

CG Report 7: PCR Testing in the UK During the SARS-CoV-2 Pandemic – Evidence From FOI Requests

Data Summary

Access to responses from public health authorities to Freedom of Information (FOI) queries shows there is a lack of knowledge on how many PCR tests are in use, their practical usage, and a lack of means of identifying contagious individuals. The current system requires significant changes to ensure it offers accurate diagnostic data to enable effective clinical management of SARS-CoV-2. PCR is an important and powerful tool, but its lack of standardisation risks undermining its usefulness and credibility.

Our report interrogated the public authorities' understanding of PCR testing for SARS-CoV-2 in the United Kingdom by accessing Freedom of Information requests submitted in 2020-21. We searched [WhatDoTheyKnow](#) and found [300 FOI requests](#), from over 150 individuals covering four topics.

1. Test numbers in use

The number of [validated](#) tests in use in the UK, and who is responsible for their oversight, is currently not clear. In FOI responses, Public Health England (PHE) report it may be [80](#) or [85](#). DHSC has approved [16 tests](#) based on [regulations](#) set out that those supplying COVID-19 tests must apply to DHSC for approval. Analysis of European CE marked test kits reveals there are many more tests (over [141](#), and possibly [over 400](#)), that might be available for use.

There is no central holder of the list of tests, their validation, or their accuracy. The responsibility lies with the individual laboratories to oversee which tests they use - only a few responded by naming the tests in use.

2. Cycle threshold (Ct) reporting

The cycle threshold (Ct) of the PCR test is the number of amplification cycles at which a sample yields a positive result. Laboratories have a statutory duty to report positive cases to PHE, but they do not have to advise which tests they are using nor submit Ct values. Additionally, there is also no duty by individual laboratories to report what is meant by a "positive," and all tests may preform differently (especially across laboratories).

3. Cycle threshold (Ct) values

Only two FOI responses provided answers on Ct values, indicating that in a set time span, 24–38% of the Ct values were over 30. The most common FOI asked if there was a cycle threshold for positivity. In those that responded, the Ct for a positive result varied from 30 to 45.

4. PCR test accuracy

We found limited information on the technical accuracy of the tests. Several responses stated there is no ‘static’, ‘specific’, or ‘standard’ cycle threshold. The false-positive and negative rates are related to the prevalence of the disease, but we found no information answering this question either.

Recommendations

- Mandatory control and validation of tests should be introduced.
- In parallel, UKHSA should be running a validation programme similar to the one described by [Vierbaum et al. \(2022\)](#)
- As with all tests, PCR should never be interpreted outside a clinical context, i.e., a past, recent medical and drug history and careful assessment of exposure to the agent.
- One-off validation should include calibration of the test against its capacity to detect infectious samples. This should preferentially entail comparison with viral culture.
- No unvalidated tests should be used.
- A central repository of tests in use and their validation evidence should be published.
- Standard reporting on PCR based tests should include an estimated measure of viral burden.
- The reporting of cycle thresholds with test positivity should be mandated.
- Any adding or comparison of cases should only include those for whom a reasonable expectation of comparability exists.
- PCR tests should be validated in the real world of clinical practice.
- For the public: we recommend focusing FOI requests to meet Section 12 limits, such that the question can be reasonably answered by authorities.