

Ref: FOI/GS/ID 6471

Please reply to:
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Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to Covid-19.

You asked:

- 1. Confirmation that all reported cases of SARS-COV2 in your Trust 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;*
- 3. Details of the laboratories performing the PCR tests producing the confirmation of SARS-COV2 on behalf of your Trust;*
- 4. Details of the Ct thresholds currently employed in the PCR tests performed by the labs at 3.;*
- 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;*
- 6. Details of the manufacturers of the PCR tests used to confirm the presence of SARS-COV2 in your Trust;*
- 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."
 - a. Please confirm which manufacturers have been engaged that employ such a 'black box' method,*
 - b. which labs have used such a manufacturer, and*
 - c. which results confirming the presence of SARS-COV2 in the UK have been based on such techniques;**
- 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.*

Trust response:

1. All positive patients were diagnosed through a PCR test.
2. Not applicable.
3. Maidstone & Tunbridge Wells NHS Trust Department of Microbiology at Maidstone Hospital

4. CT threshold of <28

Sample with CT >28 are confirmed by second platform looking at different targets

5. 1/1/20 to 12/11/20 CT <24 confirmation required
12/11/20 to date CT <28 confirmation required
6. Bosphore: SARS-CoV-2 (ORF1ab gene)
Hain: SARS-CoV-2 (RdRp and N genes)
7. a. Roche LIAT and SAMBA 11 instruments.
b. Rapid covid test team in ED at Tunbridge Wells Hospital and Rapid covid test team in ED at Maidstone Hospital.
c. Unable to answer as specific results are attributable to identifiable patients.
8. Robust verification against laboratory RT PCR methodology conducted before implementation of these instruments. No confirmatory testing is conducted since implementation.