

3<sup>rd</sup> November 2020

**PQ Number:** 34126/20

**Question:** To ask the Minister for Health the number of amplification cycles being used for PCR testing; if this is a static number used for every test; and if the number has remained constant from March to October 2020 - Marian Harkin.

**Request Type:** Direct Written Response to <a href="mailto:marian.harkin@oireachtas.ie">marian.harkin@oireachtas.ie</a> with a copy to pquestions@hse.ie

Dear Deputy Harkin

I refer to the above Parliamentary Question.

Currently in Ireland the approved testing methodology to detect COVID-19 in patients is called Polymerase chain reaction (PCR) testing. HIQA has published a rapid health technology assessment of alternative diagnostic testing methods for detecting Covid-19. According to this assessment, PCR testing is the most clinically-effective test available. It remains the 'gold standard' test for detecting and confirming COVID-19 cases.

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.

The number of PCR cycles used in Ireland is decided by the manufacturer of the assay, so there is no single answer. The HSE uses a wide range of assays. As a general rule, most assays run for 40-45 cycles.

I trust this information is of assistance to you, but should you have any further queries please contact me.

Yours sincerely,

**Damien McCallion** 

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**National Director**