European Commission

# TESTING KITS FOR COVID-19 : WHAT IS THE EU DOING ?

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**KEY MESSAGES:**

- Testing for the presence of or exposure to the SARS-CoV-2 virus is an essential aspect of combatting the COVID-19 outbreak.
- The rapidly developing nature of the pandemic means that **testing kits are key tools for both the control of spread and future de-escalation measures.**
- **The Commission, supported by the ECDC, health technology assessment experts and in vitro diagnostics competent authorities, will assist Member States with a centralised overview of available information on test performance.**
- **The Commission, in cooperation with Member States, will facilitate the placing on the market of safe and reliable test devices.**

## Why is it important to coordinate our efforts?

For this cross-border public health crisis, the pooling of resources and sharing of scientific results across Member States is key to ensuring effective performance of devices.

- **Insufficient diagnostic sensitivity** could lead to missing infected individuals
- **Insufficient diagnostic specificity** could lead to imposing confinement measures on individuals who are not true positives

Development of tools such as commonly accepted reference materials and methods will be most successful through an EU-wide collaboration.

## What should the Member States do?

- National strategies should take account of the **intended purpose of each type of test** and the importance of the use of the device in a specific context
- Support the Commission in the **establishment of a network of COVID-19** reference laboratories across the Union
- Support the establishment of a **centralised overview of available information on test performance and ongoing validations**
- Continue **active participation in regulatory exchanges,** including on counterfeit devices

## What is the Commission already doing?

- Continuous exchange of information between competent authorities for in vitro diagnostics through a **dedicated subgroup of the Medical Device Coordination Group**
- **Dialogue with industry on** device availability and performance as well as exchanges with WHO regarding COVID-19-related actions
- **Guidance on medical device conformity assessment and an overview of international recognition of standards**
- Development of a **positive control material, which can be used for quality assessment** and distributing it to laboratories across the EU

## What is next?

- Centralised **overview of available information on test performance**
- Development of **tools to enable assessment of device performance**
- A network of **COVID-19 reference laboratories** across the Union, together with a platform to support them
- On-going efforts to **detect and remove counterfeit devices** from the market
- Full use of instruments at EU level to **coordinate supply and demand**
- Promotion of solidarity for **fair distribution of available stocks and laboratory equipment**

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