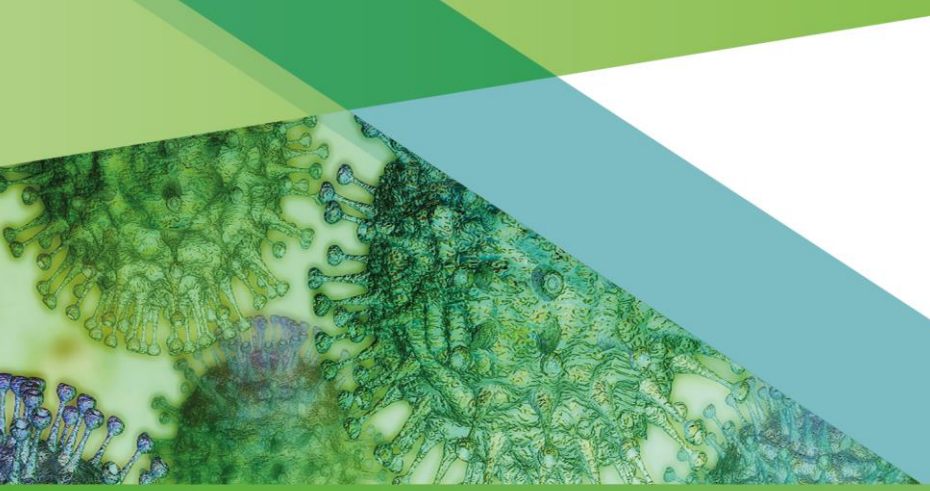


ECDC TECHNICAL REPORT

ECDC rapid assessment of laboratory practices and needs related to COVID-19

18 January 2021

Key messages

- EU/EEA Member States and the UK have increased their laboratory capacity tremendously over the past 11 months as the majority of the Member States reported sufficient testing capacity until March 2021.
- Many countries are adding rapid antigen detection tests (RADT) to their testing strategies in order to reduce pressure on RT-PCR testing.
- Some Member States have already included RADT in their case definition.
- The main bottlenecks, such as shortages of laboratory consumables and human resources, as well as sample storing facilities, continue to exist and may affect the overall laboratory response to COVID-19.

Background and methods

ECDC has mapped current laboratory practices and needs of Member States in terms of diagnostic testing and laboratory shortages across the EU/EEA and the UK. This is the fourth such survey since the beginning of the pandemic in December 2019.

A concise questionnaire (see Annex 2) was sent out on 25 November 2020 to 29 Member States and the UK using the EU Survey Tool. The recipients included ECDC's Operational Contact Points for Influenza and COVID-19 (Microbiology), the EU/EEA laboratory Focal Points belonging to the EVD-LabNet, the National Focal Points for Viral Respiratory Diseases and the National Coordinators. They were asked to answer the questions where appropriate and estimate numbers for the whole of their country. We have summarised the answers in this report.

The assessment of the sequencing capacity in Member States was not part of the current laboratory capacity survey. It is, however, being investigated in the most recent survey on 'Detection and characterisation capability and capacity for SARS-CoV-2 variants', of which the report is expected to be published in February 2021.

