



By email

request-714156-7a77fda9@whatdotheyknow.com

Our ref: 15/01/hf/2467

24 March 2021

Dear Jonathan Dench,

Re: Internal review of Case ref: 2467 COVID-19 PCR Test protocol, Sensitivity, Specificity and therefore Operational False Positive Rate, and how the official figures are corrected for this

I refer to your email of 15 January 2021 requesting an internal review of the handling of case reference 2212, in relation to your request for information under the Freedom of Information Act 2000 "the Act".

Your Request case ref: 2212

Public Health England (PHE) received your information request on 22 December 2020. Under the FOI Act PHE had until the 22 January 2021 to respond to your request.

Response Case ref: 2212

PHE sent you its response on the 15 January 2021 and, correctly confirmed it partly held the information you requested.

PHE confirmed that it did not hold the information you requested on the full PCR test protocol, test sensitivity and test specificity.

PHE explained that there are multiple tests in use with their own interpretive criteria and thresholds as recommended by the manufacturer. PHE provided a link to its evaluation of laboratory tests and assays.

Additionally, PHE highlighted that the Medicines and Healthcare products Regulatory Agency is the national regulator for medical tests and provided a link to their process for developing and evaluating molecular assays for COVID-19.

In response to your questions on how data is being corrected for operational false positive rate, PHE explained that daily reported case numbers exclude results that have been identified as false.

Internal review decision

PHE has now conducted the internal review and conclude that PHE sent you its response to your request for information within the statutory deadline. PHE correctly confirmed it did not hold information on the full PCR test protocol, test sensitivity and test specificity; and it correctly explained that daily reports case numbers exclude results that have been identified as false.

In assessing your internal review, PHE's teams have provided additional detail below.

There is an extensive menu of tests currently used to detect SARS-CoV-2 in a sample. Whilst most of these tests are PCR based, there are also assays that use alternative technology for the detection of SARS-CoV-2 nucleic acid. In the case of the CE-IVD tests the thresholds used for result interpretation will be defined by the manufacturer of the assay. Currently there are over 80 different testing platforms in use across the various networks of laboratories and the thresholds for result interpretation will be configured in each case by the manufacturers of the assays and the instrumentation. Each laboratory will regularly assess the performance of their assays within their local quality management system. The results are monitored in accordance with defined quality control procedures. Whilst each laboratory has a statutory duty to report positive cases into Public Health England, additional information, such as Ct values in the case of PCR tests, is not submitted.

In June 2020 the Scientific Advisory Group for Emergencies published a briefing paper on the impact of false positives and false negatives in the United Kingdom's COVID-19 reverse transcription polymerase chain reaction (RT-PCR) testing programme.

The briefing paper states that the United Kingdom operational false positive rate is unknown, and an attempt has been made to estimate the likely false-positive rate of national COVID-19 testing programmes by examining data from published external quality assessments (EQAs) for RT-PCR assays for other ribonucleic acid viruses carried out between 2004-2019. Results of 43 EQAs were examined, giving a median false positive rate of 2.3%. The paper can be accessed here:

<https://www.gov.uk/government/publications/gos-impact-of-false-positives-and-negatives-3-june-2020>

Additionally, you may find the following document on the cycle threshold useful:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/926410/Understanding_Cycle_Threshold_Ct_in_SARS-CoV-2_RT-PCR_.pdf

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 Manager