BRIEFING

European Parliament

Coronavirus testing

Contributing to efforts to stem the second wave

SUMMARY

The coronavirus (Covid-19) pandemic remains a major threat to public health in the European Union (EU). Testing is considered an essential aspect of the response to the pandemic.

There are different types of coronavirus tests, each having its own merits and limitations. The timing of tests is also critical. Among the tests that detect current infection, (rapid) antigen tests have recently come to the fore.

In view of a resurgence of coronavirus cases, the European Commission adopted on 28 October 2020 a recommendation for a common EU testing approach for Covid-19. It addresses key points linked to testing capacities and resources, as well as rapid antigen tests. This was followed on 18 November by a recommendation on the use of rapid antigen tests for the diagnosis of Covid-19, which provides guidance on how to select rapid antigen tests, when they are appropriate and who should perform them. It also calls for validation and mutual recognition of tests and their results.

EU and international public health bodies, including the European Centre for Disease Prevention and Control and the World Health Organization, have given testing recommendations and outlined strategies and objectives.

Several Member States have started to use rapid antigen tests in practice. Testing policies range from testing only people who both have symptoms and also meet specific criteria, to testing anyone with symptoms, to open public testing, including asymptomatic people.

In a September 2020 resolution, the European Parliament called for the adoption and implementation of a common testing strategy under which test results would be recognised in all Member States.

Since the outbreak of the pandemic, coronavirus testing has rapidly evolved and will continue to play an important role. New methods are emerging, including 'out of the box' options.

In this Briefing

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Testing, an essential tool in fighting the pandemic

The coronavirus (Covid-19) pandemic remains a major threat to public health in the EU. In view of a new surge in coronavirus cases, the European Commission adopted on 28 October 2020 a recommendation for a common EU testing approach for Covid-19, followed on 18 November by a recommendation on the use of rapid antigen tests for the diagnosis of Covid-19. Experts agree that there is an urgent need for more tools to combat the coronavirus at multiple levels. Testing is considered an essential aspect of the response to the pandemic and of the efforts to keep the spread of the virus to a minimum. While healthcare is primarily a national competence, the Commission's recommendation aims to promote a common EU-wide approach to testing, not least to ensure that testing policies contribute to the smooth functioning of the internal market, cross-border travel and free movement of people, services and goods.

The European Parliament's call for testing

In a September 2020 resolution, Parliament called for the adoption and implementation of a common testing strategy under which test results would be recognised in all Member States and adequate testing capacities would be provided to ensure that everyone who needs to take a test can do so without any disproportionate waiting times. It called on the Commission and the European Centre for Disease Prevention and Control to evaluate the possibility of using reliable, yet inexpensive, 15-minute tests.