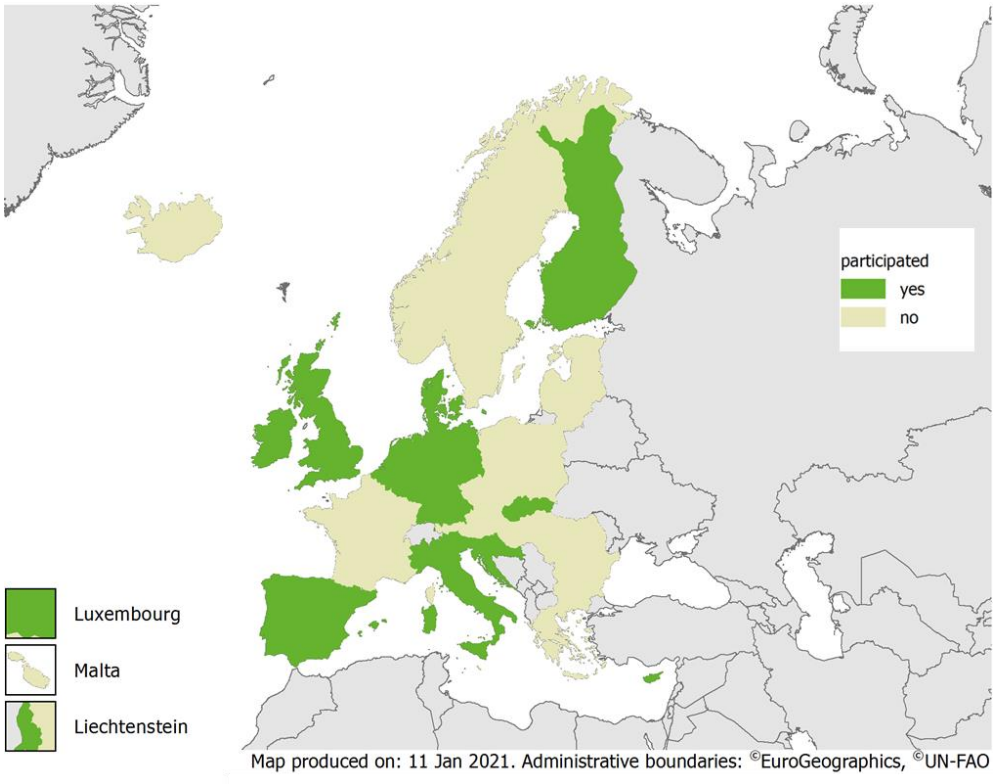
Results

As of 7 December 2020, 19 laboratories from 16 Member States from the EU/EEA and the UK have replied to the survey (Figure 1). Twelve national reference laboratories reported being the focalpoints for the European COVID-19 reference laboratory network (ECOVID-LabNet). Seven of those laboratories also reported being the focal points for the European Influenza Surveillance Network (EISN) and five of them are focal points for the European Expert laboratory network for emerging viral diseases (EVD-LabNet).

Suggested citation: European Centre for Disease Prevention and Control. ECDC rapid assessment of laboratory practices and needs related to COVID-19 – 18 January 2021. ECDC: Stockholm; 2021.
Erratum 20 January 2021: A sentence was added to the Backgrounds and Methods section about a new report to be published in February 2021.

The remaining seven laboratories are either focal points for EISN (one laboratory) or focal points for EVD-LabNet (three laboratories) or both (three laboratories). One laboratory reported being the poliovirus contact point.

Figure 1. Countries (n=16) with laboratories (n=19) that took part in the survey (green), EU/EEA and the UK, December 2020



Countries that were invited but did not provide responses are depicted in light green. Countries outside EU/EEA and UK region are in grey.

Testing capacity in the next four months

We asked the countries about their COVID-19 testing capacity for the next four months until March 2021, assuming that the testing demands will be constant or increase during this time. Fourteen of the 16 countries reported sufficient testing capacity for the near future. One country did not consider their overall testing capacity sufficient for the next four months and will expand it. Two laboratories in two countries did not know as they lacked information from all laboratories in the country.

When asked about the prospects of reaching the limit of their testing capacity, 12 laboratories from 11 countries did not expect to reach their testing capacity limit within the next four months. Two countries expected to reach their testing capacity limit and five laboratories did not know.

