

IVD Industry Calls for Clear Testing Protocols to Prepare for the Winter Season during the COVID-19 pandemic

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In *vitro* diagnostic (IVD) tests are an indispensable part in managing many types of infectious diseases. The COVID-19 pandemic has demonstrated that the diagnostic industry continues to play a role in dealing with this global health emergency.

Together with the ongoing response to COVID-19, the industry shares the concern around the public health risk posed by respiratory viruses such as influenza, respiratory syncytial virus (RSV), etc. The convergence of the spike of COVID-19 cases in Europe with the start of the winter season can place a tremendous burden to patients, healthcare professionals and healthcare systems.

Member States and the European Commission have rightly expressed that strategies and measures are needed to guarantee the protection of patients and the effective management of this additional layer of complexity brought by the combination of COVID-19 and other respiratory viruses, especially influenza.

The IVD industry has been active in developing and producing IVD tests which reliably guide patient management decisions in the upcoming winter season and resurging COVID-19 pandemic. Several diagnostic tests already exist and are being produced to detect SARS-CoV-2 and seasonal diseases individually. Combined diagnostic tests (for laboratory-based and point-of-care / near-patient testing) that allow the detection of SARS-CoV-2 and other seasonal viruses at the same time have been developed, and more tests are likely to become available over the next weeks.

A clear testing strategy needs to be available now, way before the start of the next winter season, in order for the industry to have enough time to develop the appropriate tests needed, to receive approval for these tests, and to ramp up their deployment.

The diagnostics industry envisions that this testing strategy must include:

1. clear diagnostic algorithm, guidelines and protocols which define what testing type and order depending on different patient populations, settings (acute care, primary care, nursing homes) and staff are requested,
2. rapid path to market for new assays that will be developed,
3. effective deployment of the tests and integration of the results into the existing healthcare systems both for COVID-19 and flu surveillance, triage of patients and contact tracing.

The IVD industry, therefore, urges health authorities to find solutions and enact a diagnostic testing strategy to better prepare in managing COVID-19, flu and other seasonal respiratory infections and the potential health crisis that this can have towards patients, healthcare professionals and the whole healthcare ecosystem. The IVD industry is fully ready to engage in further discussions to develop and implement an effective strategy.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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