

07 January 2021  
Our Ref: AC/JM/FOI 7257

Dear Applicant,

**Freedom of Information Act 2000 – Request for Information Reference: 7257**

Further to your request for information received 18 December 2020; please find the Trust's response below.

On 1st October 2019, Liverpool University Hospitals NHS Foundation Trust was created, through the merger of Aintree University Hospital NHS Foundation Trust and Royal Liverpool and Broadgreen University Hospitals NHS Trust.

1. Confirmation that all reported cases of SARS-COV2 in your Trust have been diagnosed and confirmed by PCR test;  
No, The Trust can confirm that we utilise transcription mediated amplification (TMA) and PCR methodologies.
2. If not with a PCR test, provide details of what method was employed to confirm the presence of SARS-COV2;  
Please see response to Q1.
3. Details of the laboratories performing the PCR tests producing the confirmation of SARS-COV2 on behalf of your Trust;  
Currently all PCR SARS-COV2 tests for the Trust are dealt with by the In-House Laboratory.
4. Details of the Ct thresholds currently employed in the PCR tests performed by the labs at 3.;  
For samples tests on the ViaSure PCR assay, any samples with a CT value up to 38 is classed as positive. Any CT value greater than 38 would have the amplification curve analysed by a HCPC registered Biomedical Scientist who will determine whether the sample is a weak positive, negative or requires re-extraction and repeat PCR. For the Cepheid GeneXpert Infinity assay, the instrument software determines what the CT value cut off is and cannot be altered or amended by the user.
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;  
From the beginning of 2020 until March – all samples were sent to Virology, Manchester Royal Infirmary for testing as we were not set up for in-house testing at the time.  
From April onwards – all samples were dealt with in-house, extracted and run on the ViaSure PCR assay, see question 4 for the CT values. The Cepheid assay was implemented over the summer, see question 4 for details regarding CT values on these platforms.
6. Details of the manufacturers of the PCR tests used to confirm the presence of SARS-COV2 in your Trust;  
Fully automated platform is – Cepheid GeneXpert Infiinty.

In addition we extract using the Qiagen Qiasymphony, Qiacube and ThermoFisher KingFisher Plex. These extracts are then tested using the ViaSure SARS-CoV-2 Real Time PCR by CerTest Biotec and this is run on the Roche LightCycler 480.

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;  
[The Cepheid GeneXpert Infiinty utilises software specific to the analyser to determine whether a sample is positive, negative or invalid based on a system specific algorithm and pre-determined criteria.](#)
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 further action is taken to confirm these results.](#)

If you have any queries about this response or wish to discuss your request further please contact the Freedom of Information Team.

### **Right to Review**

If you are dissatisfied with the handling of your request you have the right to ask for an internal review.

To do this, please email [FOIRequests@liverpoolft.nhs.uk](mailto:FOIRequests@liverpoolft.nhs.uk) and quote the reference number above.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided by the Trust. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Kind Regards

Freedom of Information Team  
Liverpool University Hospitals NHS Foundation Trust  
[FOIRequests@liverpoolft.nhs.uk](mailto:FOIRequests@liverpoolft.nhs.uk)

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