KEY INSIGHTS ON COVID-19 TESTING IN EUROPE

1. Context

One of the functions of the Clearing House for medical equipment (COVID-19) is to produce analysis of the demand of medical equipment in the EU. In the third week of May 2020 the Clearing House invited national authorities in Member States, EEA countries and the UK to take part in a short survey on testing strategies and capacities. Twenty-nine countries contributed to the exercise on a non-attributable basis. The nature of the survey means its results reflect subjective opinions, which together can help provide a broad understanding of the demand for tests in the EU at the time of the survey, as well as forecast potential needs in view of a possible second wave of COVID-19 outbreak. This note presents the overall findings of the survey and identifies some insights for further consideration.

2. Results overview (third week of May 2020)

Testing strategies:

- Most countries are testing all symptomatic people, even with only one symptom.
- Some countries are also testing asymptomatic individuals (frontline healthcare professionals and those in contact with confirmed positive cases).
- Around 75% of the countries have criteria to repeat the tests (confirmation of the recovery, risk of infection of hospitalised patients, persons in nursing homes, patients in quarantine or healthcare professionals).
- Most countries include PCR tests for screening individuals and 87% for confirmatory purposes.
- A bit less than two-thirds of countries prohibit or discourage the use of some types of tests, for instance self-tests and some rapid tests.
- Some countries also include antibody tests for screening.
- On the purchasing of tests: around 75% of countries allow individual laboratories or hospitals to buy them directly and a bit less than half of countries do so centrally.
- A bit less than half of countries identified limited test capacity or availability of the tests as hindering factors to the definition of their testing strategies.
- Challenges associated with procuring test kits and reagents for PCR tests seem to have eased in May. However, the availability of swabs remained a concern at the end of May.

Current and planned capacities:

- According to the numbers reported, the weekly testing capacity in Europe in the third week of May was around 4.4 million PCR tests, but with high national variations.
- The number of PCR machines is often unknown, but a conservative estimate is that there are between 1.200 and 1.500 machines on aggregate.
- Less than half of countries (45%) are using PCR machines not initially foreseen for testing of human samples (e.g. food or veterinary labs).
- National objectives for the number of tests carried out have been reached in some countries, while most countries also indicated that they intend to increase the number of tests.
- PCR testing objectives amount to 5,1 million of tests per week on aggregate.
- 76% of the countries will reach their objective before summer.
- The limited availability of tests and test materials as well as limited availability of personnel to carry out the tests (including to take the samples) and the number of PCR machines are strong limiting factors to increasing testing capacity.

3. In more detail

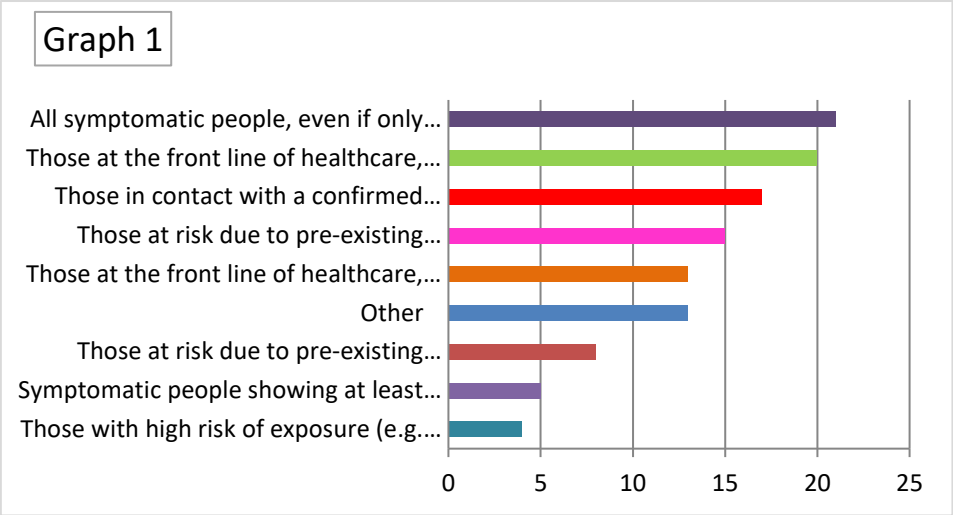
I. Testing strategies

Testing strategies set out whom to test, when, with what methods and how to interpret and use the results. In the context of COVID-19, the Commission[1] and the European Centre of Disease Control[2] have outlined recommendations for prioritising testing for certain individuals. The Clearing House developed a set of questions to obtain information on the testing strategies in place in the different countries and to better understand their current and future needs for COVID-19 testing. The survey addressed the different sub-subsets of population to be tested, the types of tests to be used for different purposes, the way in which participants purchase tests and most importantly, the main limitations encountered when defining testing strategies.

