

The dual role of IVD information during the SARS-CoV-2 pandemic

IVD tests provide information to act for:



Risk management

Slow down or break the chains of transmission of SARS-CoV-2 by:

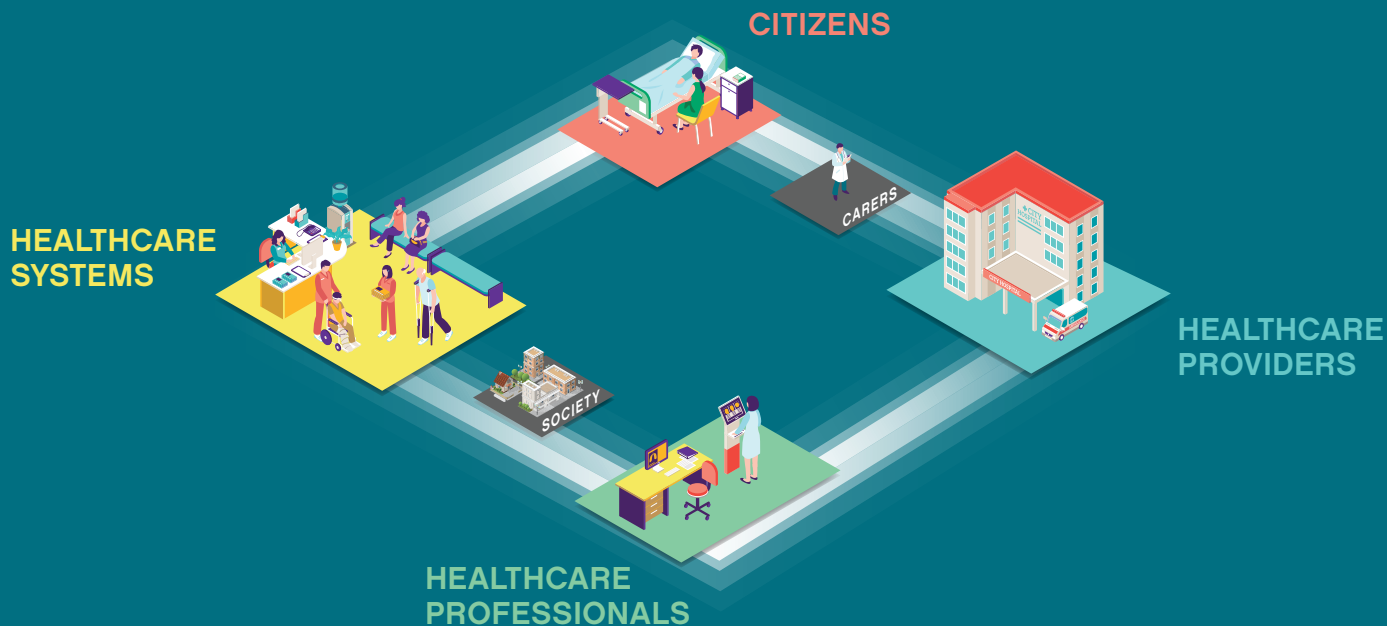
- Detecting a SARS-CoV-2 infection in pre-symptomatic and asymptomatic people
- Identifying who has been previously infected with SARS-CoV-2, who still has antibodies against the virus and once vaccination has been administered.

Disease management

Ensure patients with respiratory symptoms are accurately diagnosed and follow the right treatment and care pathway by:

- Differentiating other types of acute respiratory infections with similar presentation from COVID-19 based on pathogen identification
- Guiding treatment and care of acute respiratory infections following diagnosis

Diagnostic information provides value to all stakeholders, in line with the Value of Diagnostic Information Framework* throughout the COVID-19 pandemic and beyond



*The Value of Diagnostic Information in Personalised Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems, 2019



Risk management

IVD tests provide critical information helping to effectively manage the risk of SARS-CoV-2 in the population, delivering value to:

Citizens

- Value of knowing about an ongoing infection in people with no symptoms^A
- Reduced unnecessary interference with activities of daily life (e.g. discontinuation of quarantine, return to work, essential cross-border travel)
- Sense of security for people at high risk of developing severe COVID-19^{A,B}

Healthcare professionals

- Increased safety at work when recurring screening is applied^{A,B}
- Increased protection for non-COVID-19 patients during care provision^{A,B}

Healthcare providers

- Uninterrupted care for both COVID-19 and non-COVID-19 patients by ensuring that healthcare facilities remain operational^{A,B}

Healthcare systems

- Value of recourse planning to cope with the high numbers of incoming COVID-19 patients^{A,B}
- Reduced pressure on the health system's budget by avoiding infections in the most vulnerable groups^{A,B}

Society

- Informed decision-making on tightening, lifting or easing restrictions on social and economic activity, ultimately minimising adverse effects on society^{A,B}
- Early identification of clusters and outbreaks to avoid unnecessary social distancing measures in the population^{A,B}
- Epidemiological surveillance^C
- Determination of a baseline of neutralising antibodies presence



Policy asks

Well beyond the COVID-19 pandemic, IVD information can be part of the solution to address healthcare challenges arising from both infectious and chronic diseases.