Turn-around time of RT-PCR test results

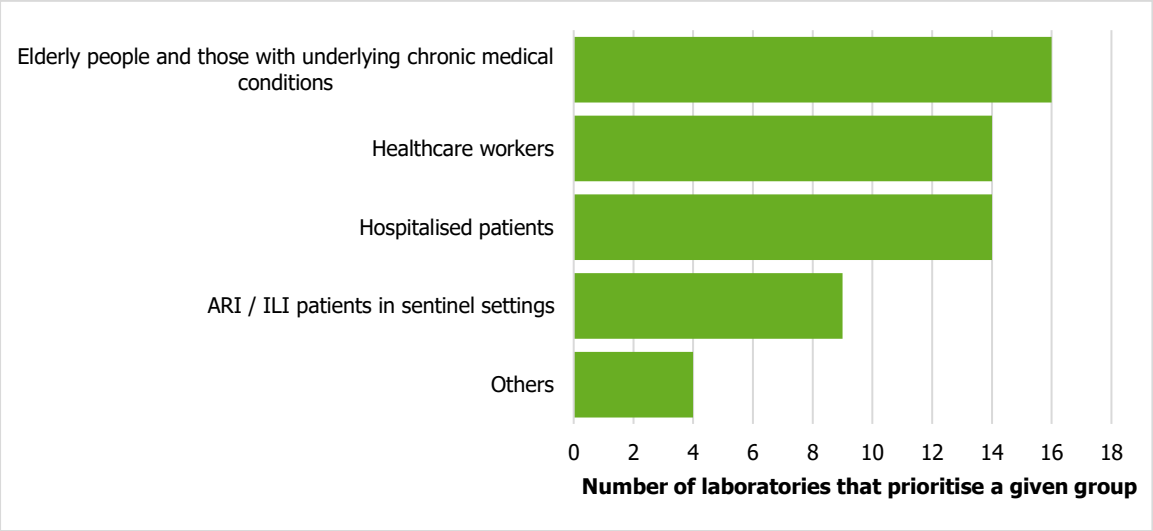
Based on the survey, the majority of laboratories are able to return all or most of the RT-PCR test results within 24 hours. Four national reference laboratories and two regional laboratories report 100% of the test results within 24 hours. Nine laboratories report up to 75% of the test results within 24 hours and four laboratories report up to 50% of the test results within that target time. One country reported that the time between making the appointment and communicating the results is on average 37 hours and for priority groups the time is 23 hours.

Prioritisation of target groups for testing

Participants were asked whether they foresee a need for prioritisation of certain target groups for testing within the next four months. The results are presented in Figure 2. Elderly people and those with underlying chronic medical conditions, healthcare workers as well as hospitalised patients were among the highest reported groups for prioritisation. One country reported that they may need to prioritise sample handling within their clinical laboratory system and also reported an ongoing population wide testing programme. Other groups that were not listed but were mentioned were e.g. inhabitants and workers at closed institutions.

One country included its complete testing criteria and prioritisation based on vulnerability, severity of clinical symptoms and likelihood of exposure in the response.

Figure 2. Target groups prioritised for COVID-19 testing in the country within the next four months, EU/EEA and the UK, December 2020



** multiple choices could be made*

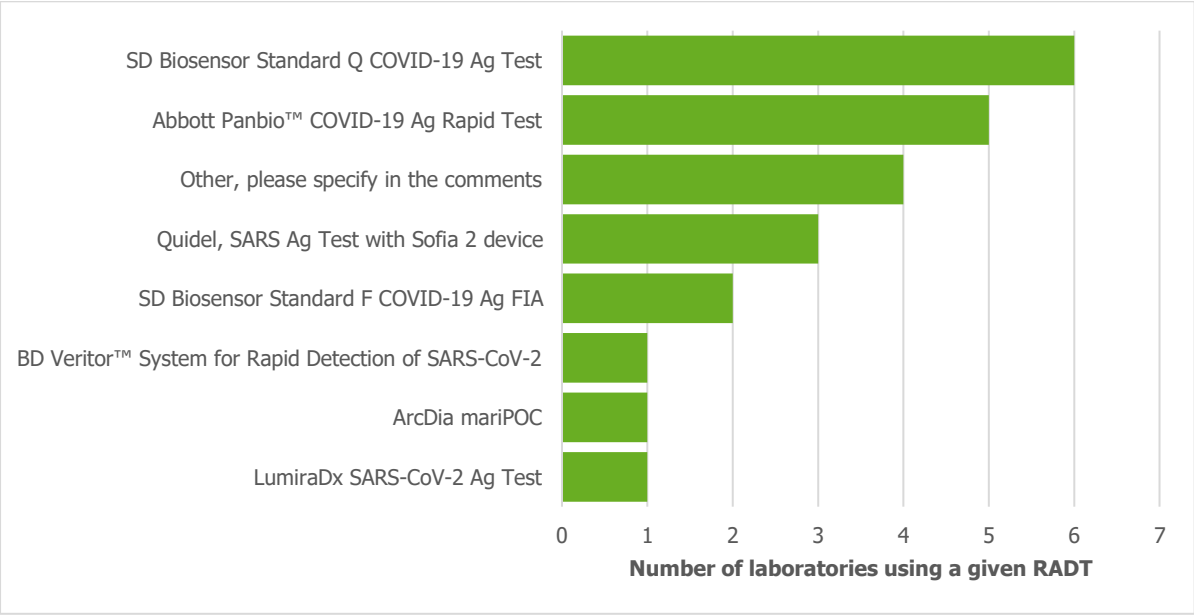
COVID-19 case definitions in use

If applicable, the participating countries included their current case definitions in this survey. The list of provided links and answers can be found in Annex 1. Six national reference laboratories have already integrated RADT into their case definitions and eight countries stated that they are planning to do so within the next four months (Annex 1). One country reported not knowing if they are going to do so.

Rapid antigen tests in use

All six countries which have included RADTs in their national testing strategies are using one or more of the tests listed in Figure 3. Five out of the six countries are using various tests and one country is using only one test.

Figure 3. Rapid antigen detection tests in use among the national reference laboratories in the six countries within the EU/EEA and the UK that have integrated rapid antigen detection tests or other rapid tests into their COVID-19 case definition, December 2020

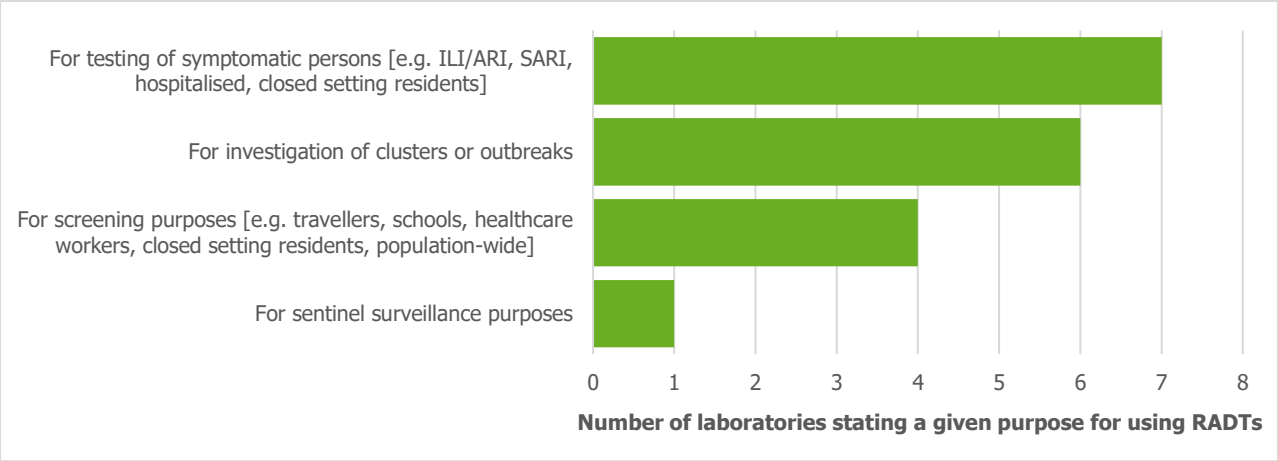


** multiple choices could be made*

Purpose for using rapid antigen detection tests

Participants were asked to define the purpose for which they are using RADTs. Only countries who had included RADTs in their case definitions received this question and they could choose multiple purposes. National reference laboratories from the six countries and one additional regional laboratory had implemented testing with RADTs for symptomatic persons, e.g. influenza-like illness (ILI)/severe acute respiratory infections (SARI). For investigation of clusters or outbreaks three of the six countries are using RADTs. Four laboratories also use RADTs for screening purposes (Figure 4).

