Australian Government

Department of Health

Department Reference: [redacted]

[redacted]
via email [redacted]

Dear [redacted]

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

I refer to your request of 15 February 2021 to the Therapeutic Goods Administration (TGA) seeking access under the *Freedom of Information Act 1982* (Cth) (the Act) to the following documents:

> *The currently held scientific papers, such as a controlled trial (in animals or humans), that prove there is a novel strain of SARS-CoV-2 (including but not limited to the strain B.1.1.7), that is up to 70% more infectious.*

The TGA, a Division within the Department of Health (the department), has referred your request to the department's Freedom of Information Unit for processing and response.

FOI decision

I am authorised under subsection 23(1) of the 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.

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, on the basis of the consultation undertaken and the searches conducted, that the department does not hold any documents referred to in your request.

As a consequence, relying on section 24A of the Act, I cannot provide access to the documents you requested.

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: [redacted]

[redacted]

By Email: [redacted]

Dear [redacted]

FREEDOM OF INFORMATION REQUEST FOI 2182
Notice of Decision

I refer to your request dated 12 January 2021 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"...one document that shows and provides scientific factual evidence of the testing procedure being used in Australia that 100% positively identifies Covid-19 otherwise known as SARS-CoV-2 (not any other type of Corona Virus) in a living human, beyond any reasonable doubt."*

Decision Maker

I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

I am notifying you of my decision under section 24A of the FOI Act to refuse your request for access, as the documents you have requested do not exist.

Reasons for Decision

Section 24A of the FOI Act states that requests may be refused if all reasonable steps have been taken to find a document and the document does not exist. The relevant electronic databases, files and corporate file lists in the TGA have been searched for the documents you have requested, and following these searches I am satisfied that all reasonable steps have been taken to find the documents requested and that the documents you have requested do not exist. Instead, I offer you the following publically available information regarding testing specificity for COVID-19 test kits.

As background, point-of-care testing is a form of testing in which the analysis is performed where healthcare is provided, close to or near the patient. All point-of-care test kits for identifying the SARS CoV-2 virus (COVID-19 test kits) approved by the TGA for supply within Australia and inclusion in the Australian Register of Therapeutic Goods (ARTG) are listed on the TGA website at: www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia.

The TGA approved the COVID-19 test kits under an expedited assessment processes and were evaluated in accordance with the *Therapeutic Goods (Medical Devices) Regulations 2002*: www.legislation.gov.au/Details/F2020C00682.