

11th December 2020

Deputy Michael Fitzmaurice
Dáil Éireann
Kildare Street
Dublin 2

Re: PQ 39908/20

Question: “To ask the Minister for Health the percentage of PCR tests that have been false positives; the number of cycles of amplification used; and if he will make a statement on the matter.”

Dear Deputy Fitzmaurice,

I refer to the above Parliamentary Question which has been referred by the Minister for Health to the Health Service Executive for direct response.

SARS-CoV-2 PCR assays in Ireland are operated in accordance with the manufacturers' instructions, and the CE marking for the assay. It is the manufacturer that decides the optimal number of cycles for the assay, not the testing laboratory.

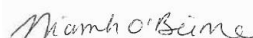
Higher Cycle threshold values typically indicate a lower amount of virus in the sample. However, the CT value alone does not indicate whether the virus load is increasing or decreasing, it does not indicate whether the individual is infectious or not, and it does not provide an indication of the specimen quality (i.e. how closely the specimen mirrors what is actually happening in the patient's respiratory tract).

In the Irish context, specificity (or false positive) data are not collated centrally. However, based on the data we do have available, and based on our growing level of experience with the SARS-CoV-2 assays in use in Ireland, we believe the false positive rate to be somewhere between 0.1% and 0.2% (suggesting a specificity of around 99.8-99.9%). This does mean that for every 10,000 tests performed, there will potentially be 10-20 false positives, although this number can be reduced by repeat testing of some low level (or weak) positives. However, it is often not possible to distinguish between true positives and false positives.

In addition, as the prevalence of the infection increases, the likelihood of any given positive result being false is reduced. More importantly, the context in which the test is being performed also has to be taken into account i.e. a positive result in an individual who is sick with typical CoViD-19 symptoms is more likely to be genuine (based on the prior probability of infection).

I trust this addresses your question.

Yours sincerely,



Niamh O'Beirne
National Lead for Testing and Tracing