Figure 4. Purposes for using rapid antigen detection tests in countries within the EU/EEA and UK which have integrated RADTs into their case definition, December 2020



** multiple choices could be made*

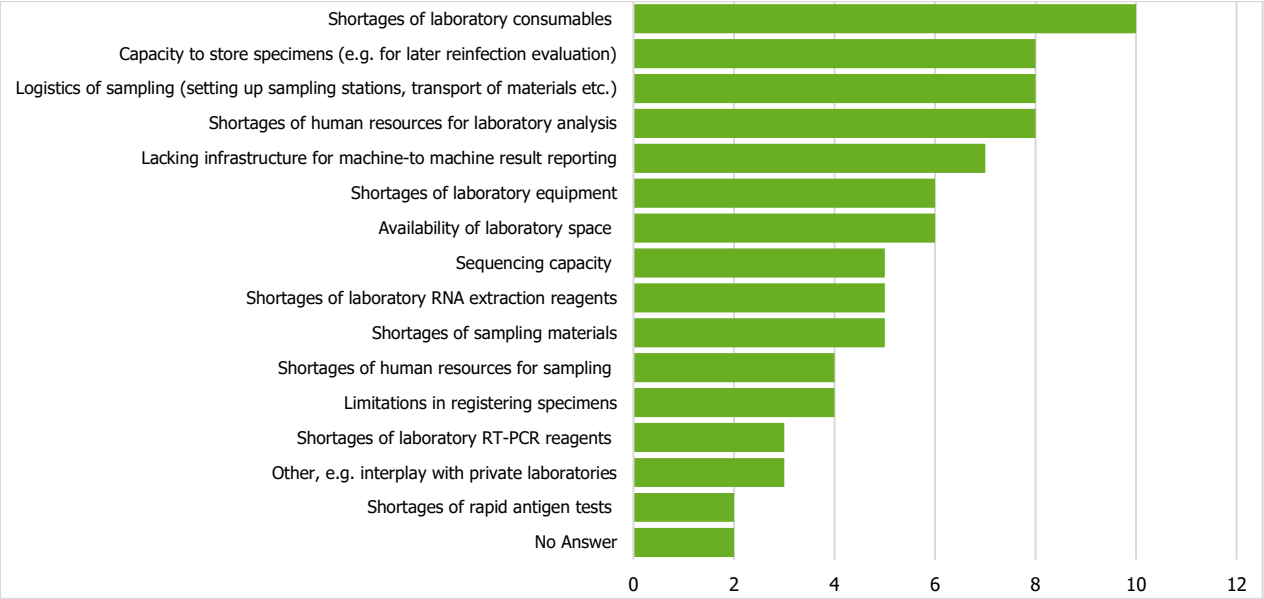
Plans for implementing alternative rapid tests

In the survey, the participants were asked about their plans to implement other rapid detection tests than RADTs, e.g. Loop-mediated Isothermal Amplification (LAMP) based assays. Laboratories in seven countries had plans to implement other rapid diagnostic tests for detection of SARS-CoV-2 infection, while four countries did not. Eight laboratories in seven countries did not know about plans to include other types of rapid tests. In one country, validation of LAMP-based tests was ongoing, and another country reported that LAMP-based tests are being prepared for validation if other testing capacities are not available.

Bottlenecks for laboratory response

The main bottlenecks for the national laboratory response were reported as laid out in Figure 5. The bottlenecks varied across all areas that were given as options. The main categories of bottlenecks were shortages in laboratory consumables, logistics of sampling, shortage of human resources for laboratory analysis, capacity to store specimens for later analysis and lacking infrastructure for machine-to-machine result reporting. One topic that was raised in the comments was that technical laboratory staff is not stable and therefore constant training is required. Such training needs require additional resources of the other staff members.

