



Public Health
England

Protecting and improving the nation's health

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By email

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Our ref: 31/01/ay/2650

19 February 2021

Dear Dan C,

Re: 2650 - FOI The current cycle threshold required on a PCR test to be considered positive for SARS-CoV-2

Thank you for your request received on 31 January 2021 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 does hold the information you have specified. I have answered your questions in the order raised.

What is the current cycle threshold required on a PCR test to be considered positive for SARS-CoV-2?

PHE can confirm it does hold the information requested in relation to PCR tests used within PHE laboratories.

Your request for information is too broad in scope and our initial assessment of the searches that need to be carried out indicate that to determine whether we hold the information, retrieve and extract the information to respond to your request as it stands would exceed the cost limit of £600. The cost limit is calculated at a staff rate time at £25 per person per hour working for 24 hours to respond to the request. Therefore, the information is exempt in accordance with Section 12 of the Act.

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.

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>

PHE does not hold information for non-PHE laboratories. Many laboratories contribute to the government's testing programme and PHE does not maintain central records of testing undertaken in each lab.

Under our Section 16 duty to provide advice and assistance, you may wish to contact the Department of Health and Social Care (DHSC), who may be able to advise further. You can contact DHSC here:

<https://www.gov.uk/government/organisations/department-of-health-and-social-care>

In addition, Medicines and Health Products Regulatory Agency (MHRA) 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>

If this has changed previously and if so, what was the previous cycle threshold and when was this change implemented?

PHE can confirm it does hold the information requested. PHE confirms there has been no change.

If there have been any changes, what was the reason for a new cycle threshold being used?

PHE can confirm it does not hold the information in the way requested. Please refer to question 1.

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