To fully unlock its potential, we call for:

A Enhancing integration of IVD information in healthcare systems.

B Raising awareness of IVDs through multi-stakeholder engagement at EU and national level.

C Building an enabling ecosystem that recognises and rewards the value of diagnostic information and hence incentivises future IVD innovation.



Disease management

The co-circulation of SARS-CoV-2 and other respiratory viruses such as influenza, causing symptoms indistinguishable from COVID-19, adds another level of complexity to tackle the SARS-CoV-2 outbreak

Burden of influenza

Influenza causes **±10%** of absense from work in the EU, and estimated costs of lost productivity are high, e.g. in France (**€6.4 billion/year**) and Germany (**€9.8 billion/year**)³

Pressure and costs on healthcare services: primary care in the EU was estimated at €267.2 million/year and the cost of hospital visits at €11.5 billion/year³

4 - 50 million cases and 15 - 70,000 deaths every year in the EU/EEA¹

Influenza responsible for an estimated 145,000 deaths among all ages in 2017²

Influenza accounted for 9,459,000 hospitalisations for respiratory tract like-infection and 81,536,000 hospital days²

IVD tests provide vital information that help to appropriately manage patients with acute respiratory symptoms (not only caused by SARS-CoV-2 but also from other respiratory pathogens such as influenza), generating value to:

Citizens

- Value of knowing the cause of their symptoms^D
- Value of ruling out a COVID-19 infection, benefitting from additional clarity around their overall health and wellbeing in the future^D
- Reduction of stress and reduced risk of mental disorder such as anxiety and depression due to uncertainty about the origin of their condition^D
- Clinical benefits and increased safety, as unnecessary complications can be avoided by following the right treatment^D
- Value of knowing and deciding on preventative measures to take^F

Healthcare professionals

- Rapid, appropriate clinical management by bringing the patient onto the correct treatment path as fast as possible^D
- Ability to avoid further (unnecessary) testing and prevent side effects for patients arising from non-targeted administration of antibiotics based on empirical data^D
- Manage patients' expectations regarding prognosis and treatment course^D
- Take informed decisions concerning necessary isolation measures when the patient is admitted to the hospital^D
- Monitoring patients' conditions and adjusting the treatment pathway, especially in case of a secondary (bacterial) infection^D

Healthcare providers

- Optimise their operational costs and turnaround time by avoiding unnecessary and inappropriate use of potentially overburdened COVID-19 wards^E
- Improvement of quality of care in hospitals, ensuring rapid, appropriate clinical management of care and curbing inappropriate treatment choices^D
- Greater ability to confirm influenza virus cases, and shorten the time of isolation and length of stay^D

Healthcare systems

- Creation of economic efficiencies by rapid virus detection based on IVD information^{D, E}
- Improved triage decisions (e.g. need for isolation), more efficient investigation, treatment (targeted anti-viral prescribing) and disposition of patients^E
- Public health benefits in terms of improved antimicrobial stewardship and control of COVID-19 and influenza spreading^F

For simplified presentation, these value statements refer to the value of diagnostic information with the help of an exemplary pathway of a patient presenting at the emergency department (ED) with severe symptoms of an acute respiratory tract like-infection during the influenza season and at times of the SARS-CoV-2 pandemic, assuming that the final diagnosis is influenza not COVID-19. The statements below have a pure illustrative purpose and do not claim to be an exhaustive description of the potential testing procedure to be applied in the situation as described above.

References

A) Molecular based (RT-PCR) SARS-CoV-2 tests

B) Antigen detection-based SARS-CoV-2 tests

C) Serology tests for COVID-19 detection (antibody tests)

D) Influenza SARS-CoV-2 (Flu SC2) multiplex assay / PCR influenza test

E) SARS-CoV-2 (Flu SC2) multiplex assay / RT-PCR influenza test / antigen detection-based SARS-CoV-2 at point of care

F) Serology tests for COVID-19 detection / influenza detection

1) ECDC, Factsheet about seasonal influenza

2) The Lancet, Mortality, morbidity, and hospitalisations due to influenza lower respiratory tract infections, 2017: an analysis for the Global Burden of Disease Study 2017, 12 December 2018

3) Uhart et al., Public health and economic impact of seasonal influenza vaccination with quadrivalent influenza vaccines compared to trivalent influenza vaccines in Europe, 11 May 2016