

IVDR: A risk of shortages of tests?

The new *In Vitro* Diagnostic Medical Devices Regulation (IVD Regulation) will enter into force 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 implementation, the **new regulatory system will not be ready in time**, as the needed infrastructure will not be there to make sure that medical tests are legally allowed to be used in Europe. Unfortunately, this may lead to **severe shortages of medical tests** which are key to prevent and diagnose many illnesses. An example of this scenario is the Laboratory Blood Glucose test.

What are Laboratory Blood Glucose Tests?

Laboratory Blood Glucose tests are used to measure the **glucose levels** in your blood. Glucose (a simple sugar) is the body's **main source of energy** and its body level is regulated through a hormone called insulin.



Why do these tests matter?

The Laboratory Blood Glucose test is **key to checking abnormal levels of glucose in your body**: too much or too little glucose in the blood can be a sign of a serious medical condition. High blood glucose levels may be a sign of **diabetes**, a disorder that can cause heart disease, blindness, kidney failure and other complications. Low blood glucose levels can also lead to **major health problems**, including brain damage, if not treated.

What's the problem?

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

Unfortunately, there is a real risk that some **Laboratory Blood Glucose 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 such tests sufficiently ahead of the 26 May 2022 date of application.