1. Testing 'priority targets'

Countries were asked to indicate which sub-set(s) of the population were tested as a matter of priority. This included testing according to symptoms or people subject to specific risks. Respondents could identify multiple sub-sets of the population.

[1] https://ec.europa.eu/info/sites/info/files/covid19_-_eu_recommendations_on_testing_strategies_v2.pdf
[2] European Centre for Disease Prevention and Control. Strategies for the surveillance of COVID-19. Stockholm: ECDC; 2020 - https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-surveillance-strategy-9-Apr-2020.pdf



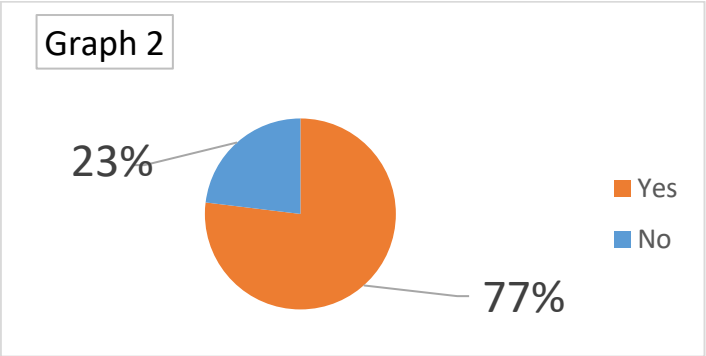
Graph 1 summarises the answers received. Most of the countries include in their testing strategy the testing of: symptomatic individuals (i.e. including healthcare workers and those at risks due to pre-existing conditions); those in contact with a positive case; and healthcare workers even if asymptomatic.

Several countries indicated they also prioritised: patients admitted to hospitals (including asymptomatic individuals before surgery in general, or transplant procedures and donors of stem cells before donation); residents in nursing homes, other social healthcare settings and older persons in home care; essential services (police, rescuers, border officials etc.); symptomatic patients and suspected cases following the specific request by a family doctor, even if not in accordance with the pre-defined criteria for testing;

Several countries indicated that their testing strategies have changed during the pandemic, depending on testing capacity. This means that more strict criteria were put in place for accessing testing where capacity was limited, probably due to the combination of higher demand and less availability of tests.

2. Criteria to repeat tests

Countries were asked to indicate if their testing strategy included the need to repeat tests in certain circumstances. For instance, in case a negative result following a confirmed infection was needed to allow a certain individual to return to work.



As can be seen in graph 2, in 77% of countries there are criteria to repeat tests under certain conditions. For hospitalised patients several strategies were reported before hospital admission: two negative PCR tests, at least 24 hours apart (either: 1) performed at least 14 days after the onset of symptoms once they demonstrate complete absence of fever (without the use of antipyretics) and significant improvement in symptoms for 3 consecutive days; or 2) at 7 days since the first positive test and after 3 days without fever).

Several strategies were also reported before hospital discharge, such as: the need for two negative tests (24 h apart); or one negative result coupled with 28 days of home quarantine and another negative result; or a second biological product for laboratory diagnosis if the disease worsens.

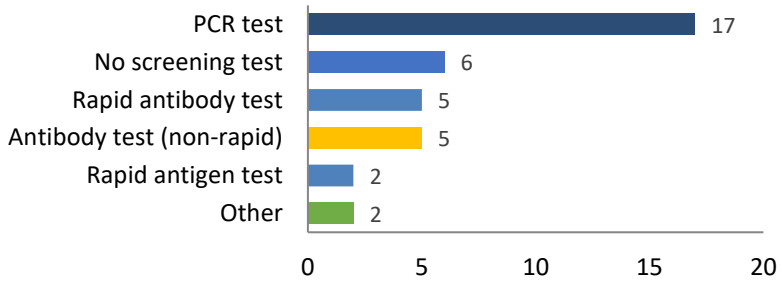
Some countries conduct a PCR test in a reference lab after a positive antibody test from a private laboratory. Other countries request a second test for individuals who were in contact with a confirmed positive case, symptomatic or not (1st test on day 4) on day 6. Lastly, in some specific situations, the assessment is done on a case-by-case basis, depending on the resolution of symptoms and the period already spent in isolation.