Testing methods currently used

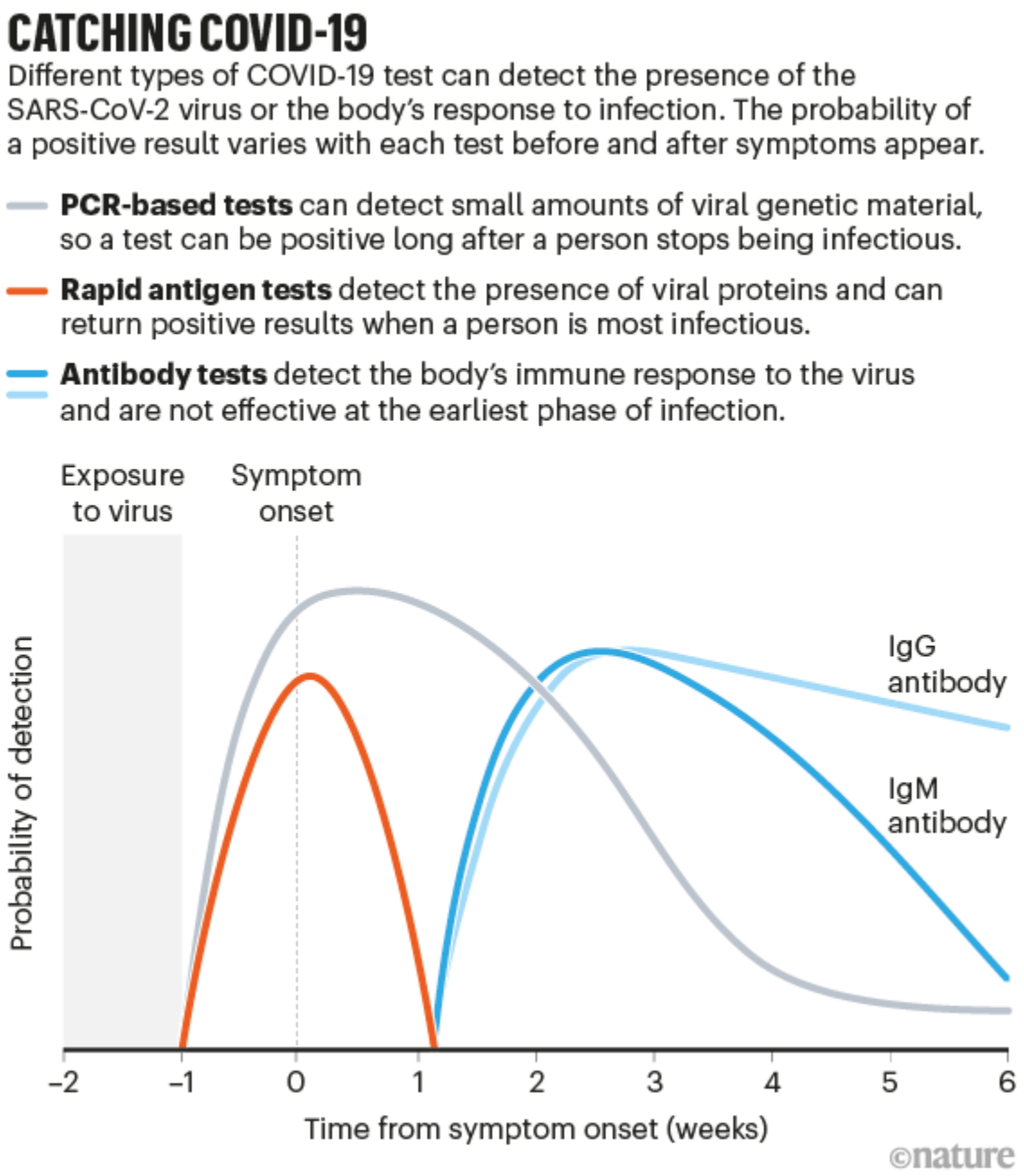
Coronavirus tests fall broadly into two types: those detecting current infection with the coronavirus (Covid-19) and those detecting past exposure to the virus.[1]

Molecular tests detect current infection, i.e. the presence of the virus in a sample obtained by deep nasal (nasopharyngeal) or throat swabs (or both). This can be done by focussing either on the virus's specific genetic material, using a technique known as reverse transcriptase polymerase chain reaction (RT-PCR), or on specific molecules (antigens) present on the viral surface. These two test types are referred to, respectively, as RT-PCR-based tests (**PCR tests** in short) and **antigen tests**. PCR tests – the earliest available since the start of the pandemic – are considered the most reliable method for detecting Covid-19.[2] However, they require trained personnel, specific substances and expensive machines that take hours to provide results. This has led to capacity bottlenecks and long testing turnaround times. Antigen tests (often called **rapid antigen tests**) offer the possibility of faster, simpler and more inexpensive detection using rapid immunoassays on swab samples. New-generation tests return results within 15 to 30 minutes. At present, antigen tests are performed by trained personnel, but they may soon be simple enough to be used at home (see 'Outlook'). On the downside, they are generally regarded as having a lower diagnostic accuracy[3] than PCR tests,[4] and their appropriate use appears to depend on timing (see Figure 1) and settings (more under 'EU and international public health bodies' recommendations').[5] **Saliva tests** – also based on viral genetic detection – are emerging as another fast and convenient testing option, but the jury is still out on their real role. Some studies show that saliva is less sensitive than nasopharyngeal swabs, with the number of false negatives too high to make them really useful, while others suggest that saliva is better. Saliva sampling may likely be of value for identifying asymptomatic people with a medium to high viral load in the context of screening campaigns.

Serological tests (also referred to as **antibody tests**) are used on blood samples (by a finger prick or blood draw) to reveal past exposure to the virus, i.e. the presence of antibodies produced as an immune response to infection, such as immunoglobulins G (IgG) and M (IgM) (see Figure 2). Compared to PCR tests, antibody tests deliver quicker results with less sophisticated equipment, but are of limited value for diagnosing active coronavirus infection, since antibodies become detectable only several days after infection (for most people, between day 10 and day 21). They may nevertheless still have a role to play in complementing other tests and are also likely to be useful for detecting previous Covid-19 infection if used 15 or more days after the onset of symptoms. Antibody

tests could also become important in the context of large-scale population surveys (also called seroprevalence, or antibody prevalence, studies), such as those carried out in Brazil or the United States, to gain population-level information that can help inform strategies to curb the epidemic, and to provide guidance on de-escalation strategies once the pandemic is under control. Data gained from antibody testing could also help understand the long-term effects of infections in patients post-pandemic and boost future pandemic preparedness.