Figure 5. Main bottlenecks for the national laboratory response in the EU/EEA and UK, December 2020

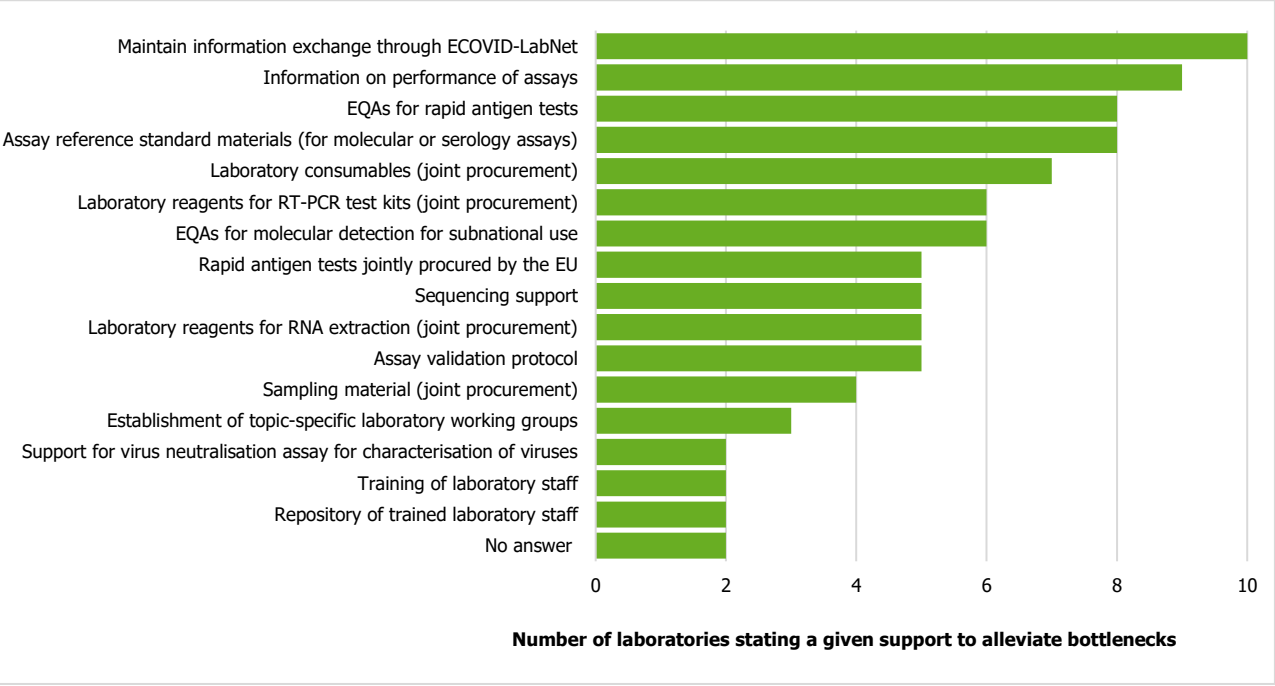


** multiple choices could be made*

Support from the European Commission and ECDC to address the bottlenecks

The support considered helpful by Member States to alleviate the bottlenecks for the laboratory response are depicted in Figure 6. The type of support varied across all reporting categories. Information on assay performance and maintaining information exchange through ECOVID-LabNet were the most popular support types followed by assay reference standard materials and EQA for RADTs. Other types of support considered helpful were joint procurements for sampling material, laboratory consumables, RNA extraction, RT-PCR kits and RADTs. Additionally, a repository of trained laboratory staff, training of laboratory staff, assay validation protocol, support for virus support in neutralisation assay for characterisation of viruses, EQAs for subnational use, establishment of topic-specific laboratory working groups and sequencing support were also considered helpful.

Figure 6. Support to alleviate bottlenecks for the national laboratory response, EU/EEA and UK, December 2020



** multiple choices could be made*

Conclusions

We assessed the current status of the EU/EEA and the UK COVID-19 laboratory response by sending out a short survey to all Member States and the UK. Only about half of the countries replied by 7 December 2020 and therefore the report is only a partial representation of the current status.

The vast majority of the responding countries (14 of 16) reported sufficient testing capacity until March 2021 (i.e. the end of the period to which the survey was addressed). Turnaround time for laboratory results within 24 hours of sampling has been set as a target by the European Commission [1]. The majority of the countries manage to report 75%-100% of their results within this timeframe. Even if the countries reported that they expect to have enough laboratory capacity available, prioritisation of testing towards elderly people and those with underlying conditions, healthcare workers and hospitalised patients has been adopted or proposed.