As it can be seen in the replies above, most of the criteria for repeating tests are currently intended to confirm recovery from COVID-19 or to conclude on the non-transmissibility of confirmed and suspected cases.

3. Screening test for individuals

Countries were asked to indicate whether a screening test for individuals (e.g. at triage stage), was performed and if that was the case, which type of tests were used for this purpose.

Graph 3

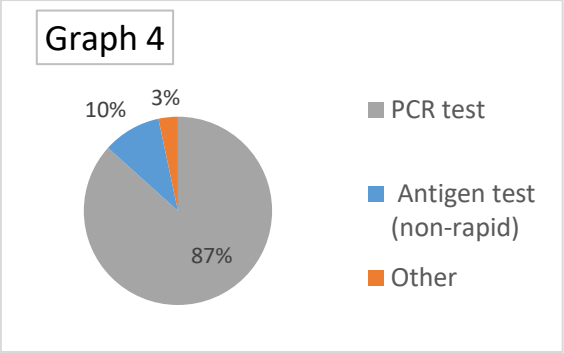


Six countries indicated that they had no screening testing, while for the countries who include screening testing as part of their testing strategy, PCR seem to be the preferred testing method to perform these tests (17 countries out of 20 apply this testing method). Some other countries identified antibody testing (rapid or automated) for these purposes, probably as the individuals testing positive for antibodies are subsequently required to undergo a confirmatory PCR test to confirm that they are not infectious any longer. Four

countries indicated that they use both types of antibody testing (rapid and non-rapid) for screening.

4. Confirmatory test for individuals

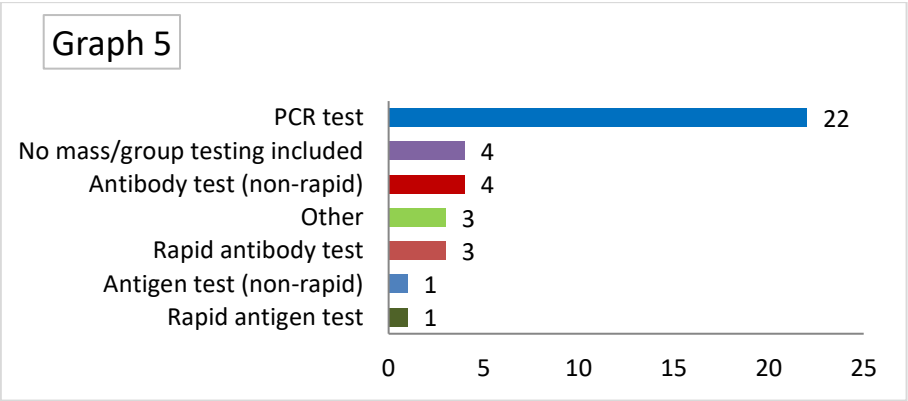
Countries were asked to indicate the type of tests were included in their testing strategy for confirmatory purposes.



PCR tests are used in most countries for confirmatory purposes (Graph 4) while 10% of the countries indicated that they use non-rapid antigen testing (in addition to PCR).

5. 'Mass' strategies

Countries were asked to indicate whether mass/group testing (e.g. in nursing homes) was carried out as part of the testing strategy and, if so, which tests were used. Graph 5 shows that only a very few number of countries do not currently perform mass/group testing. For those who include this type of testing as part of their testing strategies, PCR is used in most cases. Some countries also indicated that some other tests are used as complementary to PCR but that this method is the preferred one as it provides confirmation of infection.



6. Role of antibody tests in the strategies

Countries were asked to indicate which types of antibody tests were used for epidemiological purposes in their country and replied that automated (non-rapid) tests were the preferred option (for those countries where antibody tests are used).

7. Prohibition or discouragement of some types of tests

Countries were asked to indicate whether any particular tests were prohibited or discouraged in their country.

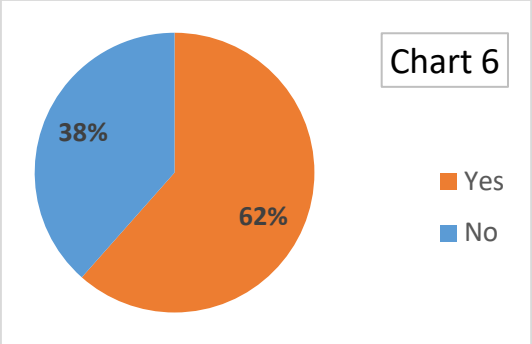


Chart 6 shows that 62 % of countries prohibit or discourage certain tests, including: antibody tests (e.g. due to specificity, low sensitivity of rapid antibody tests, open questions concerning immunity; low prevalence in the country, etc.); self-tests; rapid tests, as some are considered not reliable; serological tests for diagnostic purposes; or tests where validation showed an unsatisfactory result.

Some countries indicated that the validation of tests is currently ongoing, others stressed that they are not proactively discouraging other tests but underlined that only PCR tests are reliable.

8. Purchasing of tests

Countries were asked to indicate how tests are purchased in their country.

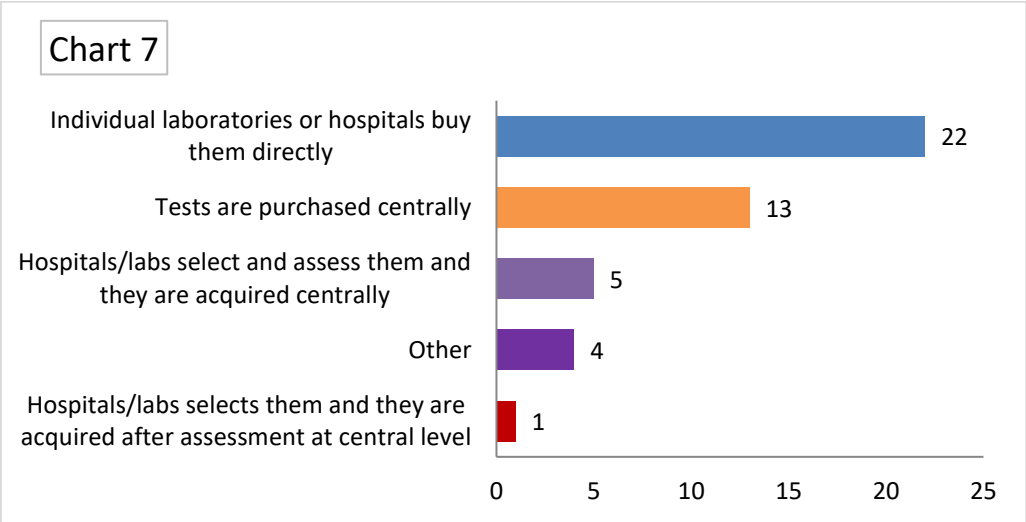
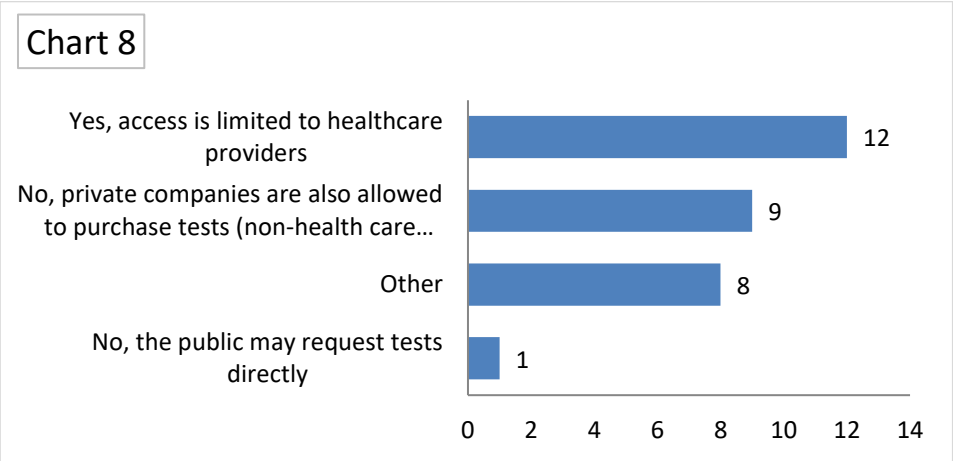


Chart 7 shows that in most countries individual laboratories buy the tests directly, which means that the market can be shared by different companies and purchases can also be made from small- and medium-sized manufacturers. A number of countries indicated that tests are purchased at central level. Some countries reported that both strategies are

applicable in some cases, as the purchases that are carried out centrally are linked to specific situations (e.g. for donations). Some countries also have a system to assess at central level the tests that are to be purchased by individual laboratories.

