TECHNICAL REPORT

An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA

1 April 2020

Introduction

According to EU recommendations [1], timely and accurate COVID-19 laboratory testing is an essential part of the management of COVID-19 for slowing down the pandemic, supporting decisions on infection control strategies and patient management at healthcare facilities, and detecting asymptomatic cases that could spread the virus further if not isolated.

Wider testing is crucial for COVID-19 control

ECDC and the World Health Organization (WHO) currently recommend COVID-19 diagnosis by molecular tests which detect the SARS-CoV-2 virus RNA. This is generally the current test strategy in Member States. However, these tests require well-equipped laboratory facilities, highly skilled technologists and multiple reagents. Currently, infrastructure limitations and supply shortages are limiting testing capacity below the growing demand for COVID-19 diagnostics across the EU. Therefore, access to reliable rapid diagnostic tests, in particular rapid antigen tests for COVID-19, could alleviate the pressure on laboratories and expand testing capacity to meet the most urgent medical and public health needs.

What COVID-19 rapid tests are available in the EU?

Rapid tests are qualitative or semi-quantitative in vitro diagnostics (IVDs), used singly or in a small series, which involve non-automated procedures and have been designed to give a fast result [2]. For COVID-19, rapid tests may take around 10-30 minutes until giving a result compared with about four hours for molecular tests done in large series, or more if samples must be transported to a distant testing laboratory. These rapid tests are relatively simple to perform and interpret and therefore require limited test operator training. They may be intended either for use in hospital laboratories or near the point-of-care.

There are two types of COVID-19 rapid tests currently in use or in development: direct SARS-CoV-2 antigen detection and indirect antibody detection tests. Antigen detection tests detect viral components present during the infection in samples like nasopharyngeal secretions. Antibody tests detect the antibodies that later appear in serum as part of the immune response against the virus.

Suggested citation: European Centre for Disease Prevention and Control. An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA. 1 April 2020. Stockholm: ECDC; 2020.

Rapid antigen tests: The non-governmental organisation FIND (https://www.finddx.org/) lists ten CE-marked rapid SARS-CoV-2 antigen detection tests, meaning they conform with the relevant EU legislation, Directive 98/79/EC on IVDs. However, they are not necessarily available to purchase on the EU market as the manufacturer may mark them for third-country markets or there may not be distributors selling these devices in all Member States. Reports from competent authorities of 18 European countries indicate three such CE-marked devices as of 26 March 2020.

Rapid antibody tests: In addition, there are many (over 60) CE-marked rapid SARS-CoV-2 antibody tests and more continue to be placed on the market. Research groups have also developed and are validating in-house antibody detection tests for SARS-CoV-2 [3, 4] which may serve as potential platforms for commercial tests in the near future. It should be underlined that SARS-CoV-2 antibody detection tests have limited usefulness for early COVID-19 diagnosis as it can take 10 days or more after onset of symptoms for patients to become positive for detectable antibodies [3,4], and because the antibodies persist long after the infection has cleared.

Are all CE-marked COVID-19 rapid tests ready to use in routine diagnostics?

According to IVD Directive 98/79/EC, to affix the CE-mark to COVID-19 diagnostic devices to be used by health professionals, the manufacturer has to specify device performance characteristics and self-declare conformity with the safety and performance requirements listed in the Directive. In contrast, self-tests intended to be used by patients themselves must also be assessed by a third party body (a notified body).

The dedicated Commission working group of Member States competent authorities for IVD serves as a forum for continuous exchange of technical and regulatory information on IVDs including COVID-19 rapid tests. While the majority of CE-marked rapid tests are compliant with EU law, the group has identified several devices with fraudulent documentation, incomplete technical files or unsubstantiated claims. Some of those were sold as alleged self-tests. Several Member States have warned against the use of rapid self-tests or even prohibited them.

For compliant CE-marked rapid diagnostic tests, their performance may vary in the routine testing laboratory in comparison with the performance study of the manufacturer done for the purposes of CE-marking. Rapid tests may also be less accurate and less sensitive than laboratory-performed diagnostic tests. Therefore, clinical validation of the diagnostic performance of rapid tests for COVID-19 in real-life should be carried out by comparison with a gold standard test in a sufficiently large number of target population subjects before introducing them into the routine as a stand-alone diagnostic test.

WHO referral laboratories for COVID-19 are currently performing validation studies of commercial assays. European Commission and Member States are funding fast-track clinical validation studies of rapid diagnostic tests for COVID-19 by hospital laboratories in several EU Member States. Scientific publications of results should soon clarify the clinical performance and limitations of rapid diagnostic tests and indicate which tests can be used safely and reliably for specific medical or public health purposes. ECDC is working in close cooperation with the European Commission, Member State authorities, FIND (https://www.finddx.org/) and WHO on ongoing validation of these rapid tests and will inform the EU/EEA countries on results as soon as those are available.

Once rapid tests are validated for a specific COVID-19 testing purpose they will be beneficial for pandemic control, subject to device production and distribution being rapidly scaled up to complement molecular tests and support decentralised testing capacity.

The priorities for rapid testing in EU countries that are now dealing with community transmission should follow EU and WHO guidance on testing strategies [1, 5]. These include: testing people who are at risk of developing severe disease, patients with acute respiratory illness who require hospitalisation and advanced care for COVID-19, symptomatic health workers and the first symptomatic individuals in a closed setting such as prison or nursing care facility.

ECDC recommends following the WHO technical guidance on testing the clinical specimens (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance). ECDC's advice for SARS-CoV-2 testing is available at: https://www.ecdc.europa.eu/en/novel-coronavirus/laboratory-support. ECDC will update its guidance when more information on validated rapid tests and evidence on their performance becomes available.

Internal contributors

Eeva Broberg, Maria Keramarou, Csaba Ködmön, Katrin Leitmeyer, Angeliki Melidou and Marc Struelens

Information on regulatory aspects of rapid diagnostic tests contributed by Olga Tkachenko, European Commission, Directorate-General for Health and Food Safety.

References

1. European Commission. EU Recommendations for testing strategies. 2020. Available here: https://ec.europa.eu/info/sites/info/files/covid19_-_eu_recommendations_on_testing_strategies_v2.pdf
2. Official Journal of the European Union 2009/108/EC: Commission Decision of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for in vitro -diagnostic medical devices (notified under document number C(2009) 565). Available here: https://eur-lex.europa.eu/eli/dec/2009/108(1)/oj
3. Okba N, Muller M, Li W, Wang C, Geurts vanKessel C, Corman V et al medRxiv 2020. SARS-CoV-2 specific antibody responses in COVID-19 patients. Available here: https://doi.org/10.1101/2020.03.18.20038059
4. Amanat F, Nguyen T, Chromikova V, Strohmeier S, Stadlbauer D, Javier A et al. A serological assay to detect SARS-CoV-2 seroconversion in humans. medRxiv 2020. Available here: https://doi.org/10.1101/2020.03.17.20037713
5. World Health Organization. Laboratory testing strategy recommendations for COVID-19. March 2020. Available here: https://apps.who.int/iris/bitstream/handle/10665/331509/WHO-COVID-19-lab_testing-2020.1-eng.pdf