Figure 1 – Probability of coronavirus detection as a function of time from symptom onset



Source: G. Guglielmi, 'The explosion of new coronavirus tests that could help to end the pandemic', *Nature*, 16 September 2020, based on data from N. Sethuraman et al., 'Interpreting Diagnostic Tests for SARS-COV-2', *Journal of the American Medical Association*, Vol. 323(22), pp. 2249-2251.

Commission recommendations on testing strategies and rapid antigen tests

The Commission's October 2020 recommendation on Covid-19 testing strategies, including the use of rapid antigen tests, was announced as part of an additional set of actions to reinforce preparedness and response measures across the EU that aim, among other things, to 'ramp up well-targeted testing'. The recommendation sets out key elements to be considered for national, regional or local testing strategies, such as scope, priority target groups and specific situations covered. It also addresses key points linked to testing capacities and resources. Given that rapid or point-of-care tests, such as antigen tests, are increasingly coming onto the market, the recommendation also puts forward indications as to when carrying out such tests may be appropriate. The recommendation suggests that Member States should test as widely as possible.

In the framework of the announced measures, the Commission undertakes to mobilise €100 million under the Emergency Support Instrument (ESI) to directly purchase rapid antigen tests and deliver them to the Member States. To do so, it will launch initiatives for the joint procurement of such tests. This follows on from the first joint procurement of laboratory equipment, including testing kits and reagents for PCR tests, organised in March to overcome test shortages, and will aim at ensuring 'a second stream of access' to such tests and their swift deployment in the EU. The Commission has also committed to working with the Member States towards creating a framework for the evaluation, approval and mutual recognition of rapid tests, and for mutual recognition of test results. It will also monitor the market and availability of new rapid antigen tests, and – building on the existing database[6] – will establish an information repository of rapid antigen tests and validation study results as they become available in the EU.

The European Council on coronavirus testing

The Commission recommendation came ahead of the European Council virtual meeting of 29 October 2020, at which it considered short-term containment measures with a view to stemming the second wave of coronavirus infections. EU Heads of State or Government stressed that testing and tracing are key to limiting the spread of the virus and will help better control the situation. EU leaders agreed on the need for common recognition of existing PCR tests and their results, and for validation of the new rapid antigen tests. These tests are complementary, and can serve to both ascertain the spread of the virus and preserve the internal market. Meeting again virtually on 19 November to discuss how to develop a common EU approach for the use of rapid antigen tests, leaders stressed the need to work towards mutual recognition of tests and their results. They also talked about national testing strategies.

Furthermore, the Commission has proposed that hospitals and medical practitioners should be exempt from paying value-added tax (VAT) on testing kits used against the coronavirus, and has prolonged the current temporary relief from customs duties and VAT on the import of protective and medical equipment from non-EU countries.

Building on guidance developed with the Member States and the ECDC's expert advice, the Commission's November 2020 recommendation on the use of rapid antigen tests for diagnosing Covid-19 infection provides specific guidance on: the selection criteria of rapid antigen tests (those with 'acceptable test performance', i.e. ≥ 80 % sensitivity and ≥ 97 % specificity, to avoid as many false negative and false positive test results as possible); when they should be used (within five days after the onset of symptoms or within seven days after exposure to a confirmed Covid-19 case); the recommended contexts and settings for the use of these tests; and on the testing capacities and resources needed to perform them. It also calls for the validation and mutual recognition of tests and their results, as provided for in the 13 October 2020 Council recommendation on a coordinated approach to the restriction of movement in response to the pandemic.

The Commission has also signed an agreement with the International Federation of the Red Cross and Red Crescent Societies, under which it will contribute €35.5 million of ESI funding to scale up

coronavirus testing capacity in the EU, among other things, to support training of staff to do sampling collection and test analysis and performance, especially via mobile equipment.

