

Ref: FOIA Reference 2020/21-413

Date: 29th December 2020

Email foi@uhnm.nhs.uk

Dear

I am writing in response to your email dated 18th December 2020 requesting information under the Freedom of Information Act (2000) regarding SARS-COV2.

As of 1st November 2014 University Hospitals of North Midlands NHS Trust (UHNM) manages two hospital sites – Royal Stoke University Hospital, and County Hospital (Stafford). Therefore the response below is for the two sites combined from that date where appropriate.

Q1 Confirmation that all reported cases of SARS-COV2 in your Trust have been diagnosed and confirmed by PCR test

A1 Confirmed, all reported cases of SARS-COV2 tested at UHNM have been diagnosed and confirmed by a PCR test

Q2 If not with a PCR test, provide details of what method was employed to confirm the presence of SARS-COV2

A2 Not applicable

Q3 Details of the laboratories performing the PCR tests producing the confirmation of SARS-COV2 on behalf of your Trust

A3 Performed on site at Royal Stoke University Hospital

Q4 Details of the Ct thresholds currently employed in the PCR tests performed by the labs at 3.

A4 If not interpreted by manufacturer's software:

- CT<34 positive
- CT-34-38 weak positive

Q5 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

A5 If not interpreted by manufacturer's software:

- CT<34 positive
- CT: 34-38 weak positive

Q6 Details of the manufacturers of the PCR tests used to confirm the presence of SARS-COV2 in your Trust

A6 Please see below:

- Roche: Cobas 8800
- Cepheid: GeneXpert
- DRW Samba
- Certest = viasure SARS Cov-2 PCR test
- BioMérieux = Biofire film array

Q7 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

A7 Please see below:

- BioMérieux = Biofire film array
- DRW = Samba

Q8 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.

A8 All assays verified before implementation.

*Please note that any individuals identified do not give consent for their personal data to be processed for the purposes of direct marketing.

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An anonymised copy of this request can be found on the Trust's disclosure log, please note that all requests can be found at the following link: <http://www.uhnm.nhs.uk/aboutus/Statutory-Policies-and-Procedures/Pages/Freedom-of-Information-Disclosure-Log.aspx>

This letter confirms the completion of this request. A log of this request and a copy of this letter will be held by the Trust.

If you have any queries related to the response provided please in the first instance contact my office.

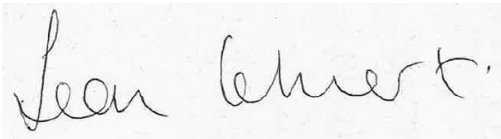
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and request an assessment of the manner in which the Trust has managed your request.

The Information Commissioner may be contacted at:

Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF or via www.ico.org.uk.

If following review of the responses I can be of any further assistance please contact my secretary on 01782 671612.

Yours,



Jean Lehnert
Data, Security & Protection Manager