



11th Feb. 2022

Deputy Róisín Shortall,
Dáil Éireann,
Kildare Street,
Dublin 2

Issued via email to: roisin.shortall@oireachtas.ie

PQ Number: 63281/21

Question: To ask the Minister for Health if his Department is monitoring the reliability of Covid-19 PCR tests; the false positive rates for PCR tests; and if he will make a statement on the matter

Dear Deputy Shortall,

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

The HSE uses ISO accredited laboratories for COVID testing. All accredited laboratories - under the auspices of their quality management system (QMS) - monitor the performance of all their PCR assays (SARS-CoV-2 is no different to other assays in use) and their laboratory processes through Internal Quality Control (IQC), and Internal & External Quality Assurance (IQA/EQA) Programmes.

Any assay performance issues that are identified are brought to the attention of the manufacturer and the Irish National Accreditation Board (INAB) in the first instance. The Health Products Regulatory Authority (HPRA) is the national regulator of medical devices and any concerns relating to a diagnostic test would also be routed through the regulator.

Based on the data available, and 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. In addition, as the prevalence of the infection increases, the likelihood of any given positive result being false is reduce.

I trust this information is of assistance.

Yours sincerely,

Damien McCallion
National Director
National Lead Test & Trace and Vaccination Programme