

## 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 the Prothrombin Time test.

### What are Prothrombin Time (PT) Test?

Prothrombin time (PT) tests are used to evaluate **coagulation of blood**. These tests are needed to check for **abnormal blood clots**, for unusual **bleeding**, for **clotting function** before surgery, and for **liver problems**.



### Why do these tests matter?

**Among other things, the PT test is key to prevent strokes.** Prothrombin is a clotting factor made by the liver. Levels that are **too low** can cause you to bleed too much after an injury or surgery. Levels that are **too high** can cause **dangerous clots** to form in your arteries or veins which are **responsible of 80% of all strokes**.

### What's the problem?

Currently, PT tests are self-certified by manufacturers before being supplied to healthcare systems. However, with the IVD Regulation this will change. Conformity assessment bodies (called 'Notified Bodies') must be involved in assessing PT tests for them to remain available on the EU market for patient care.

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