time. We are proactively following and working collaboratively with the World Health Organization, Gavi (the Vaccines Alliance), the Coalition for Epidemic Preparedness Innovation (CEPI) and others about development, testing and availability of vaccines.

As part of our work with Gavi, New Zealand joined the COVAX Facility from 1 July 2020 to help ensure access to vaccines for New Zealanders. On 27 August and 21 September, the Government announced investments into COVAX Facility to further development and manufacture of vaccines.

In addition, on 17 December 2020, the Government announced that four pre-purchase agreements have been signed to date: 750,000 courses from Pfizer/BioNTech; 5 million courses from Janssen; 3.8 million courses from the University of Oxford/AstraZeneca; and 5.36 million courses from Novavax. These, and any other vaccines to be considered for use in New Zealand, are subject to the vaccine successfully completing all clinical trials and passing regulatory approval in New Zealand.

On 3 February 2021, Medsafe, the body responsible for the regulation of medicines, provisionally approved the use of the Pfizer/BioNTech vaccine. The best protection for everyone in New Zealand is to protect those who are most at risk of infection and their household contacts. The priority is to vaccinate border workers, managed isolation and quarantine facility and essential staff first which began in Auckland on 20 February 2021. The day before (19 February 2021), a group of 29 vaccinators in Auckland gave and received themselves the very first COVID-19 vaccinations in New Zealand. The Ministry expects to complete vaccinating these priority groups within three to four weeks. Ensuring equity of outcomes is a key measure of success. This includes protection for Māori, Pacific peoples and our most vulnerable population groups. Further information on the vaccine safety monitoring process is available on the Medsafe website: [www.medsafe.govt.nz/COVID-19/monitoring-process.asp](http://www.medsafe.govt.nz/COVID-19/monitoring-process.asp).

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](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Yours sincerely



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