

FREEDOM OF INFORMATION ACT 2000

THE ROYAL CORNWALL HOSPITALS NHS TRUST RESPONSE TO INFORMATION REQUEST

Date Request Received: 18th December 2020

FOI Ref: 12176

Requested Information

Please provide details of the following:

- 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."

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;

- 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.

Response

- 1) Laboratory confirmed SARS-CoV2 cases across the Royal Cornwall Hospitals Trust are diagnosed by PCR testing. Earlier in the Pandemic when testing was not readily available, some SARS-CoV-2 cases were diagnosed clinically.
- 2) Clinical diagnosis based on clinical presentation in addition with radiological findings were employed to confirm the presence of SARS-COV2
- 3) The Clinical Microbiology Department at Royal Cornwall Hospital is performing the PCR tests producing the confirmation of SARS-COV2 on behalf of your Trust

- 4) For all tests, results are interpreted as per manufacturer guidelines and in conjunction with clinical presentation. Results are interpreted by instrument software for our high throughput (Hologic Panther) and two other analysers (Ct thresholds have not been indicated by manufacturer). For the PCR assay (CerTest Viasure) which is manually interpreted, Ct threshold of < 38 is employed.
- 5) Ct threshold <38 was used to confirm all reported cases of SARS-COV2 in the Trust between 01/01/2020 and 18/12/2020
- 6) The following manufacturers of PCR tests have been utilised to confirm the presence of SARS-COV2 across the Trust
 - Hologic Panther
 - Cepheid Genexpert
 - Aus Diagnostics Highplex system
 - CerTest Viasure
- 7) The Hologic Panther manufacturer has been engaged and employs a 'black box' method and confirms results for the presence of SARS-COV2
- 8) The Verification data conducted locally and by PHE laboratory have shown these results to be true and as always, results are interpreted in conjunction with clinical presentation. Confirmation of first result is performed during periods of low prevalence as dictated by [PHE guidelines](#)

Attachment(s)

None

Date Response Sent:

January 2021