In addition, countries were asked to indicate whether the access to tests is limited in their country. As it can be seen in chart 8 below, tests are limited to healthcare providers in many countries but in several other countries private companies can purchase tests. It was clarified by many countries that private companies purchase the tests through private laboratories that will acquire and perform these tests. Some other countries clarified that serological tests are accessible to private companies and the public, but this is not the case for PCR tests.

Some countries have additional requirements for access to tests by the public, for instance that these tests on request cannot exceed one third of the number of the total tests carried out by a given laboratory.



9. Challenges in strategy setting

The main challenges which countries face in defining their testing strategies include capacity and availability limitations, which influences the sub-sets of the population that need to be tested (e.g. asymptomatic persons); the procurement of swabs and logistic issues, test kits, or reagents for PCR testing; the tracking of samples, including electronically; the willingness of the population to be tested; or the quality assessment of the tests.

Several countries have been constantly adapting their testing strategies to the evolving circumstances. At the beginning of the crisis, testing was limited to certain risk groups due to limited availability of tests and limited capacity. As the crisis evolves, more resources are in place and plans for more extensive testing and for the use of another type of tests have been developed.

II. Testing capacities

Testing capacity refers to the number of tests that can be performed by a given country taking into consideration the resources needed to carry out the different steps of the process, not only human resources but also in terms of laboratory equipment and tests. The Clearing House developed a set of questions to obtain information on current and planned testing capacity. The survey addressed the current and planned capacity per week with regard to PCR testing, the number of PCR machines and the main limitations encountered when trying to increase their testing capacity.

1. PCR testing capacity per week

Whilst there were significant differences across countries, the aggregate weekly test capacity appears to be around 4.4 million tests per week.

2. Number of PCR machines

Most countries reported that information on the number of PCR machines was not available or was unknown. Some countries provided the number of laboratories (which could have one or more machines) as a proxy, or gave a reference number or a range. Taking into account the above limitations, a conservative estimate is that the total number of PCR machines currently used for COVID-19 testing is likely to be around 1200 to 1500 on aggregate.

3. PCR machines outside usual human samples

Countries were asked to indicate whether PCR machines that were not initially foreseen for testing human samples (e.g. food labs, veterinary laboratories) are used now for COVID-19 in order to increase the testing capacity.

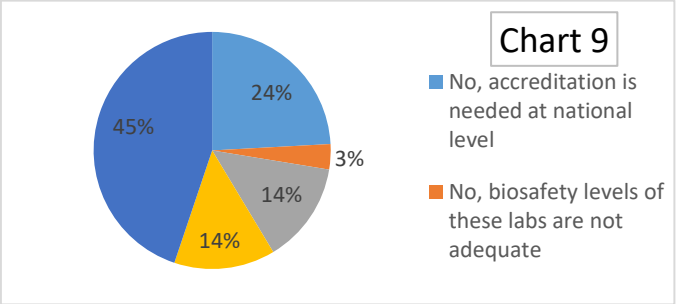
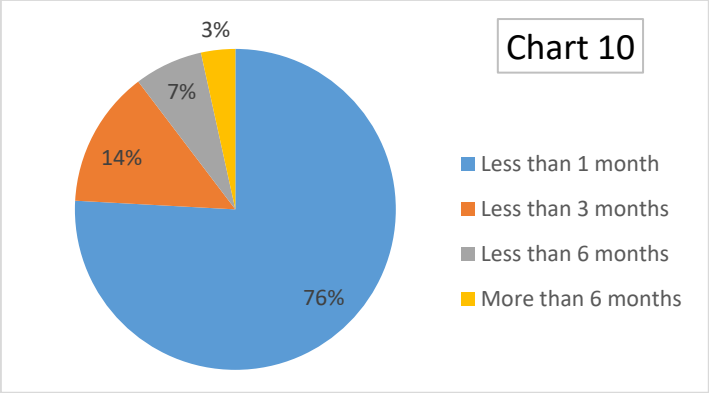


Chart 9 shows that almost half of countries are using PCR machines initially foreseen for other purposes. Most of the other countries indicated issues with accreditation as limiting the increased use of these machines.

