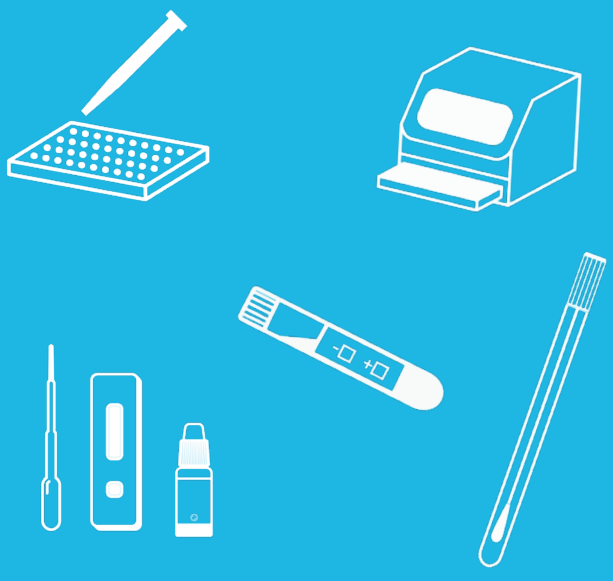
European Commission

COVID-19 TESTS

Q&A on *in vitro* diagnostic medical device conformity assessment and performance in the context of COVID-19



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Abbreviations and terms

The following explanations are intended to assist the lay reader and are not legal definitions. For the latter please consult Directive 98/79/EC or other relevant legislation.

- **authorised representative** – an organisation that legally represents a manufacturer in the EU, when the manufacturer is based outside the EU;
- **CE marking** – symbol "CE" marked on the product, demonstrating that the product satisfies the applicable EU requirements;
- **competent authority** – a government body that implements and enforces legislation, in this case in the field of *in vitro* diagnostic medical devices;
- **distributor** – a natural or legal person making devices available in the Union, other than the manufacturer or the importer;
- **importer** – a natural or legal person importing devices into the EU from outside the Union;
- **IVD – *in vitro* diagnostic medical device**, a medical device intended by the manufacturer for the *in vitro* examination of specimens derived from the human body for a medical purpose;
- **manufacturer** – natural or legal person responsible for the production, packaging and labelling of the device before it is placed on the market in their own name;
- **notified body** – an organisation that issues certificates to manufacturers, demonstrating that the manufacturer has fulfilled certain legal requirements;
- **self-test** – device intended by the manufacturer to be used by lay persons in a home environment.

For readability, the term "COVID-19 tests" in this document refers to COVID-19 *in vitro* diagnostic medical devices, unless stated otherwise. The term "device" is used as shorthand for *in vitro* diagnostic medical device.

Types of test

1. What is the difference between a medical device and an *in vitro* diagnostic medical device?

A medical device is a device intended by its manufacturer for a medical purpose, such as treatment of disease, alleviation of a handicap or investigation of a physiological process[1]. A cardiac stent, an X-ray machine or a leg prosthesis are medical devices. They are regulated at EU level by two pieces of legislation: Directive 90/385/EEC on active implantable medical devices (e.g. pacemakers) and Directive 93/42/EEC on other medical devices (e.g. the cardiac stents or X-ray machines). The Directives are to be replaced by Regulation (EU) 2017/745 as of 26 May 2021.

An *in vitro* diagnostic medical device is a subtype of medical device intended specifically for examination of specimens that come from the human body for a medical purpose, e.g. to give a diagnosis or to monitor treatment[2]. In contrast to the examples of medical devices in the previous paragraph, they are not intended for contact with the patient directly but rather for contact with specimens coming from the patient (such as blood or urine) or for analysing data coming from a specimen. *In vitro* diagnostic medical devices are governed by a specially dedicated EU law: Directive 98/79/EC (and as of 26 May 2022, Regulation (EU) 2017/746, see **question 6** and **question 13**). An *in vitro* diagnostic medical device must bear an indication that it is for *in vitro* use[3] on its label, distinguishing it from a medical device.

This document refers to placing COVID-19 *in vitro* diagnostic tests on the market under Directive 98/79/EC, unless stated otherwise.

2. What kinds of COVID-19 tests are there?

There are broadly two types of COVID-19 *in vitro* diagnostic tests performed on specimens from the human body in terms of the scientific rationale: those detecting the SARS-CoV-2 virus (e.g. the RT-PCR[4] tests detecting the viral genetic material, or antigen tests detecting the viral protein) and those detecting the immune response of the human body to the infection (e.g. antibody tests).[5]

[1] See Article 1 (2) (a) of Directive 93/42/EEC or Article 1 (2) (a) of Directive 98/79/EC for a full definition.
[2] See Article 1 (2) (b) of Directive 98/79/EC for a full definition.
[3] For example, a symbol "IVD", as mentioned in standard EN ISO 15223-1:2016 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*, harmonised (OJ L 090I, 25 March 2020)
[4] Reverse transcription polymerase chain reaction
[5] See also information from the European Centre for Disease Prevention and Control here: https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing

Tests can also be further classified by:

- intended user (healthcare professional vs lay user, the latter are termed self-tests);
- type of technology (automated, manual, or rapid tests which are non-automated and designed to give a fast result);
- location of testing (sent off to a laboratory or performed near the patient, the latter also referred to as point-of-care tests).