EU and international public health bodies' recommendations

Health Security Committee

The Health Security Committee (HSC) supports the exchange of information on policy, strategy and technical issues relating to health security. It is made up of representatives from the EU Member States' ministries of health, with the Commission providing the HSC secretariat and presidency. In its 17 September 2020 meeting, the HSC agreed recommendations for a common EU testing approach to Covid-19. The recommendations aim to achieve an agreement on a coherent approach to testing across the EU and set out actions for the Member States to consider when updating or adapting their testing strategies. These refer, among other points, to: the objectives of testing strategies; testing capacities; testing turnaround time; testing in specific settings (schools); incoming travellers; and to antigen and antibody tests. At its meeting of 19 October 2020, the HSC agreed to develop a common position on the use of rapid antigen tests that would address, inter alia, the application of these tests and the use of their results.

European Centre for Disease Prevention and Control

According to the European Centre for Disease Prevention and Control (ECDC), the implementation of sustainable testing strategies for Covid-19 supports the overall public health response to the pandemic and helps mitigate its impact on vulnerable populations and healthcare systems, while ensuring that societies and economies can continue to function. A September 2020 report outlines strategies and objectives for coronavirus testing of populations to achieve specific public health objectives in different epidemiological situations. It proposes five main objectives for testing:

- control transmission;
- monitor Covid-19 transmission rates and severity;
- mitigate the impact of Covid-19 in healthcare and social-care settings;
- detect clusters or outbreaks in specific settings;
- maintain Covid-19 elimination status once achieved.

One message from the report is that, ideally, all people with Covid-19 symptoms should be tested as soon as possible after symptom onset. Test turnaround time should be minimised, people testing positive should isolate, and timely contact-tracing should be carried out, making sure that all close contacts are tested, irrespective of symptoms.

In November 2020, the ECDC published a report laying out the options for the use of rapid antigen tests. The report seeks to help the Member States agree on what criteria to use when selecting rapid antigen tests and the settings in which to apply them, and delivers several key messages:

- Rapid antigen tests can contribute to overall Covid-19 testing capacity, offering advantages in terms of shorter turnaround times and reduced costs, especially in situations with limited PCR testing capacity;
- Test sensitivity for rapid antigen tests is generally lower than for PCR;
- The minimum performance requirements set by the WHO at ≥ 80 % sensitivity and ≥ 97 % specificity should be adhered to (see more under 'World Health Organization');
- Rapid antigen tests perform best in cases with a high viral load, i.e. in pre-symptomatic and early symptomatic cases up to five days from symptom onset.
- The use of rapid antigen tests is appropriate in high-prevalence settings, where a positive result is likely to indicate true infection, and in low-prevalence settings to rapidly identify highly infectious cases;
- Rapid antigen tests can help reduce further transmission through early detection of highly infectious cases, thereby enabling a rapid start of contact-tracing.

World Health Organization

The World Health Organization (WHO) has developed a wide range of technical guidance to assist policy-makers and laboratories in testing for Covid-19. Its 11 September 2020 interim guidance on the use of rapid antigen tests for Covid-19 detection, which is referenced in the October 2020 Commission recommendation, offers advice on the potential role of rapid antigen tests and the need for careful test selection. While recognising the shortcomings of the available evidence on rapid antigen tests and the limitations of their performance, the WHO identifies a range of settings and scenarios in which they may (or may not) be used. As the WHO points out, these tests are most likely to perform well in patients with high viral loads, which usually appear in the pre-symptomatic (one to three days before symptom onset) and early symptomatic phases of the illness (within the first five to seven days of illness). Patients who present more than five to seven days after the onset of symptoms are more likely to have lower viral loads, and the likelihood of false negative results is higher. Concretely, the WHO recommends the use of rapid antigen tests that meet the minimum performance requirements of ≥ 80 % sensitivity and ≥ 97% specificity.[7] These tests should be used, in particular, when PCR tests are unavailable or where prolonged turnaround times preclude clinical utility. Rapid antigen testing should be conducted by trained personnel, in accordance with the manufacturer's instructions and within the first five to seven days following the onset of symptoms. The use of rapid antigen tests in the case management and surveillance of Covid-19 can be considered in situations of widespread community transmission, where the health system may be overburdened and where it may not be possible to test suspect cases with PCR tests.

