



Public Health
England

Protecting and improving the nation's health

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By email

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Our ref: 22/12/hf/2212

14 January 2021

Dear Dr Jonathan Dench

Re: COVID-19 PCR Test protocol, Sensitivity, Specificity and therefore Operational False Positive Rate, and how the official figures are corrected for this

Thank you for your request received on 22 December 2020 addressed to Public Health England (PHE). In accordance with Section 1(1)(a) of the Freedom of Information Act 2000 (the Act), I can confirm that PHE partly holds the information you have specified.

Request

I have some strong scientific concern about COVID-19 testing and the handling of data by the UK Government.

Firstly no-specificity or sensitivity is provided which is completely unacceptable. It appears data is not being corrected for the Operational false positive rate of such tests. Current estimates of specificity from the literature are 95-99% ,this does not sound alarming at first, but once you account for test frequency and prevalence this is quite alarming, as it would provide an operational false positive rate of 90%. This can be confirmed from "with COVID death' data ie died within 28 days of positive PCR. If you compare current excess death with the average of the past 5 years with the governments estimates of COVID death, you get an Operational false positive rate of 70% for a sample with the highest pre-test probability of having COVID and therefore the lowest OFPR. This means the government statistics are meaningless without correction. This also means no mass indiscriminate testing should take place as this would further worsen this problem. You should be doing a full investigation on this matter, as the Government draws us further into a pseudo pandemic.

What I am requesting:

Full PCR test protocol

Test sensitivity

Test specificity

How data is being corrected for Operational false positive rate.

Response

PHE does not hold the requested information on the full PCR test protocol, test sensitivity and test specificity.

There are multiple tests being used and every kit will have its own interpretative criteria and thresholds, as recommended by the manufacturer. PHE evaluation is not mandatory for COVID-19 diagnostic tests and assays. PHE has undertaken rapid assessment of commercially provided diagnostic tests with further evaluations ongoing, please refer to this link for further information on PHE's work in this area <https://www.gov.uk/government/collections/covid-19-phe-assessment-of-laboratory-tests-and-assays>

The Medicines and Health Products Regulatory Agency is the national regulator for medical tests and any test can legally be marketed and deployed in the UK once it receives a CE mark. For further information refer to this link <https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/process-for-developing-and-evaluating-novel-molecular-assays-for-covid-19>

Regarding the operational false positive rate, daily reported case numbers exclude results that have been identified as false. Where confirmatory tests are undertaken, results are only reported when they have been confirmed.

If you have any queries regarding the information that has been supplied to you, please refer your query to me in writing in the first instance. If you remain dissatisfied and would like to request an internal review, then please contact us at the address above or by emailing foi@phe.gov.uk.

Please note that you have the right to an independent review by the Information Commissioner's Office if a complaint cannot be resolved through the PHE complaints procedure. The Information Commissioner's Office can be contacted by calling the ICO's helpline on 0303 123 1113, visiting the ICO's website at www.ico.org.uk or writing to the ICO at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely
FOI Team