Australian Government

Department of Health

Department Reference: FOI 3525

Attention: verifysp
by email: foi+request-7811-90e93639@righttoknow.org.au

Dear verifysp

NOTICE OF DECISION UNDER SECTION 24A
OF THE FREEDOM OF INFORMATION ACT 1982

I refer to your request of 3 September 2021 received by the Department of Health (the department) seeking access under the *Freedom of Information Act 1982* (Cth) (the FOI Act) to the following documents:

> *any report/advice/doc issued to advise public that the cdc recalled pcr tests as they are deemed unreliable to confirm sar-cov2 when cycled above 24 false positives of 50-80%*
>
> *Below is the cdc/fda directive (links) I am referring to.*
> *DIRECTIVE*
> *The FDA announced that the CDC's PCR test for COVID-19 "failed its full review" because it is "unable to differentiate between COVID and flu," resulting in the diagnostic tool's emergency use*
>
> *https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html*
> *https://www.fda.gov/media/139109/download*
> *https://www.cdc.gov/csels/dls/locs/2021/07-18-2021-lab-alert-FDA_Revokes_EUA_Curative_SARS-CoV-2_Assay_1.html*
>
> *as such public advice or doc discussing such a report or statement should exist in the public sphere this request should not require a formal gipa form or any fee since such advice or reporting to the public would not require deep searching, and this informal request should suffice.*

Information about PCR testing

In Australia, nucleic acid amplification testing (NAAT) using polymerase chain reaction (PCR) on a respiratory sample collected by a throat and bilateral deep nasal

(or nasopharyngeal) swab is the gold standard test for confirming an acute diagnosis of SARS-CoV-2 infection. This test method is very sensitive and detects nucleic acid sequences specific to the virus. PCR testing has been comprehensively validated and continues to be monitored by pathology laboratories both locally and internationally to ensure a high testing and performance standard is met.

During the testing process, the PCR amplifies (i.e., makes many copies of) a highly specific target region of the SARS-CoV-2 genome so that it can be detected. Each amplification reaction is known as a cycle. The cycle threshold (Ct) value of a reaction is the cycle number when the fluorescence of a PCR product can be detected above the background signal. Each PCR assay may have a different Ct value that is used for detecting SARS-CoV-2. Ct values for one in vitro diagnostic (IVD) device should not be compared with Ct values from other platforms. Ct values are IVD dependant. This means there is no 'set' Ct value to aim for across all platforms. There are also nucleic acid amplification devices used for the diagnosis of SARS-COV-2 infection which do not record a Ct value. This emphasises the need for interpretation of results by a suitably qualified pathologist or laboratory medicine scientist.

Furthermore, commercial IVD Devices are subject to Therapeutic Goods Administration (TGA) regulations and require that pathologists and medical laboratory scientists to follow the manufacturer's instructions for use. For in-house assays, the parameters for determining a result have been determined by the laboratory through the assay development and evaluation process.

The recent testing advice from the United States Centers for Disease Control and Prevention intended to provide guidance on the use of PCR tests which incorporate multiple pathogen targets for different viral respiratory infections. For example, these tests can diagnose infections like COVID-19 and influenza at the same time and correctly differentiate between the two. These type of PCR tests which incorporate multiple targets are commonly used in Australia. They can be designed to correctly detect influenza viruses, parainfluenza viruses, Human Metapneumovirus, Respiratory Syncytial virus as well as others including some of the commonly circulating human coronaviruses which were circulating before SARS-COV-2.

The SARS-CoV-2 PCR test type used in Australia varies depending on the laboratory. Any testing technology new to Australia requires very careful assessment by the TGA and be included in the Australian Register of Therapeutic Goods (ARTG) before they can be legally supplied in Australia. Once approved for supply in Australia, all testing methodologies continue to be closely monitored by the TGA and by laboratories, through mandatory participation in quality assurance program modules that have been developed specifically for SARS-CoV-2.

FOI decision

I am authorised under subsection 23(1) of the FOI Act to make decisions in relation to Freedom of Information requests. I am writing to notify you of my decision in response to your request.

I am satisfied that appropriate steps have been taken to find the documents referred to in your request including consultation with relevant departmental officers and searches of departmental file management systems.

I am satisfied, based on the consultation undertaken and the searches conducted, that the department does not hold any documents relevant to your request.

My decision is made pursuant to section 24A of the FOI Act.

FOI review rights

If you are dissatisfied with my decision, you may apply for a review.

Internal review

Under section 54 of the FOI Act, you may apply in writing to the department for an internal review of my decision.

The internal review application must be made within 30 days of the date of this notice (or such further period as the department allows). To assist in the internal review process, please provide reasons you consider review of my decision is necessary. The internal review will be undertaken by another officer of the department within 30 days of receipt of your application.

An application for an internal review can be sent to:

Email: FOI@health.gov.au
Mail: FOI Unit (MDP 516)
Department of Health
GPO Box 9848
CANBERRA ACT 2601

Information Commissioner review

Alternatively, under section 54L of the FOI Act, you may apply to the Office of the Australian Information Commissioner (OAIC) for review of my decision. An application for review must be made in writing within 60 days of this notice (if you do not request an internal review).

You may also make a complaint to the OAIC about action taken by the department in relation to your application.

The OAIC can be contacted by:

Email: enquiries@oaic.gov.au
Phone: 1300 363 992

More information about OAIC review and making a complaint is available on the OAIC website:
https://www.oaic.gov.au/freedom-of-information/reviews/

Relevant provisions of the FOI Act

The FOI Act, including the provisions referred to in this letter, can be accessed from the Federal Register of Legislation website:
https://www.legislation.gov.au/Details/C2021C00382

Contacts

If you require clarification of any of the matters discussed in this letter you should contact the department's Freedom of Information Unit on (02) 6289 1666 or at FOI@health.gov.au.

Yours sincerely

Dr Gary Lum
Digitally signed by Dr Gary Lum
Date: 2022.01.27 10:04:27 +11'00'

Dr Gary Lum, AM
Principal Medical Advisor
Office of Health Protection and Response

Thursday, 27 January 2022