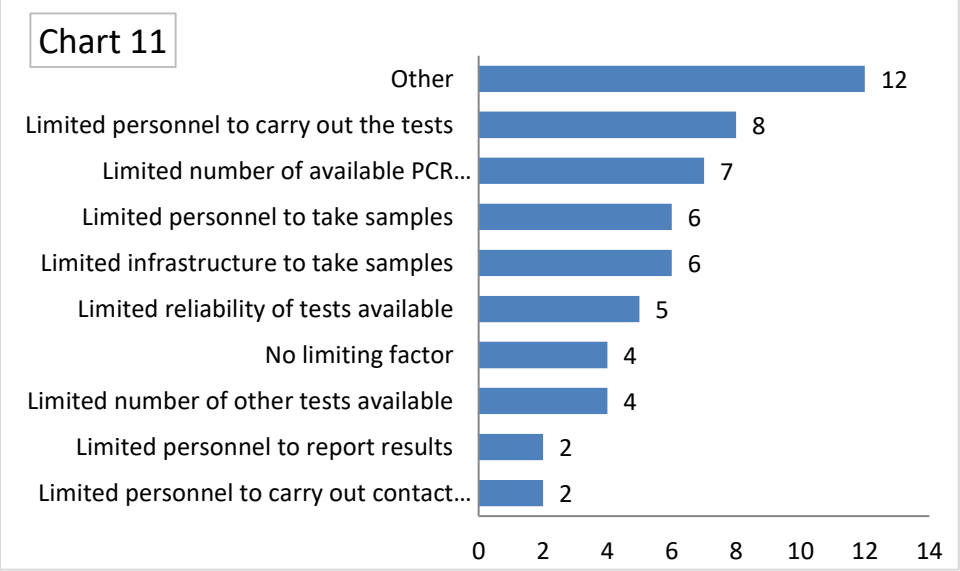
4. PCR testing objective per week

Countries were asked about their objectives in terms of PCR testing capacity per week. For some countries, the objective is to reduce the turnaround time to get the results (e.g. test result available within 36 hours), while for others the objective is to extend the number of sub-sets of the population that can be tested or the absolute number of tests per week. Some other countries indicated that there is no testing objective as the testing volumes match the epidemiological situation or as a matter of policy choice. As a broad estimate, the countries who set objectives aim to increase the number of tests to an aggregate total of around 5 million per week. When asked about the time needed to reach the testing objectives in terms of PCRs per week, as indicated in the chart below, more than 76% of countries have either reached their objective or plan to reach it in less than 1 month as of the third week of May.



5. Main limiting factor preventing an increase of the testing capacity

Chart 11 shows the main limiting factors identified by countries as preventing an increase of the overall testing capacity (PCR and other tests):



Most countries indicated "others" as a limitation and provided additional comments on the issues found. The issues raised by most countries were related to shortages in swabs, test kits and reagents during the peak of the crisis. The second most important limitation indicated is the limited personnel to carry out the test. Limitations in terms of personnel to take samples and of infrastructure for taking these samples were also reported. In addition, several countries reported a limited number of PCR machines. In most cases, countries reported more than one limitation, which indicates that there are many interlinked aspects affecting testing capacity.

6. Other comments

Many countries indicated that testing capacities currently meet the needs as the containment measures triggered a decrease in positive cases and therefore in the number of individuals that fulfil the testing criteria. Many countries are planning to increase their testing capacity in different ways, either by carrying out seroprevalence studies with antibody tests or by starting to perform mass/group testing in higher numbers. Also, some countries indicated that they are currently preparing an excess in capacity to better face the potential challenges of an increase in symptomatic patients in the autumn and winter, also due to seasonal influenza.

4. Conclusions

Testing strategies and testing capacity are closely interrelated. Testing strategies can only be extended to include additional sub-sets of the population when there is sufficient testing capacity to allow for it. Similarly, strategy planning is of the essence to allow sufficient time to scale up testing capacity. The main limitations faced by countries as they work to expand testing strategies and testing capacity were mainly due to limited test kits and test materials when demand was higher (e.g. as the peak of the crisis required more people to be tested in order to avoid further spread of the virus). Planning, in particular of the necessary human resources, will ensure that activities such as taking samples, processing them and reporting or contact tracing are not a limiting factor in case of a possible second wave in autumn (overlapping with the flu season) and of a need to increase testing capacities in the coming months.