Testing situation in different EU Member States

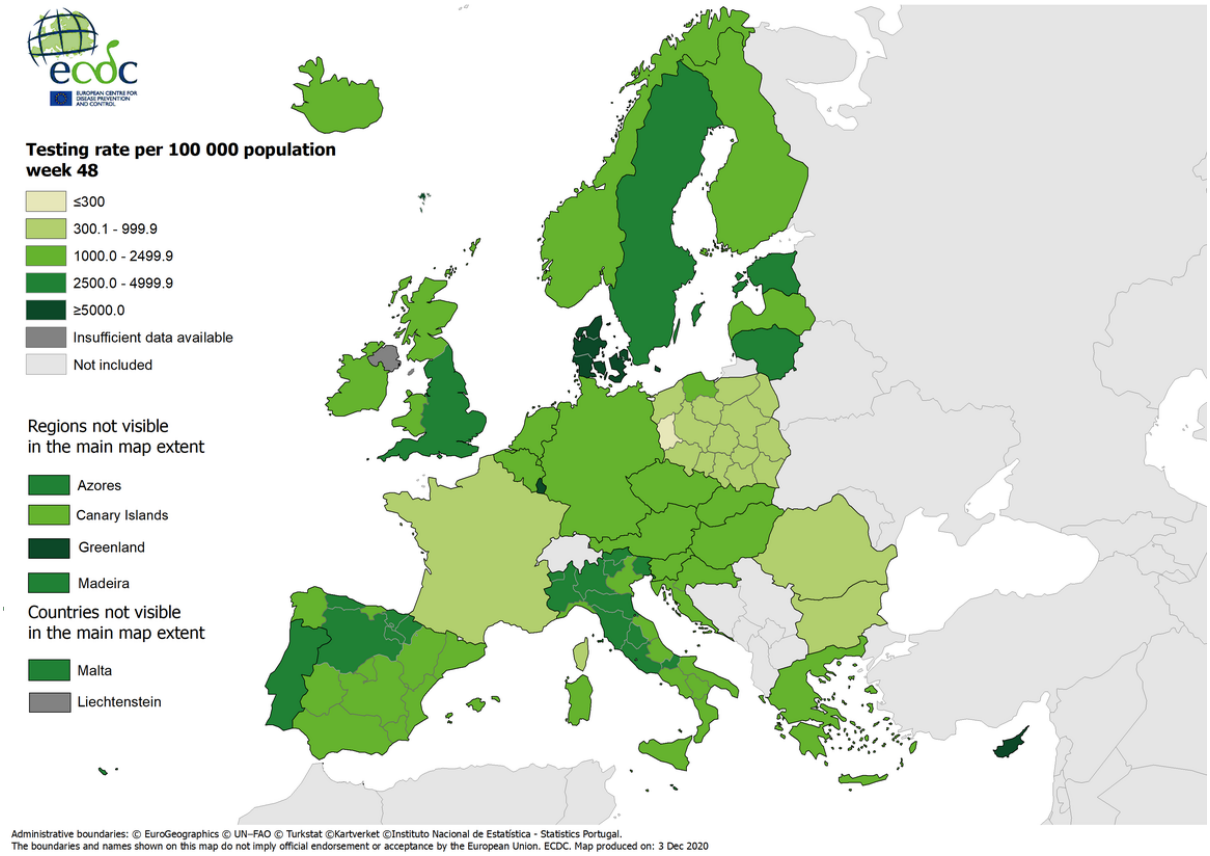
As pointed out in the Commission recommendation, several Member States have started using rapid antigen tests[8] and have included them in their national Covid-19 testing strategies. Moreover, the majority of Member States are currently carrying out validation studies or pilots to assess the clinical performance of rapid antigen tests in specific settings[9] and for the diagnosis of Covid-19 infection among certain target populations.

Data on Covid-19 and testing are available from several authoritative sources. The open-access research website Our World in Data publishes statistics and research on coronavirus testing, for instance, the daily number of tests per 1 000 people and the daily number of tests per confirmed case. As regards testing and contact-tracing policy, a number of European countries (EU plus United Kingdom) can be grouped into several categories:[10]

- **only people who** both **have symptoms and meet specific criteria** (for instance, key workers, those admitted to hospital, those who came into contact with a known case): Bulgaria;
- **anyone with symptoms**: Belgium, Czechia, Estonia, Finland, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Romania, Slovenia, Spain, Sweden and the United Kingdom;
- **open public testing** (including **asymptomatic people**): Austria, Croatia, Cyprus, Denmark, France, Germany, Greece, Luxembourg, Portugal and Slovakia.

The ECDC publishes regularly updated Covid-19 maps, based on data reported by the EU Member States (see Figure 2).

Figure 2 – Testing rates per 100 000 inhabitants, updated 3 December 2020



Source: ECDC.

