MedTech Europe
from diagnosis to cure

IVDR: A risk of shortages of tests?

The new *In Vitro* Diagnostic Medical Devices Regulation (IVD Regulation) will enter into full application on 26 May 2022. This Regulation will bring **many benefits** by strengthening safety and performance and enforcing stricter oversight of medical tests. However, at the current rate of work, the **new regulatory system will not be ready in time**, as the needed infrastructure will not be there to ensure timely transition of tens of thousands of medical tests to the new regime. There may therefore be severe shortages of medical tests which are key to prevent and diagnose many illnesses. An example of this scenario is for COVID-19 tests.

What are COVID-19 Tests?

COVID-19 molecular tests (PCR) and COVID-19 antigen tests (rapid) are used to **detect the presence of the SARS-CoV-2 virus in individuals** at a given moment.

COVID-19 serology tests are used to **detect individuals' immune response to the virus**.

Why do these tests matter?

COVID-19 tests play a crucial role in **managing the COVID-19 pandemic**, by enabling the **diagnosis**, **screening**, contact **tracing** and isolation of citizens. They are key in the **triage** of patients with other respiratory diseases, like influenza, to avoid burdening of healthcare systems, as well as great tools for **knowledge and control**. Continued, seamless availability of well-performing COVID-19 tests is essential for achieving **socio-economic recovery** and maintaining **free movement** of citizens.

What's the problem?

Currently, COVID-19 tests are self-certified by manufacturers[1] before being supplied to healthcare systems. With the IVD Regulation this will change, conformity assessment bodies (called 'Notified Bodies') must assess and certify COVID-19 tests for them to remain available on the EU market for patient care.

Unfortunately, there is a real risk that many **COVID-19 tests will not be able to be certified on time** under the new Regulation. The new regulatory system is still being built and there are not enough Notified Bodies available to audit and certify COVID-19 tests sufficiently ahead of the 26 May 2022 date of application.

1) except for many COVID-19 self-tests