



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

**24<sup>th</sup> November 2020**

**PQ: 34127/20**

**Question :** To ask the Minister for Health the standard the PCR tests are being compared against; the person or body that set the standard; and the way in which it was decided that the chosen genetic sequence was definitively from SARSCOV2 and could not be confused with another coronavirus - Marian Harkin.

**Reply due: 18/11/2020**

**Dear Deputy Harkin,**

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

PCR tests that are available in Ireland are CE marked and licensed for use by the Health Products Regulatory Authority (HPRA). Ongoing performance of the PCR assay is monitored in accordance with the Quality Management System of the testing laboratory, the majority of which in Ireland would be accredited to the international standard (ISO:15189) by the Irish National Accreditation Board (INAB).

The genetic sequence of SARS Coronavirus Type 2 (SARS-CoV-2) was published by Wu and colleagues online in the scientific journal Nature on February 3<sup>rd</sup>, 2020 (and subsequently in print on March 12<sup>th</sup> 2020). Phylogenetic analysis of the sequence confirmed that this was a novel coronavirus that had not previously been identified.

Following the publication of the SARS-CoV-2 genetic sequence, the first specific PCR test was published by Corman and colleagues on January 23<sup>rd</sup> 2020. The primers for the PCR assay were specifically designed to detect SARS-CoV-2 (based on the genetic sequence) and the absence of cross-reactivity with other human coronaviruses was confirmed in the same publication.

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

Yours sincerely,

A handwritten signature in blue ink that reads "Damien McCallion".

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**Damien McCallion**  
**National Director, HSE**