According to some experts, population-wide testing irrespective of whether people are displaying symptoms ('mass testing'), might be better than only testing people with symptoms, since there would be a bigger reduction in the spread of the virus if a larger proportion of people carrying the virus were identified and isolated. For instance, Slovakia tested over 3.6 million persons (out of a total population of 5.5 million) in November and found that over 1 % of them were positive. Mass testing has also been conducted in Italy (South Tyrol/Alto Adige) and is planned in Austria. A June 2020 analysis found that weekly testing of an entire population, along with contact-tracing and strict quarantine of households where people are infected, could stop transmission within a few weeks.

Outlook

Coronavirus testing will continue to play an important role, from diagnosing infections, to enabling enhanced understanding of disease spread, to helping contain disease transmission, to providing insights into immunity and aiding the development of therapeutics and vaccines. Since the outbreak of the pandemic, the scope of Covid-19 testing has rapidly expanded, and new test methods have emerged (e.g. the recent invention of a paper-strip test in India based on the gene-editing technique CRISPR that would return results in under an hour). Some experts promote the idea of tests that are cheap and simple enough to use at home, envisioning a world where taking a coronavirus test would be as easy as brushing one's teeth.

'Out of the box' coronavirus testing options

For example, researchers are testing the feasibility of breath analysis to distinguish Covid-19 from other respiratory infections, including influenza. An artificial intelligence (IA) model based on cough recordings has been used to create an algorithm that identifies if a person has Covid-19 only by the sound of their cough, even if they do not show any visible symptoms. Once granted regulatory approval, it could be developed into an app. There have also been studies on dogs as coronavirus detectors, including a promising pilot using sniffer dogs to provide testing at Helsinki airport.

MAIN REFERENCES

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Dumbrava C., Lifting coronavirus restrictions: The role of therapeutics, testing, and contact-tracing apps, EPRS, in-depth analysis, European Parliament, July 2020.

Guglielmi G., 'The explosion of new coronavirus tests that could help to end the pandemic', *Nature,* 16 September 2020.

Sheridan C., 'Coronavirus testing finally gathers speed', *Nature,* 5 November 2020.

ENDNOTES

1 For a comprehensive overview of tests and testing strategies during the first wave of the pandemic, see a July 2020 EPRS-in-depth analysis on Lifting coronavirus restrictions: The role of therapeutics, testing, and contact-tracing apps.

2 According to recent UK research, as more and more asymptomatic people undergo testing, false-positive Covid-19 swab test results might be increasingly likely, with substantial consequences at the personal, health system, and societal levels.

3 For more on scientific concepts, such as sensitivity, specificity, false positive, false negative, etc., see '"What do you mean, it was a false positive?" Making sense of COVID-19 tests and terminology', *The Conversation*, 21 September 2020.

4 According to a November 2020 report by the European Centre for Disease Prevention and Control on the clinical performance of rapid antigen tests versus PCR tests, the sensitivities and specificities of rapid antigen tests calculated against PCR tests ranged between 29 % and 93.9 % for test sensitivity and between 80.2 % and 100 % for test specificity (more on the report under 'European Centre for Disease Prevention and Control').

5 A preprint (not yet peer-reviewed) paper suggests that an approach based on frequent, population-wide rapid testing could be more effective at curbing the spread of the virus than one-off PCR testing of suspected cases. According to the results, effective surveillance depends largely on the frequency of testing and the speed of reporting, and is only marginally improved by high test sensitivity.

6 The Commission's Joint Research Centre (JRC) has developed a database on Covid-19 *in vitro* diagnostic devices and test methods, which gathers information on available tests in one place.

7 The WHO cautions that 'the prevalence of disease in the community being tested strongly affects the predictive value of a positive or negative result'. Example: if the prevalence of active Covid-19 infection in a community is 1 %, even a test that is 99 % specific would have poor positive predictive value, as half of all positive results would be false positive.

8 As of 19 October 2020, these were Belgium, Finland, France, Germany, Italy and Spain.

9 The Commission's July 2020 communication on short-term EU health preparedness for Covid-19 outbreaks states that 'specific settings require specific measures. The situation of healthcare workers, workers in long-term care settings and other front-line workers, as well as vulnerable groups and settings such as residential homes, will need continuous and adequate monitoring through regular testing in order to avoid further spread of the virus in these settings'.

10 ourworldindata.org; using drop-down selection 'Europe'. Malta: no data as of 16 November 2020.

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