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Request for Information Reference: 12.20.37

Email: [cdda-tr.cddftfoi@nhs.net](mailto:cdda-tr.cddftfoi@nhs.net)  
Email only

20 January 2021

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

Thank you for submitting a request for information which we received on 18 December 2020 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 SARS-COV2 and I am providing the following information in response to your specific questions:

**1. Confirmation that all reported cases of SARS-COV2 in your Trust have been diagnosed and confirmed by Polymerase Chain Reaction (PCR) test?**

All positives reported from the Trust (including those done by other Trusts on our behalf) have been diagnosed and confirmed by PCR test.

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

All laboratory Covid-19 tests in use are PCR tests.

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

Previously the microbiology departments at the Freeman Hospital, The Newcastle Upon Tyne Hospitals NHS Foundation Trust and James Cook University Hospital, South Tees Hospitals NHS Foundation Trust have supported our capacity as part of the North 1 regional response to provide Pillar 1 diagnostic capacity across the region. We do not currently refer to any other laboratories and manage all the workload coming in from the Trust and partner services (staff and patients).

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

Please note: Ct thresholds are established to ensure specific results, but in some assays an indeterminate zone is established which may require a follow up sample to determine the significance of the result.

Methods/ kits have changed frequently at all laboratories due to reagent constraints. There has been new equipment availability and continuous developments in Covid-19 testing methodology throughout the pandemic so it would not be appropriate for the Trust to answer this question on behalf of other Trusts/ laboratories performing these tests.

The Trust would advise you to contact the relevant Trusts/ laboratories directly. For further information please contact either South Tees NHS Foundation Trust or The Newcastle Upon Tyne Hospitals NHS Foundation Trust. If you wish to contact them in accordance with Section 16 of the Act (duty to provide advice and assistance) you can contact them via the following postal addresses:

South Tees NHS Foundation Trust:  
Murray Building  
The James Cook University Hospital  
Marton Road  
Middlesbrough  
TS4 3BW

Email: [stees.foi.admin@nhs.net](mailto:stees.foi.admin@nhs.net)

The Newcastle Upon Tyne Hospitals NHS Foundation Trust  
Freeman Road  
Newcastle Upon Tyne  
NE7 7DW

Email: [FreedomofInformation@nuth.nhs.uk](mailto:FreedomofInformation@nuth.nhs.uk)

## **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?**

During the time period specified the Ct values for the tests in use at the Trust vary depending on the assay and control values in use. The positive controls have cut-off Ct values but the tests themselves vary depending on the control values and the thresholds set specific to each run.

The Cepheid 'rapid' tests in use at the Trust do not specify Ct cut-off values in the IFU because the interpretative software uses an algorithm to interpret and report as Detected/ Not Detected. The Ct values can be observed by the operator.

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

The Trust has used the Anatolia Bosphore SARS-CoV-2 assay (via Launch Diagnostics) and the Cepheid Xpert SARS-CoV2 assay to date.

Other methods are currently undergoing validation.

**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?**

None. Anatolia Bosphore SARS-CoV-2 assay – interpretation required by operator (system fully interrogatable).

Cepheid Xpert SARS-CoV-2 – results given as DETECTED/ NOT DETECTED but PCR reaction curves/ CT values can be observed on the system by the operator.

**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?**

Currently no 'black box' systems are in use at the Trust.

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.cddffoi@nhs](mailto:cdda-tr.cddffoi@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

**Joanna Tyrrell**  
**Freedom of Information Officer**