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11 December 2020

Julie Williams

By email: fyi-request-14173-8b518343@requests.fyi.org.nz

Ref: H202008356

Dear Julie Williams

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 19 November 2020 to the Ministry of Health (the Ministry) for:

"What amplification factor are your technicians using when determining test results for the CoVID-19 test kits? If a range is being used explain what that range is and detail why."

All Reverse Transcription (RT)-Polymerase Chain Reaction (PCR) assays are validated for the number of PCR cycles used for SARS-CoV-2 testing by the laboratories that perform RT-PCR testing. All testing is performed under ISO15189 accreditation which includes verification by an external organisation International Accreditation New Zealand (IANZ).

Amplification for RT-PCR is determined using Cycle threshold (Ct) values. There is no 'range' of PCR cycles (Ct) used. In order to put some context around Ct values (and PCR cycles), the 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', hence the name RT-PCR. Once this is done 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 in 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.

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 Immunisation, Testing & Supply

COVID-19 Health System Response