COVID-19 Support for diagnostics development

Background - current situation

In vitro diagnostic tests are essential for the detection of SARS-CoV-2, and a crucial part of managing the pandemic. In the EU Member States, this is currently done in health institutions such as reference laboratories and hospitals by molecular tests detecting the SARS-CoV-2 virus RNA. In addition, many commercial diagnostic devices of different types are becoming available in the EU.

It is important to distinguish **different uses in today's diagnostic technologies**: while direct methods such as RT-PCR[1] and antigen detection (be it ELISA method, tests strips or lateral flow devices (LFDs)) are suitable for diagnosis, antibody detection and analysis of patient RNA-signature are suitable for epidemiological analysis but might not be suitable for diagnosis of a current infection.

There are already numerous commercial RT-PCR assays offered in Europe with variable availability rates and prices between countries and many antibody detection assays are emerging, both automated and rapid test strips that can be used as fast point of care (POC) screening tests (sensitive enough to identify the vast majority of virus carriers).

Given the speed at which COVID-19 test methods evolve and devices are placed on the market, information to assist assessment and comparison of their performance would be of use for relevant competent authorities, as well as market actors, clinicians and other stakeholders.

What is the EC doing?

Since 2003, the EU has invested around € 47 million under FP6 and FP7 on diagnostics research supplemented under Horizon 2020 with more than € 42 million invested before the coronavirus outbreak, in particular through the 'PERFORM' and 'Value DX' projects.

Since January 2020, several initiatives have been taken that address diagnostic issues:

- An **emergency call** supported by €47.5 million allowed the funding of 18 proposals among which "CoNVat" 'CORONADX', 'HG nCoV19 test', 'CORESMA' and 'RECOVER' are particularly relevant to diagnostic solutions.
- A special fast track call from the **Innovative Medicines Initiative (IMI)** on developing therapeutics and diagnostics should gather €90 million from both Horizon 2020 the pharmaceutical industry. (evaluation of proposals ongoing)
- A "bottom call" from the **European Innovation Council (EIC)** for start-ups and SMEs with a minimum budget of €164 million will support best-received COVID-19 applications. (evaluation of proposals ongoing)
- COVID-19 applications under the **InnovFin Infectious Diseases Finance Facility** co-funded by Horizon 2020 and the EIB could receive up to € 75 million (and beyond in exceptional cases). This would include companies producing diagnostics tests.
- Special derogations to the **Medical Devices Regulation** allow putting on the market non-certified devices that are crucial to safeguard public health.
- A **positive control material** produced by the Joint Research Centre has been distributed to testing laboratories in the EU. It will facilitate the reliability of the detection of the SARS-CoV-2.
- A joint procurement on laboratories equipment (kits, reagents, hardware) was launched on Thursday 19 March with a deadline for applications extended to 12 April.
- The EC has adopted on April 15, a communication on "Guidelines on different COVID-19 in vitro tests and their performance". It provides guidance on the intended purpose of a given test, and on its performance. It provides elements to be considered by Member States in defining national strategies,

[1] Real time reverse transcription polymerase chain reaction

and by economic operators in placing devices on the market, with the objective of ensuring that safe and effective devices for COVID-19-related testing are available in the EU.

What can the EC do?

In times of growing number of infections across the EU, it is important to support the **development and validation of faster and simpler POC screening tests**, especially rapid antigen detection tests. To cope with current little information on performance of the many SARS-Cov-2 tests on the EU market or in the pipeline[2], specific activities could be immediately considered:

- The EC services, in collaboration with the ECDC, is producing an overview of available studies on test method and device performance in the EU. The document should also include **guidance for performance criteria for different types of test and devices**. These performance criteria would be an essential tool to help MS surveillance and testing strategies. This document will be finished by 12-04 and is to be presented at the Council of Health Ministers.
- ECDC is developing a discussion paper on a common strategy for EU/EEA/UK countries to perform sero-prevalence cross-sectional surveys in Europe. A number of countries have taken some initiative to start such surveys, using in-house tests that have not necessarily been cross-validated.
- The JRC is starting to produce new control samples for serological test (complex because of the necessary biosafety requirements)
- A **dedicated Horizon 2020 initiative could be explored to support further actions needed as identified in the communication:**

  The Commission, together with Member States, will put efforts into the development of tools to enable evaluation of device performance and align approaches across the Union, such as reference materials and methods for standardised comparison. This will require close cooperation between regulators, health technology assessment bodies[3], the COVID-19 reference laboratory network, research organisations and industry to ensure the most optimal outcome. The Commission will consider which funding opportunities will provide support for these activities

[2] https://www.finddx.org/covid-19/pipeline/
[3] https://eunethta.eu/