

An Oifig Ceannasaí Náisiúnta Tástála agus Rianaithe, Foireann Bainistíocht Feidhmiúcháin, Ospidéal an Dr. Steevens, Baile Átha Cliath 8,

National Lead Testing and Tracing Office, HSE Dr Steevens' Hospital, Steevens' Lane, Dublin 8, D08 W2A8

## 29<sup>th</sup> June 2021

Deputy Michael McNamara Dáil Éireann Kildare Street Dublin 2

## PQ 22976/21 "To ask the Minister for Health the number of amplification cycles, cycle threshold currently being used in laboratory PCR testing; and if he will make a statement on the matter."

Dear Deputy McNamara,

I refer to the above Parliamentary Question which has been referred by the Minister for Health to the Health Service Executive for direct response. We have not been in a position to issue our response until now due to the Cyberware attack on our systems but please now see below information.

I wish to advise the current testing strategy in Ireland, based on expert advice, involves the use of polymerase chain reaction (PCR) testing techniques. This detects genetic material of the virus and can detect if a person is currently infected with Covid-19. RT-PCR remains the gold standard test internationally for diagnosing suspected cases of Covid-19. It is the recommended test for Covid-19 by the European Centre for Disease Prevention and Control (ECDC) and the World Health Organisation (WHO).

The PCR Tests utilised in Ireland are manufactured by companies that distribute their products globally. 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 or other body. 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).

There are many different SARS-CoV-2 RT-PCR assays/platforms in use by the HSE. Each assay will have a slightly different limit of detection (LoD) – the lowest concentration of virus that can be reliably and consistently detected by the assay, and will be configured according to local arrangements. While some RT-PCRs are designed to identify a single gene target, others are designed to detect multiple targets. As above, the number of PCR cycles used in Ireland is decided by the manufacturer of the assay, so there is no single answer. However, many assays run for 40-45 cycles.

I trust this addresses your question.

Yours sincerely,

Miamh O'Beino

Niamh O'Beirne National Lead Testing and Tracing