Many countries are in the phase of adding rapid antigen detection tests to their testing strategies and expect to reduce pressure on RT-PCR testing through that. Six countries have updated their case definitions to include rapid antigen detection test results and intended to test symptomatic persons and use rapid antigen detection tests for investigation of clusters or outbreaks. Four countries have decided to implement other rapid tests such as LAMP-based assays.

We consulted with Member States on their laboratory responses in March 2020. At that time, many laboratories reported shortages of laboratory consumables (unpublished results). Additional bottlenecks that were mentioned in the survey in March 2020 included shortcomings in the logistics of sampling, shortages of human resources for laboratory analysis, limited capacity to store specimens for later analysis and lacking infrastructure for machine-to-machine result reporting. Such capacity issues continue to hamper the overall laboratory response to COVID-19. If shortages in laboratory consumables and reagents continue, laboratories may not be able to deliver the testing volumes that are expected. This will reduce the detection of the SARS-CoV-2 virus in the population and therefore leave a gap of knowledge to perform contact tracing and isolation of persons who are infected and their contacts, and therefore reduce the possibility to stop the transmission. Lack of trained staff in laboratories is a constant issue as a lot of the laboratory work is still performed manually. The training of new staff requires resources from existing staff and may therefore slow down the laboratory response.

In the current survey, Member States express a need for support from the European Union services. The expected support varies from information on appropriate assays to training of laboratory staff. The joint procurement of laboratory consumables and tests is already ongoing and will continue to support the Member State laboratories. ECDC is providing sequencing support through an existing framework contract and the ECOVID-LabNet is going to host a virology characterisation working group in 2021 and continues with the regular ECOVID-LabNet information sharing mechanisms. ECDC has already performed a molecular detection external quality assessment of COVID-19 detection (accepted manuscript) and is in progress to launch a second external quality assessment on serology. The Commission Joint Research Centre has developed an RNA standard to be used in RT-PCR and is in development of serological assay standard material. On 7 December 2020, two new reference materials for the quality control of SARS-CoV-2 antibody tests were released [2].

EU/EEA Member States and the UK have increased their laboratory capacity tremendously over the past 11 months [3] and appear to have reached testing levels which cover the current needs. The main issues for the COVID-19 laboratory response are primarily the shortages of laboratory reagent and consumables as well as limited human resources. The joint procurement mechanism of the EU should alleviate part of the reported shortages of reagents and consumables in Member States. External Quality Assessments (EQAs) are part of ECDC capacity building for laboratories as they provide quality assessment and guide training. Further EQAs for COVID-19 are planned for 2021. In addition, international knowledge and laboratory sharing mechanisms have been established this year and will continue. ECOVID-LabNet has been seen as a valuable interaction platform and therefore activities within the network will be continued and expanded towards training through twinning between countries and working groups, as well as development of guidance and sharing of laboratory protocols.

Contributors (in alphabetical order)

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- Jan Richter, Cyprus Institute of Neurology and Genetics, Cyprus
- Lasse Dam Rasmussen, Statens Serum Institut, Denmark
- Niina Iikonen, Finnish Institute for Health and Welfare (THL), Finland
- Thorsten Wolff, Robert Koch-Institute, Germany
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- Angela Dimartino, Istituto Superiore di Sanità, Italy
- Elisa Burdino, Amedeo di Savoia Hospital-ASL Città di Torino, Italy
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3. European Centre for Disease Prevention and Control. Risk of COVID-19 transmission related to the end-of-year festive season – 4 December 2020. ECDC: Stockholm; 2020. https://www.ecdc.europa.eu/sites/default/files/documents/Risk-assessment-COVID-19-transmission-related-the-end-of-year-festive-season.pdf

Annex 1. COVID-19 case definitions in use as of 3 December 2020

Country	Link to COVID-19 case definition currently used
Belgium	https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_Case%20definition_Testing_NL.pdf
Croatia	https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition
Cyprus	https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition
Denmark	https://www.sst.dk/da/udgivelser/2020/retningslinjer-for-haandtering-af-covid-19
Finland	https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition
Germany	https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Falldefinition.pdf?__blob=publicationFil
Ireland	https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/casedefinitions/
Italy	https://snlg.iss.it/wp-content/uploads/2020/03/CircolareMinSal_DefinizioneCasoCOVID19.pdf
Liechtenstein	https://www.bag.admin.ch/bag/de/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/information-fuer-die-aerzteschaft.html
Portugal	https://covid19.min-saude.pt/wp-content/uploads/2020/11/Norma_020_2020.pdf
Slovak Republic	https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition
Slovenia	https://www.nijz.si/sites/www.nijz.si/files/uploaded/definicija_za_prijavo_in_spremljanje_novega_koronavirusa_16_3_2020_usklajeno_poslano_beovic_.pdf
Spain	https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/COVID19_Estrategia_vigilancia_y_control_e_indicadores.pdf
The Netherlands	ttps://lci.rivm.nl/richtlijnen/covid-19
United Kingdom	

Annex 2. Questionnaire

Question 1. Do you consider your overall country testing capacities sufficient for the next 4 months, assuming the current or increasing COVID-19 testing demands?

- Yes
- No [if no, please explain in comments]
- Don't know

Question 2. Do you foresee reaching the limit of testing capacities in your country in the next 4 months based on the current testing demand?

- Yes [please explain in comments]
- No
- Don't know

Question 3. What proportion of RT-PCR tests are currently returned within 24 hours?

- 0%
- up to 25%
- up to 50%
- up to 75%
- 100%
- Don't know

Question 4. Do you foresee a need for prioritisation of certain target groups for testing in your country in the next 4 months? [multiple choices can be made]

- Hospitalised patients
- Elderly people and those with underlying chronic medical conditions
- Healthcare workers
- ARI / ILI patients in sentinel settings
- Other [please explain your prioritisation]

Question 5. What is the COVID-19 case definition currently used in your country? Please provide a link if available.

Question 6. Have you integrated rapid antigen tests or other rapid tests into your COVID-19 case definition?

- Yes [please provide a link to your case definition in comments]
- Not yet, but plan to do so within the next 4 months
- Not within the next 4 months
- No, we don’t plan to integrate rapid tests in our case definition
- Don´t know

Question 6a. Which rapid tests are you using or planning to use? [multiple choices can be made]

Question 6b. For which purpose are you using rapid antigen tests or other rapid tests? [multiple choices can be made]

Question 7. Do you aim to implement other type of rapid tests than rapid antigen tests, e.g. Loop-mediated Isothermal Amplification (LAMP) based assays?

- Yes
- No
- Don't know

Question 8. What are the main bottlenecks for your national laboratory response? [multiple choices can be made]

- Logistics of sampling (setting up sampling stations, transport of materials etc.)
- Limitations in registering specimens
- Shortages of sampling materials
- Shortages of human resources for sampling
- Shortages of laboratory consumables
- Shortages of laboratory RNA extraction reagents
- Shortages of laboratory RT-PCR reagents
- Shortages of laboratory equipment
- Shortages of rapid antigen tests
- Shortages of human resources for laboratory analysis
- Lacking infrastructure for machine-to-machine result reporting
- Capacity to store specimens (e.g. for later reinfection evaluation)
- Sequencing capacity
- Availability of laboratory space
- Other, e.g. interplay with private laboratories [please explain in comments]

Question 9. What type of support from the European Union would you consider helpful to address the bottlenecks described above? [multiple choices can be made]

- Logistical support to organise testing stations
- Sampling material (joint procurement)
- Laboratory consumables (joint procurement)
- Laboratory reagents for RNA extraction (joint procurement)
- Laboratory reagents for RT-PCR test kits (joint procurement)
- Rapid antigen tests jointly procured by the EU
- Repository of trained laboratory staff
- Training of laboratory staff
- Facilitation of inter-country laboratory capacity
- Information on performance of assays
- Assay validation protocol
- Assay reference standard materials (for molecular or serology assays)
- Sequencing support
- Support for virus neutralisation assay for characterisation of viruses
- EQAs for rapid antigen tests
- EQAs for molecular detection for subnational use
- Establishment of topic-specific laboratory working groups
- Maintain information exchange through ECOVID-LabNet
- Other [please list in comments]