States of Guernsey

Access to Public Information Response

Date: 10 March 2021

Date request received: 1 March 2021

I have the following request regarding the Ct value(s) used for the PCR tests:

1. Can you please advise the name of the manufacturer from whom you obtained the PCR test kit, and the Ct value(s) recommended by that manufacturer when using their kit. If you are using PCR test kits from more than one manufacturer, please indicate each manufacturer's recommended Ct value(s) when using their individual kit.

2. Where Ct values vary between test runs, please indicate - for each test kit - the lowest and highest Ct values used for the same individual run. Please also advise the number of PCR tests carried out on the same patient, and the interval between each test carried out on the same patient.

Response from the States of Guernsey

Can you please advise the name of the manufacturer from whom you obtained the PCR test kit, and the Ct value(s) recommended by that manufacturer when using their kit. If you are using PCR test kits from more than one manufacturer, please indicate each manufacturer's recommended Ct value(s) when using their individual kit.

Our assumption when responding to this question is that it relates to the PCR amplification kit and not the various other parts of the PCR process.

For our primary PCR testing platform we use a kit manufactured by Certest Biotech under the brand Viasure SARS-CoV-2 RT detection.

We use a second PCR testing platform with different methodology for various scenarios including confirmation of primary analysis and urgent hospital admission testing. This is manufactured by Cepheid under the name GeneXpert Xpress SARS-CoV-2.

The element of your question regarding CT values is difficult to answer. CT means Cycle Threshold although the value of this has been given multiple names over the years. For the purposes of this response, we have assumed you are referencing the Cq – quantification cycle value.

The Cq is the point at which a sample reaction curve crosses the threshold line on a graph and indicates a positive result. The point at which this occurs is variable depending semi quantitatively on the amount of viral target present. The threshold line is a calculated value of background fluorescence. Each assay and each run of any assay will have a subtly different threshold line. This variation is a consequence of variation within reagents, samples make up, sample preparation and environmental factors.

The differences in threshold lines between runs are very small and generally not significant when performing qualitative or semi quantitative assays of this nature. We should also add that we run known controls in every assay which would detect if the assay was not performing in line with expectation.

The manufactures also recommend a maximum number of PCR cycles to perform before calling the specimen negative i.e. if the sample reaction has not crossed the threshold line within this number it is a negative specimen.

For Viasure this is 40 cycles for both N and orf gene targets.
For GeneXpert it is 45 cycles for both N end E gene targets.

Where Ct values vary between test runs, please indicate - for each test kit - the lowest and highest Ct values used for the same individual run. Please also advise the number of PCR tests carried out on the same patient, and the interval between each test carried out on the same patient.

It is not possible to provide data on the number of PCR tests per patient (and the interval of time between them) without stopping other areas of work in Public Health Services to extract this data, which would not be an appropriate use of resources given the importance of other Public Health work.

However, to give you an idea of the number of PCR tests carried out on the same patient:

- Each PCR test targets two separate genes.
    - If the results for the targets are discordant a second PCR method with a further two targets is used to confirm the result.
    - If after both PCR methods are complete discordance remains the patient may be retested.
    - Further, in low population prevalence situations all positives, regardless of Cq value are confirmed using a second PCR method.

- In a positive case of COVID-19 more than one PCR swab may be taken over the period of time the patient is unwell. Patients are generally tested on day 1 (to provide the initial diagnosis) and then again on day 10 if they no longer have COVID-19 symptoms.
- Any individual may have had multiple PCR tests over the past 12 months as a result of reporting COVID-19 like symptoms. The interval between these tests could be considerable.

As described in the response to your first question, above we measure PCR cycles until a reaction becomes positive or remains negative up to 40 or 45 cycles.

We run each sample once if it is negative. If it is positive it is run on a second assay as a confirmation procedure to exclude false positives. If the prevalence of virus in the population is high then confirmation is not performed as the positive predictive value of the primary test becomes higher.