

Freedom of Information Request

Ref: 20-623

12 January 2021

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

- We can confirm that we do hold the information you are requesting

1. Confirmation that all reported cases of SARS-COV2 in your Trust have been diagnosed and confirmed by PCR test;

Yes

2. If not with a PCR test, provide details of what method was employed to confirm the presence of SARS-COV2;

Not applicable

3. Details of the laboratories performing the PCR tests producing the confirmation of SARS-COV2 on behalf of your Trust;

University Hospitals Bristol and Weston NHS Foundation Trust and North Bristol NHS Trust

4. Details of the Ct thresholds currently employed in the PCR tests performed by the labs at 3.;

Where current tests report Ct values we record all Ct values detected by the assay. Late Ct values (>35) are confirmed by re-testing and reported as Indeterminate if the result is not repeatable.

Some tests are qualitative and the laboratory is blinded to the result if it is recorded by the equipment. Interpretation is made by the software as Positive, Negative or Invalid

Other tests may report qualitative results with a measurable endpoint signal. In this instance, the signal (RLU) can be crudely interpreted as detection of one or both of the SARS-COV-2 specific gene elements. Samples recording lower RLU values that imply low levels of virus are repeated to confirm the original result and reported as Indeterminate if the result is not repeatable.

5. Details of the Ct thresholds used to confirm all reported cases of SARS-COV2 in your Trust between 01/01/2020 and 18/12/2020;

As per Q4, all Ct value are recorded. Tests generating late Ct (>35 cycles) or atypical amplification signals have been repeat tested. Unconfirmed results have been recorded as Indeterminate.

6. Details of the manufacturers of the PCR tests used to confirm the presence of SARS-COV2 in your Trust;

- a. WHO RdRp assay.
- b. Altona Real Star SARS-CoV-2 PCR
- c. Hologic SARS-CoV-2 TMA
- d. BioFire RVP 2 Assay
- e. genexpert SARS-CoV-2 PCR

7. In the document "Understanding cycle threshold (Ct) in SARS-CoV-2 RT-PCR" published on the UK government website, page 7 includes the statement "Some commercial RT-PCR techniques are closed 'black box' systems whereby the operator cannot observe the reaction in real-time and the result is interpreted by software into a qualitative non-interrogatable positive or negative result." Please confirm which manufacturers have been engaged that employ such a 'black box' method, which labs have used such a manufacturer, and which results confirming the presence of SARS-COV2 in the UK have been based on such techniques;

- a. BioMerieux BioFire

8. Where such results have been produced using the 'black box' method, please describe what further action was taken to confirm the results produced by the 'black box' method.

No specific action, unless re-testing is requested.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Director of Corporate Governance
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

Please note that this letter and the information included/attached will be published on our website as part of the Trust's Freedom of Information Publication Log. This is because information disclosed in accordance with the Freedom of Information Act is disclosed to the public, not just to the individual making the request. We will remove any personal information (such as your name, email and so on) from any information we make public to protect your personal information.

To view the Freedom of Information Act in full please click [here](#).

Yours sincerely

Freedom of Information Team
University Hospitals Bristol and Weston NHS Foundation Trust