



Brussels, 18.11.2020
C(2020) 8037 final

COMMISSION RECOMMENDATION

of 18.11.2020

on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection

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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) In line with Article 168(7) of the Treaty on the Functioning of the European Union¹, 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, including the use of rapid antigen tests, taking into consideration countries' epidemiological and social situations as well as the target population for testing.
- (2) The number of SARS-CoV-2 infection continues to rise and is putting pressure on healthcare workers involved in sampling as well as laboratories performing the COVID-19 tests, resulting in increasing turn-around-times between the test request and result. Moreover, improved access to COVID-19 test sites and services compared to earlier in 2020 when Europe experienced its first pandemic wave, has resulted in high peaks in testing demands, often exceeding available testing capacities.
- (3) Scientific and technical developments continue to evolve, offering new insights on the characteristics of the virus and the possibilities for using different methodologies and approaches for COVID-19 diagnosis. Currently, the 'gold standard' for COVID-19 diagnostics is the RT-PCR test, which is considered the most reliable methodology for testing of cases and contacts by both the World Health Organisation (WHO) and the European Centre for Disease Prevention and Control (ECDC)².
- (4) A new generation of faster and cheaper tests is increasingly available on the European market: the so-called rapid antigen tests, which detect the presence of viral proteins (antigens), can be used to detect an ongoing infection. In the COVID-19 'In Vitro Diagnostic Devices and Test Methods Database' of the European Commission, 72 CE-marked rapid antigen tests are included³.
- (5) The currently applicable regulatory framework for placing rapid antigen tests on the market is Directive 98/79/EC⁴. According to the Directive, for SARS-CoV-2 rapid antigen tests, the manufacturer must draw up a technical file which explicitly shows that the test is safe and performs as intended by the manufacturer, by demonstrating compliance with the requirements laid down in Annex I of the Directive. Following

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN>

² https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

³ Value as of 12/11/2020, https://covid-19-diagnostics.jrc.ec.europa.eu/devices?marking=Yes&principle=ImmunoAssay-Antigen&format=Rapid+diagnostic+test&manufacturer=&text_name=#form_content

⁴ OJ L 331, 7.12.1998, p. 1–37.

this, the manufacturer may issue an EU declaration of conformity and affix CE-marking to their device. From 26 May 2022, the Directive will be replaced by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices⁵. Under the Regulation, rapid antigen tests will be subject to reinforced requirements on device performance and a thorough assessment by a notified body.

- (6) In line with the Commission Guidelines on COVID-19 *in vitro* diagnostic tests⁶, work is ongoing in the Medical Device Coordination Group (MDCG) of Member States' competent authorities to facilitate coherent application of the legal framework for placing the tests on the market, including guidance to manufacturers under Directive 98/79/EC. In addition, the Commission, with contribution from the MDCG, intends to develop and adopt common specifications according to Regulation (EU) 2017/746 for COVID-19 tests including rapid antigen tests⁷.
- (7) On 15 April 2020, the Commission adopted Guidelines on COVID-19 *in vitro* diagnostic tests and their performance⁸, providing an overview of COVID-19 testing and considerations regarding test performance. It underlines that, in line with Directive 98/79/EC, the manufacturer must state the intended purpose of the device, and that the device must be designed and manufactured so that it is suitable for that intended purpose, including the intended user and clinical aspects such as the target population. The manufacturer must also state the levels of analytical performance of the device, which must correspond to the intended purpose. The information accompanying the device must take account of the training and knowledge of the potential users.
- (8) The WHO published on 11 September 2020 interim guidance on the use of rapid antigen tests for COVID-19 detection⁹, 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.
- (9) 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 that these tests 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 offers the potential for rapid identification of those individuals at greatest risk of spreading the infection, particularly in circumstances of high community transmission.
- (10) ECDC has provided guidance on suitable SARS-CoV-2 testing strategies to achieve specific public health objectives in various epidemiological situations¹⁰. This guidance provides the framework within which testing for SARS-CoV-2 critically contributes to

⁵ OJ L 117, 5.5.2017, p. 176. The Regulation provides for a transition period starting on the date of its entry into force (May 2017) during which the conformity of *in vitro* diagnostic medical devices can be assessed either under the Regulation or under Directive 98/79/EC.

⁶ Communication from the Commission Guidelines on COVID-19 *in vitro* diagnostic tests and their performance (2020/C 122 I/01)

⁷ These common specifications may be applied on a voluntary basis before the date of application of Regulation (EU) 2017/746 which is 26 May 2022.

⁸ Communication from the Commission Guidelines on COVID-19 *in vitro* diagnostic tests and their performance (2020/C 122 I/01)

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

¹⁰ ECDC. COVID-19 testing strategies and objectives. Published on 17.09.20. Available at: <https://www.ecdc.europa.eu/en/publications-data/covid-19-testing-strategies-and-objectives>

generating reliable surveillance data, achieving control of transmission in the community, preventing transmission in high-risk settings, and limiting virus reintroduction in communities that have achieved sustained transmission control.

- (11) Most of the currently available rapid antigen tests show a lower sensitivity compared to RT-PCR tests. The ECDC guidance¹¹ on the use of rapid antigen tests defines the suitability of various testing strategies in different epidemiological contexts, settings, and expected clinical performance, based on currently available evidence. Until now, clinical evaluation studies of rapid antigen tests show a 29% to 93.9% sensitivity and a 80.2% to 100% test specificity, compared to the gold standard RT-PCR test. Sensitivity of rapid antigen tests increases if they are applied to populations up to 5 days of symptom onset and tested in specimens with high viral load.
- (12) However, rapid antigen tests can offer a significant advantage over RT-PCR tests in terms of simplicity of equipment needed, lower demands of highly skilled operators, price and timeliness of results, by providing health services with easy to use and rapid results which will also help to relieve the pressure on healthcare systems. For instance, when used in targeted population-wide testing approaches, the risk of not detecting all cases or risk of false negative results is counter-balanced by the timeliness of results and the possibility of recurred testing of initially negative individuals. The predictive value of a positive or negative test result depends on the test performance and infection prevalence in the population tested. Interpretation of the results of rapid antigen tests should therefore duly consider these elements.
- (13) Regarding the possibility to use of antigen tests in asymptomatic persons, it should be noted that, until now, very limited data is available regarding the performance of rapid antigen tests in this context. Moreover, for the currently available rapid antigen tests, manufacturers' instructions do not mention asymptomatic persons as a target population.
- (14) The possibility to use rapid antigen tests for travellers might be further considered, taking into account the latest scientific and technological developments in light of the epidemiological situation. For example, as announced in the Commission Recommendation on COVID-19 testing strategies of 28 October 2020, ECDC and the European Union Aviation Safety Agency (EASA) are jointly developing a protocol for safer air travel, including for a common testing approach at airports.
- (15) A key body in the coordination of public health crises of Union relevance is the Health Security Committee (HSC). Its role is to reinforce the coordination and sharing of best practice and information on national preparedness and response planning. The use of rapid antigen tests has been discussed since early September 2020. Several Member States 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 are 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.
- (16) The Commission Recommendation on COVID-19 testing, including the use of rapid antigen tests of 28 October 2020¹² sets out guidance for countries regarding key elements to be considered for national, regional or local testing strategies. It provides

¹¹ Guidance on a common validation protocol for rapid antigen tests, from ECDC, to be published on 18.11.2020

¹² C(2020) 7502

recommendations focused on the scope of COVID-19 testing strategies, groups to be prioritised, and specific situations to be considered, and addresses key points linked to testing capacities and resources.

- (17) It also recommends that 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 to 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.
- (18) The Recommendation also included a commitment by the Commission to 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, which this Recommendation contributes towards.
- (19) Economic operators must comply with the requirements set out in the applicable EU law. By fulfilling these requirements and affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and that its product can be sold throughout the EEA. Member States have the possibility to restrict the availability of certain devices if they believe this is in the interest of protection of health and safety or in the interest of public health¹³. The choice of tests at national level depends on the availability of the tests as well as national testing strategies in place, including, for example, the purposes for which the tests are intended to be used, in what combinations, and the accepted levels of performance, taking into consideration the epidemiological and clinical situation of the concerned Member State, region, particular health institution or patient group. Cooperation at EU level in assessing the evidence gathered from the use of these tests in clinical practice, including through the Joint Action EUnetHTA, can provide important benefit to inform national strategies.
- (20) Effective testing plays a key role in the smooth functioning of the Internal Market as it allows for targeted isolation or quarantine measures. Mutual recognition of rapid antigen tests would allow limiting restrictions of free movement in line with the Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic¹⁴.
- (21) Member States health services should mutually recognise results of rapid antigen tests following the guidance set out in this Recommendation. To support mutual recognition, joint discussions of national testing strategies among Member States should continue, notably in the Health Security Committee and taking into account input received from ECDC and other relevant cooperation efforts, such as the EUnetHTA Joint Action.
- (22) EU cooperation in the area of Health Technology Assessment (HTA) has proven useful to HTA national authorities by providing guidance related to SARS-CoV-2, including on the use of antigen tests. The Commission has proposed to further strengthen cooperation at EU level on HTA¹⁵. The implementation of an EU HTA framework would provide an important instrument to work jointly, pool resources, share expertise and provide evidence necessary to inform decisions including on the use of antigen tests.

¹³ Articles 8 and 13 of Directive 98/79/EC.

¹⁴ OJ L 337, 14.10.2020, p. 3.

¹⁵ Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018) 51 final)

- (23) Furthermore, in order to provide additional support to Member States for introducing the use of rapid antigen tests, the Commission has identified EUR 100 million from the European Support Instrument (ESI) for the purchase and distribution of rapid antigen tests to Member States. In addition, the Commission has launched a joint procurement with Member States to facilitate the fair and equitable access to rapid antigen tests.
- (24) This Recommendation is based on the latest guidance from ECDC and WHO. It may be updated in the light of new scientific evidence, the latest technological developments and evolving epidemiological situation.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE OF THE RECOMMENDATION

- (1) This Recommendation sets out guidance for Member States regarding the use of rapid antigen tests to detect SARS-CoV-2 infection, drawing on the Recommendation of 28 October on COVID-19 testing strategies.
- (2) It recommends Member States to conduct rapid antigen tests in addition to RT-PCR tests in clearly defined settings where the deployment of antigen tests is appropriate, and with the aim to contain the spread of the coronavirus, to detect SARS-CoV-2 infections and to limit isolation and quarantine measures.
- (3) This Recommendation also contributes to ensuring the free movement of persons and the smooth functioning of the internal market, in times of limited testing capacities.
- (4) In particular, the present Recommendation focuses on criteria to be used for the selection of rapid antigen tests, the settings during which rapid antigen tests are appropriate to be used, test operators, and validation and mutual recognition of rapid antigen tests and their results.

2. SELECTION CRITERIA OF RAPID ANTIGEN TESTS

- (5) Member States should aim to use rapid antigen tests with acceptable test performance, i.e. $\geq 80\%$ sensitivity and $\geq 97\%$ specificity, to avoid as many false negative and false positive test results as possible.
- (6) Rapid antigen testing should be conducted by trained healthcare personnel or trained operators where appropriate, and in accordance with manufacturer's instructions. A critical point, often neglected, is the collection of the sample. Protocols for an efficient sample acquisition and handing should also be available.
- (7) Rapid antigen tests should be used within five days after the onset of symptoms or within seven days after exposure to a confirmed COVID-19 case.
- (8) Before rapid antigen tests are adopted for use, Member States should ensure that such tests carry a CE-marking¹⁶ and, before they are introduced into clinical practice, that those tests have been validated, as described in this Recommendation, against the standard RT-PCR tests and within the target population and setting intended for use.

¹⁶ All rapid antigen tests used by Member States should carry a CE-marking with the exception of devices referred to in Article 1(5) of Directive 98/79/EC.

3. RECOMMENDED SETTINGS FOR THE USE OF ANTIGEN TESTS

- (9) When the availability of RT-PCR tests is temporarily limited, the use of rapid antigen tests can be considered for individuals with COVID-19 compatible symptoms in areas where the proportion of test positivity is high or very high, e.g. $\geq 10\%$.
- (10) The use of rapid antigen tests can be recommended to test individuals, regardless of symptoms, in settings where the proportion of test positivity is expected to be $\geq 10\%$, e.g. in the context of contact tracing and outbreak investigations.
- (11) In order to mitigate the impact of COVID-19 in healthcare and social-care settings, rapid antigen tests use should be considered at admission to healthcare facilities, as well as for triage of symptomatic patients or residents (up to 5 days since symptom onset), including for assigning patients to isolation facilities.
- (12) Rapid antigen tests use should also be considered for a targeted population-wide testing approach, e.g. in a local community as well as in other high prevalence situations, and in the context of restrictive measures, in order to detect individuals with high transmission potential in the community and to lower the pressure on health-care settings. In such situations, the risk of not detecting all cases or the risk of false negative results is counter-balanced by the timeliness of results and the possibility of recurrent testing of initially negative individuals. A confirmatory test will allow further informing the diagnosis, as stated in this Recommendation.
- (13) In high prevalence situations and/or with limited RT-PCR testing capacity to detect the individuals with high transmission potential, rapid antigen tests use should be considered for recurring testing (e.g. every 2-3 days) of staff of health-care, home and social care, other long-term care facilities, closed settings (e.g. prisons or administrative detention centres, other reception infrastructures for asylum seekers and migrants), other relevant frontline workers in relevant sectors (meat processing plants, slaughterhouses, etc.) and other similar settings.
- (14) In low prevalence situations, the use of rapid antigen tests should be focused on settings and situations where a fast identification of infected individuals is supporting the management of outbreaks and the regular monitoring of (high) risk groups, such as medical personnel or other long-term care facilities. The risk related to missing positive cases and the risk related to implementing isolation and quarantine measures due to falsely identified positive cases need to be assessed in such situations. This could be addressed by a confirmatory test.
- (15) If a rapid antigen test is used in a population with high infection prevalence, negative results should be confirmed either by RT-PCR or by a repeated rapid antigen test. If a rapid antigen test is used in a population with low infection prevalence, positive results should be confirmed either by RT-PCR or by a repeated rapid antigen test. In both situations, the use and choice of the confirmatory test depends on the tolerability of the risk associated with missing positive cases or with detecting falsely positive cases.

4. TESTING CAPACITIES AND RESOURCES

- (16) In addition to the considerations above, the choice of a given diagnostic test depends on existing testing capacities. If there are shortages of RT-PCR assays or if the result turn-around-time of these is beyond 24 hours, the choice of a rapid antigen tests can

be justified, depending on the intended use and the tolerability of the risk associated with its performance limitations.

- (17) Trained healthcare and laboratory staff are needed to carry out sampling, testing, test analysis and reporting of test results to clinical staff and public health authorities at local, regional, national and international level. Manufacturer instructions for sample collection, safe handling, use and disposal need to be strictly followed, including specimen type and intended use. Appropriate biosafety measures must be in place when sampling, handling and processing specimens. Member States need to ensure sufficient capacities and resources for sampling, testing and reporting. To ensure these capacities, it might be necessary to train additional test operators other than healthcare personnel.
- (18) Medical laboratories, notably the laboratories being part of the EU network accredited by national bodies of the Member States on the basis of harmonised standard EN ISO 15189 ‘Medical laboratories - Requirements for quality and competence’ and possibly additional standards and requirements, fulfil high quality requirements and could play an active role in rapid antigen testing. Accreditation also ensures that these laboratories are controlled on a regular basis and comply with the necessary quality and competence requirements.
- (19) Capacity for confirmatory RT-PCR testing needs to be in place when applying rapid antigen tests as appropriate.

5. VALIDATION AND MUTUAL RECOGNITION

- (20) Member States should use technical guidance developed by ECDC¹⁷ on the use of rapid antigen tests for COVID-19, particularly as regards the clinical validation of these tests, to ensure reliability and comparability of results, when performing independent validations of rapid antigen tests.
- (21) Considerations for rapid antigen test validations, as described in the technical guidance by ECDC, will include elements on validation of tests under similar settings as its intended use, respect of the manufacturer’s instructions, comparison to the current RT-PCR gold standard, elements on retrospective approaches and categorisation of samples.
- (22) Member States should share with ECDC and the Commission, as soon as they become available, their validation results and corresponding testing strategies by intended use, with the aim of aligning them as much as possible with other Member States, and share any other information on results of validation studies carried out on rapid antigen tests independently of studies conducted by test developers and manufacturers. Testing strategies should consider continuously the new information coming from these validation studies and be adapted accordingly, if necessary.
- (23) The Commission will extend the existing COVID-19 diagnostic test database (‘COVID-19 In Vitro Diagnostic Devices and Test Methods Database’) with information on rapid antigen tests and validation studies results and keep the database updated with the latest information.
- (24) ECDC, in cooperation with Commission services and Member States, will prioritise and coordinate the validation of existing and upcoming types of rapid tests (e.g. with

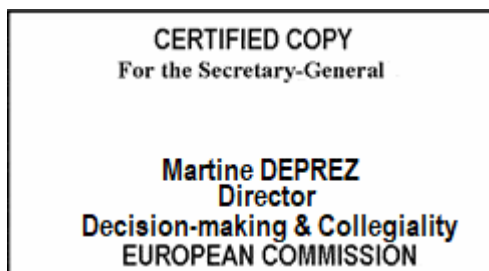
¹⁷ ECDC technical guidance, Options for the use of rapid antigen tests for COVID-19, published on 18/11/2020

different measurement techniques or sample specimen such as saliva) to facilitate an efficient entry of new tests, which meet the required performance criteria, into practice and alleviate pressures on testing and healthcare systems.

- (25) The Commission will facilitate joint work and exchange of information on nationally conducted health technology assessments on rapid antigen tests between Member States.
- (26) Mutual recognition of test results, as provided for in point 18 of Council Recommendation 2020/1475¹⁸, is essential in order to facilitate cross border movement, cross border contact tracing and treatment. Results performed with tests that have been validated at national level by one Member State and that meet the criteria of sensitivity and specificity of this Recommendation, should be recognised by other Member States.

Done at Brussels, 18.11.2020

For the Commission
Stella KYRIAKIDES
Member of the Commission



¹⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1475&from=EN>