DIRECTORATE FOR COVID PUBLIC HEALTH

COVID: Vaccinations



J Grove request-703562-44bfd861@whatdotheyknow.com

Our Reference: 202000107183

Your Reference: Internal review of Freedom of Information request - The False Positive Rate for the

COVID-19 rRT-PCR Test

23 December 2020

Dear J Grove,

REQUEST FOR REVIEW UNDER FREEDOM OF INFORMATION (SCOTLAND) ACT 2002 (FOISA)

Thank you for your email of 9 December 2020 to the Scottish Government Central Enquiry Unit, in which you requested a review of your 4 November 2020 request for information under the Freedom of Information (Scotland) 2002 (reference: 202000107183).

I have been asked to look at your request afresh, to decide whether the original response should be confirmed, with or without modifications, as appropriate, or that a fresh decision should be substituted. I can confirm that I was not involved in the handling or decision-making around the original response.

Your original request for information

You asked:

What is the most recently recorded false positive rate for the real time reverse transcriptase polymerase chain reaction (rRT-PCR) COVID-19 test that is used to test the people living in Scotland?

Response to your request:

The Scottish Government does not have the information you have asked for as this information is not held by the Scottish Government. This is a formal notice under section 17(1) of FOISA that the Scottish Government does not have the information you have requested.

Scottish Ministers, special advisers and the Permanent Secretary are covered by the terms of the Lobbying (Scotland) Act 2016. See www.lobbying.scot

St Andrew's House, Regent Road, Edinburgh EH1 3DG www.gov.scot







Although we do not hold the information you have requested it may interest you to know that there is a reflex testing procedure in place for Scotland which was put in place to reduce the likelihood of false positive results as outlined in the Public Health Scotland COVID-19 guidance for sampling and laboratory investigations which can be found here: https://www.hps.scot.nhs.uk/web-resourcescontainer/

Your request for review

I am writing to request an internal review of Scottish Government's handling of my FOI request 'The False Positive Rate for the COVID-19 rRT-PCR Test'.

By this point the Scottish Government should have been advised (by Prof Jason Leitch or one of the advisors that is covered by the Lobbying (Scotland) Act 2016) of the retraction-request letter sent to Eurosurveillance by Dr. Peter Borger et al to the extended Review Report submission via the Eurosurveillance online-submission portal.

The submission date was 27th November 2020.

covid-19-guidance-for-sampling-and-laboratory-investigations/

This report casts very serious doubt, detailed in ten points of concern, on the published COVID-19 Reverse Transcriptase Polymerase Chain Reaction test protocol. It also implies that the initial publication was not peer reviewed.

Given this information the Scottish Government must have records on the false positive rate of the "antigen test" and this must be recorded on Scottish Government systems, to suggest otherwise would indicate that the Scottish Government is responsible for enacting policies that will lead to a loss of life and not having the accurate and recorded scientific information to base these decisions on.

The Scottish Government should have this information recorded and the date when this information was first recorded on Scottish Government systems.

A full history of my FOI request and all correspondence is available on the Internet at this address: https://www.whatdotheyknow.com/request/the-false-positive-rate-for-the

Response to your request for review

I have now completed my review of your request, and I have concluded that the original decision should be confirmed without modifications. I have been mindful of our duty under FOISA to provide advice and assistance and I have offered further explanation to you in my response where I considered it may be helpful.

In conducting my review I have re-examined the searches undertaken at the initial stage to identify all of the information held within the scope of your request. I am satisfied that contributions were sought from all of the relevant officials and that the appropriate searches were completed. I am therefore satisfied that proportionate searches were undertaken by the case handler and that the information is

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not held by Scottish Government.

I have determined that we were entitled to respond under section 17(1) of FOISA as the information you have requested is not held by the Scottish Government.

While we do not have the information you have requested, you may find it helpful to refer to information from sources including Public Health Scotland.

The tests have been validated for use by the laboratories using them and are regulated and approved by the Medicines and Healthcare products Regulatory Agency.

https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19 The Scottish Government does not hold this information, you may consider contacting NHS Boards and Lighthouse Laboratories to respond to these points.

The type of laboratory tests being used for diagnosing covid-19 detect the viral genetic sequence of the causative virus, SARS-CoV-2 by a real time PCR assays. These tests are very sensitive and the gold standard for respiratory viruses. They are specific and have been tested on large panels of negative clinical samples.

The current PCR tests in use in Scotland are effective at identifying people who have COVID-19 infection when they are symptomatic. As these tests only detect the presence of RNA from the SARS CoV-2 virus they cannot distinguish between live and inactivated virus. As a result they cannot tell us if a person is currently infective. This means that testing cannot reliably tell us if someone who does not have symptoms currently has the disease, or has had it in the past and has inactivated virus in their sample.

Weak positive results can happen when the swab picks up fragments of the virus from an individual who is no longer infectious. There is a reflex testing procedure in place for Scotland which was put in place to reduce the likelihood of false positive results. The Public Health Scotland laboratory guidance provides guidance on reporting of positive results https://www.hps.scot.nhs.uk/web-resources- container/covid-19-guidance-for-sampling-and-laboratory-investigations/

It may be helpful to note the difference between an RT-PCR/PCR test which detects and amplifies specific genome 'targets' in a positive patient sample and an Antigen test which detects specific protein 'targets' in a positive patient sample and works in a similar way to a pregnancy test. Further information can be found in the COVID-19 Laboratory testing FAQ document published by Public Health Scotland: HPS Website - COVID-19 - laboratory testing frequently asked questions (scot.nhs.uk)

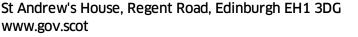
If you are unhappy with the outcome of this review you have the right to appeal to the Scottish Information Commissioner about our decision within 6 months of receiving this letter. Information on how to make an appeal, along with an application form, is available on the Commissioner's website

https://www.itspublicknowledge.info/YourRights/Unhappywiththeresponse/AppealingtoCommissioner.as

You can also contact the Commissioner:

www.gov.scot

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The Scottish Information Commissioner Kinburn Castle Doubledykes Road St Andrews Fife KY16 9DS

E-mail: enquiries@itspublicknowledge.info

Telephone: 01334 464610

Should you then wish to appeal against the Commissioner's decision, there is a right of appeal to the Court of Session on a point of law only.

Yours sincerely

Gillian Heavie

VACS: Vaccine Improvement & Delivery

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