

# Information Notice

## Medical Devices

### COVID-19 testing in Ireland by commercial entities outside the National Testing Strategy

HPRA Information Notice: IN 2020(04)

Issue Date: 22<sup>nd</sup> July 2020

#### ISSUE

In Ireland, the **National Testing Strategy** for COVID-19 involves testing people who meet the case definition (people with symptoms) or their identified close contacts. It is directed by the National Public Health Emergency Team (NPHET) and coordinated by the HSE. Currently the testing process requires healthcare professionals to take throat/nose swabs that are then sent to specific laboratories for testing to detect the virus. Results are reported centrally for monitoring, surveillance and contact tracing purposes. These tests are provided free of charge and there is currently sufficient capacity in the system for testing through this pathway. Information is available from your GP and on the HSE website on [how to get tested](#).

The HPRA is aware of several commercial tests for COVID-19 on offer in Ireland, which are not coordinated under the HSE and are not in line with the national testing strategy. This information notice is to inform members of the public of

- i. the importance of following the national testing strategy, and
- ii. the potential risks involved in seeking commercially available tests.

**There are two types of tests for COVID-19:-**

Test type	Sample	What is the test used for?
<b>Direct detection of the virus</b>	Throat/Nose swab	These tests are used to diagnose a <b>current</b> infection by testing for the virus itself [either the genetic material (PCR test) or other parts of the virus]. These tests are generally performed in laboratories
<b>Antibody tests to detect evidence of recent or past infection</b>	Blood (finger-prick or collected from vein)	These tests can indicate a <b>past or recent</b> infection. These tests aim to detect if your immune system has produced antibodies, which bind to and may fight the virus. Some antibody tests are very low technology (lateral flow) tests and others are carried out in a laboratory

In Ireland, the national testing strategy is based on the **direct** detection of the virus (see table).

### HPRA advice on commercial 'direct' testing for COVID-19

Some commercial '**direct**' tests involve 'self-swabbing' where the patient uses a swab to collect their own throat/nose sample. The swab is then sent to a laboratory for testing and the results are returned directly to the person in their home.

Collecting a good swab sample for COVID-19 testing can be difficult. If the sample is not collected properly, the test result may not be accurate. Currently, throat/nose swabs should only be collected by trained individuals. Under the testing regimen coordinated by the HSE, all samples are currently taken by healthcare professionals in a hospital setting, a community test centre, or in the patient's home. The patient is provided with results of the test, which are also reported centrally to support contact-tracing efforts.

### HPRA advice on commercial antibody testing for COVID-19

**Antibody** testing involves the testing of blood. These tests cannot be used to diagnose a current infection. While these tests may identify a past/recent case of COVID-19, there is a lot which we do not yet know in relation to immunity and COVID-19. If the test is positive, this means that you probably have been infected with the virus, and your immune system has reacted by developing antibodies. However, we don't know yet if having antibodies protects you from infection in the future. We also don't know yet if having the antibodies means you can't infect other people. In addition, the test can sometimes show a positive result in people who do not have any antibodies in their blood. It is important to note that not all individuals who have been infected produce antibodies. Therefore, if your blood is tested and a negative result is obtained it does not necessarily mean that you have not been infected.

### The HPRC cautions members of the public not to undertake COVID-19 tests provided by commercial entities outside of the national testing strategy for the following reasons

- 1) Test results **may not be accurate**
  - If the **incorrect sample type** is used. For example, a finger-prick sample may be appropriate for some tests and not for others. Using the wrong sample type could lead to inaccurate test results
  - If the process involves '**self-swabbing**'
- 2) Antibody tests are **not suitable to diagnose a current infection**, results may be misinterpreted
  - As this is a new virus, **not a lot is known in relation to immunity** and COVID-19 and the limitations of antibody testing need to be understood and carefully communicated
  - Due to the uncertainty regarding the **interpretation of antibody results**, these tests are not currently recommended for widespread use
- 3) An incorrect or misinterpreted result may give rise to an individual **failing to seek the necessary medical help**. During this time, the individual may **unknowingly spread the virus** or **their illness might progress**
- 4) Test results **may not be reported** centrally for monitoring, surveillance and contact tracing purposes

Please also note that NPHET currently recommends that lateral flow antibody tests should only be used [for research purposes](#) in Ireland and the HPRC does not support their use for any clinical decision making.

## RECOMMENDATIONS

The HPRA's advice for **members of the public**:

- **Do not purchase tests for COVID-19 online or from any other retailer.**
- Testing for COVID-19 should always be undertaken under guidance from your healthcare provider.
- If you think you have COVID-19, contact your GP immediately. To find out more about how to access a test, visit the [HSE website](#).
- If you have any concerns regarding your health, please contact your GP.

The HPRA appreciates the cooperation and support of all stakeholders, healthcare professionals and members of the public at this time.

In due course, the national testing strategy may change. Any future changes to the national testing strategy as directed by NPHE will also be communicated to healthcare professionals, members of the public and industry stakeholders.

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