



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

16th October 2020

PQ Number: 26608/20

Question: To ask the Minister for Health the reason Irish-produced Covid-19 testing kits with a 99% accuracy rate and a result in 10 minutes are not being used in place of the PCR test which is known to produce many false positives; and if he will make a statement on the matter. - Catherine Connolly

Request Type: Direct Written Response to catherine.connolly@oireachtas.ie and pquestions@hse.ie.

Dear Deputy Connolly,

I refer to the above Parliamentary Question.

There are a number of testing modalities available for COVID-19 each having its own strengths and weaknesses. Each test has different levels of sensitivity and specificity, determining its accuracy and influencing its use in particular settings.

Antibody testing has been deployed as part of the Health Protection Surveillance Centre (HPSC) prevalence study, undertaken by the National Virus Reference Laboratory. It is not an appropriate test for diagnostic purposes.

Antigen tests are diagnostic tests with limited deployment globally at this point. Thus far the sensitivity and specificity of the available tests have been very poor. The HSE has a working group evaluating antigen testing and possible deployment on an on-going basis.

PCR testing remains the gold standard test for the purposes of diagnosis. SARS-CoV-2 PCR assays in Ireland are operated in accordance with the manufacturers' instructions, and the CE marking for the assay. While PCT testing also has false positive and negative rates it remains the primary test for diagnostic purposes. This is also the case throughout the EU.

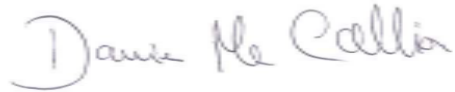
The HSE also use rapid PCR tests which have high degrees of sensitivity and specificity in our hospitals. It should be noted that these tests are more appropriate for small number of cases as the platforms only run a small number of tests at one time and hence are not appropriate for large scale community testing.

The HSE has a procurement team in place who has engaged with companies throughout the world, since the commencement of the pandemic. This team evaluate the many proposals from companies that come in on a daily basis and seek detailed product descriptions from companies so that their offering can be assessed.

The HSE would be happy to engage with any company with innovative products which meet efficacy and other necessary requirements. If the Deputy can provide details of the company referenced we will make contact to establish what may be being proposed.

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 cursive script that reads "Damien Mc Callion".

Damien Mc Callion

HSE National Director