



Ref: FOIA Reference 2020/21-569

Royal Stoke University Hospital
Data, Security and Protection
Newcastle Road
Stoke-on-Trent
Staffordshire
ST4 6QG

Date: 26th March 2021

Email foi@uhnm.nhs.uk

Dear

I am writing in response to your email dated 15th March 2021 requesting information under the Freedom of Information Act (2000) regarding Polymerase Chain Reaction

The University Hospitals of North Midlands Trust is committed to the Freedom of Information Act 2000.

However, the NHS is facing unprecedented challenges relating to the coronavirus (COVID-19) pandemic at the current time. Understandably, our resources have been diverted to support our front-line colleagues who are working tremendously hard to provide care for our patients, and to those in need of our services.

We strive to be transparent and to work with an open culture. But at this time, whilst care of our patients and the safety of our staff takes precedent, it is likely that responses to some requests for information will be delayed. We apologise for this position in advance, and will endeavour to provide you with as much information as we can, as soon as we are able.

The Information Commissioners Office has recognised the current situation in the NHS

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 What Polymerase Chain Reaction (PCR) equipment is being used by you to detect SAR-CoV-2?

A1 See below:

Royal Stoke (Hub Lab):

- Roche Cobas 8800
- Cepheid Infinity 48
- Cepheid GSX16
- Biomerieux film array
- ABI 7500 fast (open qPCR)
- Biorad CfX96 (open qPCR)
- Thermofisher QS5 (open qPCR)

- Thermofisher QS7 (open qPCR)
- DRW SAMBA
- Roche LiaT

County Hospital:

- Roche LiaT

Q2 Who manufactures the PCR testing kit(s) (as distinct from equipment) being used?

A2 See below:

- Roche (c8800 and LiaT)
- Cepheid (Infinity and GSX)
- Biomerieux (Film array)
- Certest Viasure SARS Cov2 PCR Kit– runs on all open qPCR platforms
- DRW (SAMBA)

Q3 How many cycles (Ct/Cq) are used for your PCR assays?

A3 See below:

- Roche Cobas 8800 (instrument uses algorithm which is optimised per run hence cut/off not provided)
- Cepheid Infinity 48 (instrument uses algorithm which is optimised per run hence cut/off not provided)
- Cepheid GSX16 (instrument uses algorithm which is optimised per run hence cut/off not provided)
- Biomerieux film array (Uses microarray technology melt curve analysis)
- ABI 7500 fast (open qPCR) Certest viasure: Ct \leq 38.0 cycles is classed as positive
- Biorad CfX96 (open qPCR): Ct \leq 38.0 cycles is classed as positive
- Thermofisher QS5 (open qPCR): Ct \leq 38.0 cycles is classed as positive
- Thermofisher QS7 (open qPCR): Ct \leq 38.0 cycles is classed as positive
- DRW SAMBA (PCR product detected by lateral flow)
- Roche LiaT: (instrument uses algorithm which is optimised per run hence cut/off not provided)

Q4 Have you received guidance from Government sources or bodies such as PHE regarding the PCR equipment and test settings that you should use?

A4 Whilst equipment has been deployed nationally in some cases each lab has to verify locally and develop our own use cases depending on the technology.
If we are not happy with the performance (sensitivity/Specificity) of any platforms/assays we are under no obligation put these into use

*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.

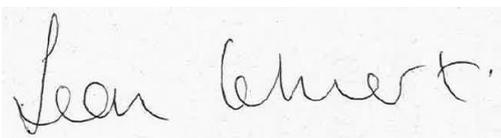
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and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