FOI 23/797

Dear

Thank you for your email correspondence with our FOI team on 17 October 2023, where you submitted an FOI request for the following:

> *What genomic sequence the following PCR test is looking for, to determine if a person is positive with covid 19*
>
> *"Abbott Laboratories Ltd*
> *Abbott House*
> *Vanwall Business Park*
> *Maidenhead*
> *Berkshire*
> *SL6 4XE"*
>
> *"Abbott Molecular Inc 1300 E. Touhy Avenue Des Plaines IL 60018 USA" United States of America Abbott Realtime SARS-CoV-2 Amplification Reagent Kit & Abbott RealTime SARS-CoV-2 Control Kit "Date: June 2020 51-608442/R2" Extracted Molecular 31-May-22 30-May-27 "Declaration of conformity. Issued 26/05/21" Nasopharyngeal"*

The MHRA holds the requested information. However, in accordance with section 43(2) of the Freedom of Information Act (Section 43 - Commercial interests | ICO), sequences used in manufacturer PCR tests are proprietary and therefore the information requested is exempt from disclosure.

For your information, we provide a summary of the PCR technique and target regions within the SARS-COV-2 genome that may be targeted by commercially available SARS-COV-2 PCR tests.

- Polymerase chain reaction (PCR) is a laboratory technique that uses selective primers to “copy” specific segments of a DNA sequence.

- COVID-19 PCR tests use primers that match a segment of the virus’s genetic material. This allows many copies of that material to be made, which can be used to detect whether the virus is present.

- Open reading frame (ORF1ab), Nucleocapsid (N) RNA-dependent RNA polymerase (RdRP), envelope (E) and spike protein (S) are regions or segments within the SARS-COV-2 genome that may be targeted by commercially available SARS-COV-2 PCR tests.

- A positive COVID-19 PCR test means that SARS-CoV-2 is present. A negative result could either mean that the sample did not contain any virus or that there is too

little viral genetic material in the sample to be detected.

Please note that the above information is publicly available and can be accessed here: Understanding COVID-19 PCR Testing (genome.gov)

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [MHRA request email]

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Kind regards,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU