EUROPEAN
COMMISSION

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COMMISSION RECOMMENDATION

of 28.10.2020

on COVID-19 testing strategies, including the use of rapid antigen tests

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) The COVID-19 pandemic continues to pose a major threat to public health. As outlined in the Commission Communication on short-term EU health preparedness for COVID-19 outbreaks[1], robust testing strategies and sufficient testing capacities are essential aspects of preparedness and response to COVID-19, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation.

(2) In line with Article 168(7) of the Treaty on the Functioning of the European Union[2], the definition of health policy as well as the organisation and delivery of health measures remain a national competence. EU Member States are thus responsible for deciding on the development and implementation of COVID-19 testing strategies, taking into consideration countries' epidemiological and social situations.

(3) In 2013, the EU adopted Decision No 1082/2013/EU[3] (hereinafter "Decision 1082") in order to improve preparedness and capacities across Europe and to strengthen its capacity to monitor, rapidly detect and coordinate responses to health threats. Together with Decision 1082/2013, various tools[4] were launched to support and coordinate Member States' response planning and actions when faced with cross-border health threats.

(4) A crucial element in the coordination of public health crises of Union relevance is the Health Security Committee (HSC). Its role is to reinforce the coordination of and sharing of best practice and information national preparedness and response planning, to promote the interoperability and intersectoral dimension of such activities, and to establish a mechanism for joint procurement of medical countermeasures.

(5) On 15 July 2020, the Commission adopted the Commission Communication on short-term EU health preparedness[5], which aims at ensuring the EU's short-term health preparedness in case of further COVID-19 outbreaks in Europe. One of the action areas included in this Communication is to achieve, via the HSC, EU level agreement for aligned testing strategies and methodologies.

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1 https://ec.europa.eu/info/sites/info/files/communication_-_short-term_eu_health_preparedness.pdf

2 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN

3 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02013D1082-20131105

4 For example, this includes EWRS, HSC coordination and Joint Procurement, etc.

5 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0318

(6) The Council adopted a Recommendation on the gradual lifting of the temporary restrictions on non-essential travel into the EU on 30 June[6]. This was done on the basis of a set of principles and objective criteria, including the health situation, the ability to apply containment measures during travel, reciprocity considerations and data from relevant sources such as the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO).

(7) The Health Security Committee reached an agreement on 17 September 2020 on "EU health preparedness: Recommendations for a common EU testing approach for COVID-19"[7], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations aim to achieve an agreement on a coherent approach to COVID-19 testing across Europe. Its content is based on the situation in European countries early September 2020 and the respective testing strategies and objectives implemented at that moment.

(8) Member States should aim to avoid any travel bans. To safeguard the freedoms under the single market, any limitations should be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination, and should not extend beyond what is strictly necessary to safeguard public health.

(9) On 13 October 2020, the Council adopted a Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic[8], which sets out, among others, more clarity on the measures applied to travellers from higher-risk areas (testing and self-quarantine) providing clear and timely information to the public.

(10) Effective testing plays a key role in ensuring the free movement of people and allowing the smooth functioning of the internal market. Since the outbreak of the COVID-19 pandemic, the field of diagnostic testing has been rapidly evolving and has underpinned the central role it plays in outbreak control. Recognising the importance of diagnostic tests, the EU is supporting its development through a number of EU Research and Innovation actions[1].The accurate use of COVID-19 testing, in high volumes and by ensuring a rapid turn-around-time between the test request and result plays a significant role in reducing the spread of SARS-CoV-2. Currently, the most reliable methodology for testing of cases and contacts is the RT-PCR (reverse transcription polymerase chain reaction) based testing approach; such tests were among the earliest available when the pandemic reached the European continent.

(11) However, while RT-PCR testing rates have increased across the EU, resulting in the identification of more COVID-19 positive cases, particularly among younger individuals who are showing mild symptoms or who are asymptomatic, laboratories are struggling to ensure that sufficient resources and capacities are in place to keep up with demands. Consequently, this has resulted in shortages of RT-PCR testing materials and longer testing turn-around-times, thereby limiting the effective implementation of mitigation measures as well as swift contact tracing. To mitigate these shortages, the Commission has organised a Joint Procurement of Laboratory

6 https://data.consilium.europa.eu/doc/document/ST-9208-2020-INIT/en/pdf

7 https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf

8 https://data.consilium.europa.eu/doc/document/ST-11689-2020-REV-1/en/pdf

equipment on the 19th of March already, including testing kits and reagents for RT-PCR tests, in which 20 Member States participated.

(12) Despite the implementation of this Joint Procurement, Member States are faced again with problems of limited testing capacities and high testing turn-around-times, particularly in the current epidemiological context where Europe is experiencing a resurge in COVID-19 positive cases. In this context, Member States are increasingly turning to the possibility of using rapid or point of care tests (e.g. antigen tests), mostly in medical settings, and exploring their wider use. This new generation of faster and cheaper COVID-19 tests, allowing for a test result in often less than 30 minutes, are increasingly hitting the market.

(13) The WHO published on 11 September 2020 interim guidance on the use of rapid antigen tests for COVID-19 detection[9], offering countries with advice on the potential role played by these tests and the need for careful test selection. As stressed by WHO, while the rapid antigen tests may offer helpful solutions for the diagnosis of SARS-CoV-2 infection in a range of settings and scenarios, their clinical performance is not (yet) optimal and caution should be exercised.

(14) Among existing models, WHO recommends the use of rapid antigen tests that meet the minimum performance requirements of $\geq$ 80% sensitivity and $\geq$ 97% specificity, and should in particular be used when the availability of RT-PCR tests is temporarily limited or where prolonged turn-around-times preclude clinical utility. The use of rapid antigen tests for screening of individuals offers the potential for rapid identification of those individuals at greatest risk of spreading the infection, particularly in circumstances of high community transmission. Moreover, rapid antigen testing should be conducted by trained operators, in accordance with the manufacturer's instructions and within the first 5-7 days following the onset of symptoms when viral loads are at their peak.

(15) Several Member States[10] have started to use rapid antigen tests in practice and have included their use in their national COVID-19 testing strategies. Additionally, the majority of Member States is currently carrying out validation studies or pilots to assess the clinical performance of rapid antigen tests in specific settings and for the diagnosis of SARS-CoV-2 infection among certain target populations. The Health Security Committee agreed at its meeting on 19 October 2020 that it will develop a common position on the use of rapid antigen tests, addressing, amongst other elements, the application of these tests and the use of their results.

(16) Particularly in the context of incoming travellers at airports, the use of rapid antigen tests has been assessed by the EU Healthy Gateways Joint Action[11]. It provides, amongst others, an analysis of options for laboratory testing methods, the timing of testing of travellers, resources needed and practical arrangements at airports. This may also be relevant for travellers using other transport means.

(17) Moreover, the Commission recently requested the European Centre for Disease Prevention and Control (ECDC) and the European Union Aviation Safety Agency (EASA) to develop a protocol for safer air travel, including a proposal for a common

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9 https://apps.who.int/iris/bitstream/handle/10665/334253/WHO-2019-nCoV-Antigen_Detection-2020.1-eng.pdf?sequence=1&isAllowed=y

10 As of 22 October, these are Belgium, Finland, France, Germany, Greece, Italy and Spain, as well as the UK.

11 https://www.healthygateways.eu/

EU Health Safety testing protocol at airports. The protocol should include elements such as timing of tests, target population, types of test and possible implementation at airports, and could be further expanded to cover other transport modes. The development of testing strategies, based on validated technologies for the specific context and on available capacities, should also inform approaches on quarantine or other restrictions, e.g. the mutual recognition of test results could adequately mitigate the risk of case importation to a level equivalent to or below the prevailing risk within the destination region and therefore lead to lifting of quarantine or other restrictions

(18) The development of testing strategies, based on validated technologies and available capacities, should also inform an EU policy on quarantine. The Commission has tasked the European Centre for Disease Prevention and Control (ECDC) to provide scientific guidance on quarantines with the view to proposing a European approach.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE

(1) This Recommendation sets out guidance for countries regarding key elements to be considered for national, regional or local testing strategies.

(2) In particular, the recommendations focus on the scope of COVID-19 testing strategies, groups to be prioritised, and specific situations to be considered, and address key points linked to testing capacities and resources. Finally, considerations for the use of rapid antigen tests are also put forward.

(3) The recommendations also aim at ensuring testing policies contribute to the smooth functioning of the internal market, cross border travel and free movement of people, services and goods within the Union.

2. TESTING STRATEGIES

(4) Early detection through testing remains essential. Member States should test as widely as possible, and prioritise symptomatic individuals, persons who had contacts with confirmed cases, severe local outbreaks and as far as possible also the testing of asymptomatic individuals, in line with the available resources, testing and contact tracing capacities, and taking into consideration the scenarios presented in the testing guidelines published by ECDC[12].

(5) When sufficient capacities are not available Member States should prioritise the testing of individuals showing COVID-19 compatible symptoms, including mild symptoms, and particularly those presenting symptoms of acute respiratory infection. This should be combined, if possible, with testing for influenza and other respiratory infections, e.g. through available multiplex or other relevant assays. Criteria for prioritisation of testing should be objective and applied in a non-discriminatory manner.

(6) Member States should pay specific attention to avoiding and/or eliminating, the transmission of COVID-19 in healthcare and long-term care settings, such as residential and nursing homes for elderly persons. Staff working in these sectors

[12] https://www.ecdc.europa.eu/en/publications-data/covid-19-testing-strategies-and-objectives

should be tested in regular intervals and testing schemes should be put in place. Moreover, patients should be tested at or just prior to admission to the hospital, and hospitalised individuals should be monitored for COVID-19 symptoms for at least 14 days following admission, and be tested regularly along an agreed scheme (e.g. once a week).

(7) In case of focalised and well identified outbreak clusters, Member States should consider testing the majority of the community concerned, regardless of whether they show symptoms or not, as this may minimise or even avoid the need for introducing more stringent public health measures. Local authorities should develop a testing and compliance scheme for foreseeable critical situations, e.g. in schools or work places.

(8) Member States should ensure that testing schemes are in place for critical staff (including workers in healthcare, long-term care and education), and that these groups have access to frequent COVID-19 testing.

(9) Member States should ensure clear communication and provision of public health based information to citizens. They should also ensure there are centres for testing accessible to their population and an overall participation in COVID-19 testing, particularly in case of asymptomatic testing and in outbreak situations.

3. TESTING CAPACITIES AND RESOURCES

(10) The Commission underlines again that Member States should define the necessary testing capacities and resources (for taking samples, performing the test and contact tracing) based on testing objectives, demand and supply planning, the latest scientific evidence on the characteristics of the disease.

(11) Member States should ensure that capacities and resources are in place that allow for targeted, timely and accurate testing, including a quick turn-around-time of ideally 24 hours between the test request and the result as well as timely contact tracing to facilitate the fast identification and containment of cases and clusters, and the most rapid return to normality for non-affected groups.

(12) In addition, tracking the presence of SARS-CoV-2in wastewater can be used as a complementary way of tracking the spread of the virus in the population, as well as an early warning system. This surveillance is already in place in some Member States and should be expanded as far as possible.

(13) Member States are encouraged, in line with the current ECDC guidance, to conduct RT-PCR tests or validated equivalents for contacts after the exposure, with the aim to shorten the quarantine. Member States are invited to monitor and update national quarantine provisions in line with forthcoming scientific evidence.

(14) Member States should run scenario-based stress tests for testing capacities and testing deployment, as well as contact tracing systems. Such stress tests should not only be performed at national level, but also focus on localised outbreaks and be based on specific scenarios, such as super-spreader events, outbreaks in specific industry sectors, educational settings and residential homes. Member States should share, for example through the Health Security Committee, lessons learnt and best practices post exercise.

(15) Member States should explore cross-border cooperation to ensure sufficient RT-PCR and rapid testing capacities across the EU, for example through the provision of mobile labs or technical running of tests between countries.

4. RAPID ANTIGEN TESTS

(16) Member States should agree on criteria to be used for the selection of rapid antigen tests, particularly those related to their clinical performance such as sensitivity and specificity, as well as reach agreement on the scenarios and settings during which rapid antigen tests are appropriate to be used, such as for example in circumstances of high community transmission.

(17) Member States should actively share and discuss, particularly through the Health Security Committee as well as other knowledge sharing platforms such as the Council's Integrated Political Crisis Response (IPCR), information on results of validation studies carried out on rapid antigen tests within EU countries and independent of such studies conducted by the companies that developed them.

(18) The Commission will work with Member States towards creating a framework for evaluation, approval and mutual recognition of rapid tests, as well as for mutual recognition of test results, as a matter of urgency. Furthermore, the Commission will monitor the market and availability of new rapid antigen tests, taking into consideration their clinical performance and criteria to be agreed, and will establish an information repository of rapid antigen tests and validation study results as they become available across the EU, building on the existing 'COVID-19 In Vitro Diagnostic Devices and Test Methods Database'. The Commission will launch initiatives for the procurement of tests in order to ensure equitable access to rapid antigen tests as well as their swift deployment across the EU.

Done at Brussels, 28.10.2020

For the Commission
Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION