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Request for Information Reference: 12.21.41

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Email only

10<sup>th</sup> January 2021

**Freedom of Information Act 2000 – Request for Information**

Thank you for submitting a request for information which we received on 20<sup>th</sup> December 2021 in relation to County Durham and Darlington NHS Foundation Trust (the Trust). Your request has been processed under the provisions of the Freedom of Information Act 2000 and I am now able to provide you with a response.

Your request was in relation to PCR tests and I am providing the following information in response to your specific questions:

**1. Please provide the number(s) of thermal cycles run on the PCR tests for your patients.**

| <b>Analyser</b>                | <b>Date in Use</b>     | <b>Kit</b>                    | <b>No of Cycles</b>             | <b>Info Source</b> |
|--------------------------------|------------------------|-------------------------------|---------------------------------|--------------------|
| Quant Studio 5<br>Thermofisher | Nov 2021 – present     | Anatolia SARS<br>CoV2/Flu/RSV | 40                              | Product IFU        |
| Quant Studio 5<br>Thermofisher | Dec 2020 – Nov<br>2021 | Anatolia SARS<br>Cov 2 V4     | 40                              | Product IFU        |
| Gene Xpert<br>Cepheid          | Apr 2021 – present     | SARS CoV2                     | 45                              | Analyser<br>Graph  |
| Gene Xpert<br>Cepheid          | Oct 2021 – present     | SARS<br>CoV2/Flu/RSV          | 45                              | Analyser<br>Graph  |
| SAMBA II<br>DWR                | Dec 2020 – present     | SARS CoV2                     | N/A isothermal<br>amplification | NA                 |
| ID Now Abott                   | May 2020 – present     | SARS CoV2                     | N/A                             | NA                 |

- 2. Please provide the current cycle threshold value (ct value) applied on such PCR tests to determine if your patient has COVID-19 or not. Please include the current date.**

All but the Anatolia kits above are reported as Detected or Not detected by the analysers and their own internal parameters.

The Anatolia kits cycles run up to 40 (as per the information for users/instructions for use for this kit which is validated for in-vitro diagnostic use using these parameters). There is no 'cut-off value' lower than this within these kits but all results are interpreted by qualified Biomedical Scientists who review each PCR curve, the internal control data and the number of genes detected to determine if the result is reported as 'Detected', 'Not detected' or 'Indeterminate – request repeat'.

- 3. Please provide the cycle threshold value (ct value) used on 1st August 2021, 1st October 2021 and also on 1st December 2021 applied on your PCR tests to determine if your patient has COVID-19 or not.**

See the above table and response to question 2. The date ranges for the tests in use are in the table.

- 4. On which date(s) did you change or optimise your PCR testing to better detect the Omicron variant?**

All testing in the microbiology laboratory at CDDFT has been verified to be able to detect omicron with no variation to the previous variants. There was no need to change internal testing procedures. All positive patient Covid-19 samples are referred to the Integrated Covid Hub North East (ICHNE) for genotyping and also to Public Health England Porton for whole genome sequencing – both of which are capable of detecting omicron.

- 5. Please provide the manufacturer names and models of such testing equipment.**

Please see table in response to question 2.

- 6. Please provide information on how often a patient should be PCR tested if**

**a) positive for COVID-19**

The Trust screen our patients on Day 0 (day of admission), Day 3,5,7,10,14 and then every 7 days or if they become symptomatic.

**b) negative for COVID-19.**

Once they are positive the Trust would not routinely screen unless required for de-escalation/discharge.

7. Does the trust follow World Health Organisation guidelines for PCR testing including and most importantly, those found in the following sentence "Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information". If not, please state why?

The link to the guidelines can be found here:

<https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>

No – the Trust follows the UK Health Security Agency Guidelines.

8. Regarding the factors mentioned by the World Health Organisation for consideration in the previous question, have you had at least a single case where these overruled a positive PCR test such that the patient is not diagnosed with COVID-19? If yes, does it happen regularly?

No

9. Please provide the trust's policy for PCR testing which causes injury and incorrect care to a patient. For example, injury and incorrect care caused by: an incorrectly performed PCR test, a false positive sample result, lack of repeat testing, lack of the test being held in the appropriate medical context, lack of oversight, lack of appeals procedure on the result and so forth.

The Trust does not have a policy for this.

In line with the Information Commissioner's directive on the disclosure of information under the Freedom of Information Act 2000 your request will form part of our disclosure log on the Trust's website. However please be assured that we anonymise all responses prior to adding them to the disclosure log.

I hope that this response has provided you with the information you had requested. If you have any queries or wish to discuss the information supplied, please do not hesitate to contact me by telephone or in writing. If however, you are dissatisfied with the way in which your request has been handled and would like an internal review, you will need to contact me in writing at the above address or via [cdda-tr.cddftfoi@nhs](mailto:cdda-tr.cddftfoi@nhs).

If you remain dissatisfied with our response following an internal review you have the right to appeal to The Information Commissioner at Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF. More information is available on their website; [www.ico.gov.uk](http://www.ico.gov.uk).

Yours sincerely

**Corporate Records and Freedom of Information Facilitator**