

M. Cameron

By email: fyi-request-12850-11f24f30@requests.fyi.org.nz
Ref: H202003448

Dear M. Cameron

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 30 April 2020 for:

- "1) about whether COVID-19 has been isolated and if so, by whom, where and on what basis*
- 2) about who supplies the test kits being used in New Zealand and details on how these have been satisfactorily tested for efficacy*
- 3) about whether the testing undertaken specifically tests for and identifies COVID-19. If not, then details on what the testing does identify and whether it is testing for coronavirus in general, current influenza or something else.*
- 4) If the testing is not specific to COVID-19 - any information about whether persons who have previously received the current or prior years annual influenza vaccine would then show a "positive" result on the testing being undertaken.*
- 5) the information provided to those who may be directed to undertake 'medical examination' as detailed in the Act"*

On 15 June 2020, the due date for responding to this request was extended under section 15A of the Act as further consultation was required.

The Ministry of Health's (the Ministry) response to each part of your request is as follows:

- 1) about whether COVID-19 has been isolated and if so, by whom, where and on what basis.*

The SARS-CoV-2 virus that causes the disease COVID-19 was first described by Chinese scientists in late 2019. Their work was quickly confirmed by others internationally and the results published by the World Health Organisation (WHO) on their website: <https://who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?healthtopics=b6bd35a3-cf4f-4851-8e80-85cb0068335b&publishingoffices=aeebab07-3d0c-4a24-b6ef-7c11b7139e43&healthtopics-hidden=true&publishingoffices-hidden=true>.

In New Zealand the SARS-CoV-2 virus has been isolated and grown on numerous clinical specimens by the Institute of Environmental Science and Research (ESR) using routine viral culture techniques. SARS-CoV-2 has also been isolated by researchers at University of Otago. In New Zealand and elsewhere the results of research identifying SARS-CoV-2 as a novel coronavirus has been confirmed by whole genome sequencing.

2) about who supplies the test kits being used in New Zealand and details on how these have been satisfactorily tested for efficacy.

There are many suppliers of test kits for the SARS-CoV-2 virus. The use by individual diagnostic laboratories in New Zealand depends on availability of supply and compatibility with existing instrumentation. All test kits used for the diagnosis of COVID-19 in New Zealand must meet ISO15189 accreditation standards as described by International Accreditation New Zealand (IANZ).

This requires a validation process as described by IANZ in Appendix 3: Method Validation/Verification of the standard AS LAB C7 Medical Testing: Specific criteria for accreditation; third edition September 2019. Part of the accreditation process is enrolment and satisfactory performance in an external quality assurance programme. Currently there are three programmes available in New Zealand administered by the World Health Organisation, the Royal College of Pathologists Australasia (RCPA) and ESR.

3) about whether the testing undertaken specifically tests for and identifies COVID-19. If not, then details on what the testing does identify and whether it is testing for coronavirus in general, current influenza or something else.

COVID-19 test kits used in New Zealand are checked for specificity for the SARS-CoV-2 virus. This is part of the validation studies undertaken to ensure they do not cross react with other infective agents including other coronaviruses or influenza. ESR has been providing a service validating kits for use nationally using a panel of 16 viruses (four seasonal coronaviruses, five Influenza A viruses and one Influenza B virus, MERS-CoV, SARS, adenovirus, RSV, HMPV, PIV1-3, HRV and enterovirus) to check for specificity.

None of the COVID-19 test kits evaluated amplified any other viruses apart from SARS-CoV-2; in other words 100% specificity. This high specificity is obtained because the genetic areas selected and amplified by the COVID-19 PCR test kits are only found in SARS-CoV-2 viruses.

4) If the testing is not specific to COVID-19 - any information about whether persons who have previously received the current or prior years annual influenza vaccine would then show a "positive" result on the testing being undertaken.

The testing is specific to the SARS-CoV-2 virus which causes COVID-19 disease. Influenza vaccinations have no effect.

5) the information provided to those who may be directed to undertake 'medical examination' as detailed in the Act.

The Ministry does not provide any specific information to those who undertake the medical examinations. This part of your request is refused under section 18(g) as the Ministry does not

hold this information and has no grounds for believing that the information is held by another agency subject to the Act.

I trust this information fulfils your request. Under section 28 of the Act, you have the right to ask the Ombudsman to review any decision made on your request.

Please note that this response, with your personal details removed, may be published on the Ministry website.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Natalie Richardson', written over a thin horizontal line.

Natalie Richardson
Director
COVID-19 Response

