Science for Communities

1 February 2022

Helen Wallis
By email: fyi-request-18108-4d8702d3@requests.fyi.org.nz

Dear Helen

Official Information Act Request Nucleic acid being test by PCR test

On 27 January 2022 you sent a request for information under the Official Information Act 1982 (Act) to ESR as follows:

Thank you for your response.

I still would like some clarity about some of your answers.

Please provide the complete section(s) of RNA code which is detected by the RT-PCR test for Covid-19 and somehow identify the areas where the differences occur between the variants.

Did ESR or anyone in NZ confirm that the genetic sequence the commercial NAT assays test for belongs solely to Sar-Cov 2 and that it does not correspond to any other Corona virus?

Please provide the different sections of code (under those which are tested) for each of the 3 main variants of concern, alpha, delta and omicron.

Can you please confirm which sections of code are tested for which variant for each assay in use in NZ. Eg. Themo Taqpath assay uses the N, E and S - gene to identify both Omicron and Alpa. Themo Taqpath assay uses the ?? to identify Delta and so on.

Please provide a full disclosure explanation of how a positive NAAT RT-PCR test shows a positive case of Covid-19 after detecting a nominal amount of nucleic acid which belong to a virus rather than showing that the person is indeed infected with a replicating virus.

So just to be clear after a "positive case" of detection of the viral material no other diagnosis is made to confirm there is an infection of covid-19 rather than just the presence of viral material?

In https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268832/ it states that the RT-PCR test is only used to confirm a diagnosis of covid-19. So the assays in use in NZ only show viral material is present and no further testing is performed to identify if it is a replicating virus or not?

Please also provide a full disclosure explanation of how an asymptomatic case has been deemed to be infectious. Quoting a RT-PCR test here is insufficient as it only shows that genetic material form the searched for nucleic acid is present, not that there is any further infection. As confirmed by CDC, Dr Fauci and others the NAAT doesn't prove that the tested person is infectious only that they carry the genetic material that was tested for by the NAAT.

I believe we have used a different interpretation of the word "infectious". My definition of infectious only covers when a second person develops clinical symptoms of covid-19. Is there any direct evidence of this available (just to clarify an asymptomatic person directly causing clinical symptoms of covid-19 in another person)?

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Our response to your request:

Please provide the complete section(s) of RNA code which is detected by the RT-PCR test for Covid-19 and somehow identify the areas where the differences occur between the variants.

There are at least 18 different SARS-CoV-2 nucleic acid tests (NATs), which include RTPCR, being used in New Zealand. Almost all of them are commercial NAT assays which mean that it is not publicly known what the sequence of the primers and probes (sections of code) are and therefore it is not possible to provide you with this information.

Did ESR or anyone in NZ confirm that the genetic sequence the commercial NAT assays test for belongs solely to Sar-Cov 2 and that it does not correspond to any other Corona virus?

As stated before, the genetic sequenced amplified by commercial NAT assays are unknown. The companies usually publish the viruses the have tested their assay's specificity against which typically include seasonal coronaviruses and MERS in the instructions for use (IFUs). Individual labs will typically also test the specificity of the test against a range of respiratory viruses including some of the seasonal coronaviruses when validating a commercial assay before use.

ESR does not have access to the information from these IANZ accredited laboratories and have not tested the commercial assays' specificity against seasonal coronaviruses.

Please provide the different sections of code (under those which are tested) for each of the 3 main variants of concern, alpha, delta and omicron.

The NAT assays in use in New Zealand amplify and detect different sections of code in the following viral genes: N, E, RdRP, ORF and S - gene. The only assay in use in New Zealand which has one of the gene targets (S-gene) affected by both the Alpha and Omicron variant is the Thermo Taqpath assay.

Can you please confirm which sections of code are tested for which variant for each assay in use in NZ. Eg. Themo Taqpath assay uses the N, E and S - gene to identify both Omicron and Alpa. Themo Taqpath assay uses the ?? to identify Delta and so on.

The NAT assays cannot distinguish individual variants and therefore any NAT positive sample needs whole genome sequencing to determine if it is a variant of concern and to which lineage it belongs.

Please provide a full disclosure explanation of how a positive NAAT RT-PCR test shows a positive case of Covid-19 after detecting a nominal amount of nucleic acid which belong to a virus rather than showing that the person is indeed infected with a replicating virus.

A positive NAT cannot determine if it comes from a replicating virus or not as it detects only a piece (small amplicon) or pieces of the virus. However, if the NAT signal increases on repeat testing then one can assume that more virions are produced (viruses are replicating).

Positive cultures are more indicative of replication competent virus in clinical samples.

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So just to be clear after a "positive case" of detection of the viral material no other diagnosis is made to confirm there is an infection of covid-19 rather than just the presence of viral material?

Correct

In https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268832/ it states that the RT-PCR test is only used to confirm a diagnosis of covid-19. So the assays in use in NZ only show viral material is present and no further testing is performed to identify if it is a replicating virus or not?

Correct

Please also provide a full disclosure explanation of how an asymptomatic case has been deemed to be infectious. Quoting a RT-PCR test here is insufficient as it only shows that genetic material form the searched for nucleic acid is present, not that there is any further infection. As confirmed by CDC, Dr Fauci and others the NAAT doesn't prove that the tested person is infectious only that they carry the genetic material that was tested for by the NAAT.

Epidemiological follow up studies have shown that those who are exposed to asymptomatic cases, say for instance in a household setting, have a high probability of testing NAT SARSCoV-2 positive or develop COVID-19 (clinical syndrome) in the follow up incubation period. It can be difficult to determine if all asymptomatic cases are infectious when the NAT signal is weak, especially where someone has not had a known exposure or where they don't develop symptoms during their isolation period.

I believe we have used a different interpretation of the word "infectious". My definition of infectious only covers when a second person develops clinical symptoms of covid-19. Is there any direct evidence of this available (just to clarify an asymptomatic person directly causing clinical symptoms of covid-19 in another person)?

Yes please refer to an earlier Official Information request replied to by the Ministry of Health in November 18 2020.
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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 - Health
ESR

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