

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 work, 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 **KRAS mutation test**.

What are KRAS Mutation Tests?

KRAS Mutation tests are used to identify specific mutations to the KRAS gene. **This gene is fundamental because** it encodes a protein that is responsible to instruct cells to grow and divide or to mature and take on specialized functions. If it malfunctions, it may lead to the formation of cancer.



Why do these tests matter?

KRAS mutation tests are ordered by physicians for patients diagnosed with non-small cell lung cancer (NSCLC) or metastatic colorectal cancer (CRC) to identify those who have the presence (or absence) of specific genetic mutations. By doing so, **physicians can identify specific therapies** that will work for the selected patients, thereby minimising costs, side-effects, and ineffectiveness of a generic therapy.

What's the problem?

Under the current law, these tests are self-certified by the manufacturer. Under the IVD Regulation, things will change: KRAS tests will need to be certified by **specific conformity assessment bodies (called 'Notified Bodies')**, and, on top of that, they will need to receive a **scientific opinion by either the European Medicines Agency (EMA) or a National Medicinal Products Competent Authority**, further extending the time required to complete the conformity assessment.

The problem is that, with less than one year left to the May 2022 date of application of the IVD Regulation, **the requirements** for the overall process for gaining the scientific opinion of the authorities abovementioned **are yet to be defined**. This situation is preventing timely certification and may soon lead to severe shortages for cancer patients.