

Luton & Dunstable University Hospital  
Bedfordshire Hospitals NHS Foundation Trust  
Lewsey Road  
Luton  
LU4 0DZ

Bedford Hospital  
Bedfordshire Hospitals NHS Foundation Trust  
Kempston Road  
Bedford  
MK42 9DJ

11/01/2021

Dear Requester,

Thank you for your Freedom of Information request which was received within the Trust.

In accordance with S.1 (1) (a) of the Freedom of Information Act 2000 (FOIA), I can confirm that we do hold the information relevant to your request. FOI 324

#### [Response from Bedfordshire Hospitals NHS Foundation Trust](#)

1. Confirmation that all reported cases of in your Trust have been diagnosed and confirmed by PCR test;

**All SARS-COV2 are tested using PCR.**

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

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

**Testing in All In-House**

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

**VIASURE SAR-CoV-2, Flu & RSV . CT  $\geq 30$  or  $\leq 40$  a 2nd test is performed to confirm result using Cepheid.  $\leq 30$  Is considered positive.**

**Cepheid GeneXpert SAR-CoV-2, Flu & RSV . CT  $\leq 38$  is positive if  $\geq 38.1$  a 2nd test is performed to confirm results.**

**DRW Samba 2 SARS-CoV-2 and Hologic Panther SARS-CoV-2 do not have CT thresholds.**

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;

**VIASURE SAR-CoV-2,Flu & RSV . CT  $\geq 30$  or  $\leq 40$  a 2nd test is performed to confirm result using Cepheid.  $\leq 30$  Is considered positive.**

**Cepheid GeneXpert SAR-CoV-2,Flu & RSV . CT  $\leq 38$  is positive if  $\geq 38.1$  a 2nd test is performed to confirm results.**

6. Details of the manufacturers of the PCR tests used to confirm the presence of SARS-CoV2 in your Trust;

**VIASURE SAR-CoV-2,Flu & RSV**

**Cepheid GeneXpert SAR-CoV-2,Flu & RSV**

**DWR Samba 2 SAR-CoV-2**

**Hologic Panther Aptima SARS-CoV-2 assay**

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;

**We use the following tests which do not provide a numerical value.**

**DWR Samba 2 SAR-CoV**

**BioFire RPR2+ This is a multiplex PCR which tests 20 respiratory targets including Covid 19 however this is only used to test Group 3 and 4 patients who are covid-19 (Group1) and Influenza (Group2) negative but have respiratory illnesses.**

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.

**All Kits are CE marked**

**Stored in temperature controls and monitored areas**

**Verifications have been performed to confirm manufacturers performance characteristics**

**3rd party controls are used to independently confirm performance of test.**

**Internal quality assurance scheme IQA**

**External quality assurance scheme EQA**

**These are used to insure the tests are performing as required.**

This information is provided for your personal use and is the property of Bedfordshire Hospitals NHS Trust and subject to any existing Intellectual Property and Database Rights. Any commercial application or use of this information may be subject to the provisions of the Re-use of Public Sector Information Regulations 2015 (RPSI). This means that if you wish to re-use the information provided for commercial purposes for any reason you must ask the Trust for permission to do so.

Please note that the Trust has a formal internal review and complaints process which is managed by the Information Governance Manager/Data Protection Officer. Should you have any concerns with our response, you can make a formal request for an internal review. Requests *for internal review* should be submitted within three months of the date of receipt of the response to your original letter, and should be addressed to:

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Or by emailing [bhn-tr.foibedfordshirehospitals@nhs.net](mailto:bhn-tr.foibedfordshirehospitals@nhs.net). This option is available to you for up to three calendar months from the date your response was issued.

If you are not satisfied with the Trust review under the Freedom of Information Act 2000 you may apply directly to the Information Commissioners Officer (ICO) for a review of your appeal decision. The ICO can be contacted at: ICO, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF  
[www.ico.org.uk](http://www.ico.org.uk)

Yours sincerely,

*IG/FOI Coordinator*

Bedford Hospital, Kempston, Bedford  
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