More information is available in the Communication from the Commission Guidelines on COVID-19 in vitro diagnostic tests and their performance[6].

The manufacturer may intend their test for a medical purpose (e.g. diagnosis of COVID-19). In this case they are termed *in vitro* diagnostic medical devices and they fall in the scope of Directive 98/79/EC[9] (see **question 6**) and must be CE-marked according to that Directive before being placed on the market. If the manufacturer intends their test for a non-medical purpose such as research, that Directive does not apply (see **question 4**).

There are also tests that are done directly on patients rather than on specimens, such as computerised tomography (CT) scans. Such medical devices do not fall under the definition of *in vitro* diagnostics and they are covered by separate dedicated EU legislation (Directive 93/42/EEC). They are not covered in this document.

3. What are in-house/lab-developed tests?

In-house tests, or lab-developed tests, are devices manufactured and used within the same health institution, without being transferred to another legal entity[7]. They are not considered to be placed on the market and they are exempt from the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices. Nevertheless, they may be subject to national requirements[8].

These are distinct from devices for research use only, which are also outside the scope of Directive 98/79/EC.

4. What are research-use-only (RUO) tests in the context of COVID-19?

In general terms research-use-only (RUO) products are outside the scope of Directive 98/79/EC on *in vitro* diagnostic medical devices because they are placed on the market without an intended medical purpose. RUO tests could be used e.g. for studying the distribution of antibodies in the population or to develop new drugs, but not for medical purposes such as diagnosing COVID-19 or making treatment decisions for a patient. The requirements of Directive 98/79/EC do not apply for such research uses.

[6] OJ C 122I, 15.4.2020, p. 1–7 .
[7] See Article 1(5) of Directive 98/79/EC.
[8] For instance, national legislation may require that in-house tests fulfil the essential requirements.

The manufacturer's information accompanying RUO products must explicitly state that they are for research use only, and they must not have instructions regarding diagnosis or other medical use, which are contradictory to the research-use-only purpose.

5. Is there an EU database providing an overview of COVID-19 tests?

At the moment, there is no exhaustive public EU database of CE-marked *in vitro* diagnostic medical devices on the market in the EU Member States.

However, as part of EU efforts to provide guidance on the use of coronavirus tests, the Commission's Joint Research Centre has created a database of COVID-19 *in vitro* diagnostic devices and test methods that gathers information on available tests in one place.

The database contains publicly available information on devices, including elements of performance, and a collation of relevant scientific literature. It is regularly updated.

It does not include manufacturer technical documentation, which is not publicly available.

Although not an EU database, the page maintained by the Foundation for Innovative New Diagnostics lists information on COVID-19 tests around the world.

These databases do **NOT** represent a list of devices approved or authorised for use either by the European Commission or by Member State national authorities. There is no central approval or authorisation system for *in vitro* diagnostic medical devices in the EU (see also **question 8**).

Legal framework for COVID-19 *in vitro* diagnostic medical devices

6. What is the legal framework for COVID-19 *in vitro* diagnostic tests with a medical purpose in the EU?

COVID-19 tests that are intended by the manufacturer for *in vitro* examination of specimens derived from the human body, with a medical intended purpose, are *in vitro* diagnostic medical devices (IVDs). The currently applicable legislation in the EU for such products is Directive 98/79/EC (see **questions 3** and **4** for some exceptions). The Directive specifies what intended purposes it covers[9]. The requirements laid down in the Directive are of a general nature (see also **question 7** and **question 23**). An introduction can be found in the European Commission services' Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context.

[9] See Article 1 (2) of Directive 98/79/EC for a definition of *in vitro* diagnostic medical device and further specification of intended purposes covered.

The Directive will soon be replaced by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. The Regulation will apply from 26 May 2022, but IVDs that comply with it may already be placed on the market on a voluntary basis. Please note that, as we are in the transition period, not all structures foreseen by the Regulation have been established yet and this may affect the possibility to place devices on the market under this framework (for example, as of January 2021, expert panels and EU reference laboratories are not yet in place). See **question 13** for more information on the Regulation.

This document refers to placing COVID-19 *in vitro* diagnostic tests on the market under Directive 98/79/EC, unless stated otherwise.

7. What are the procedures for placing COVID-19 *in vitro* diagnostic medical devices on the EU market?

In summary, all kinds of COVID-19 IVDs described in **question 2**, provided they fulfil the definition in Article 1 (2) (b) of Directive 98/79/EC, must bear CE marking as proof of their compliance with the applicable requirements of Directive 98/79/EC to be placed on the EU market. It is the responsibility of the manufacturer to affix the CE marking on this type of product.

Before affixing the CE marking, the manufacturer must first verify compliance of the device with the legal requirements, and prepare the technical documentation with evidence regarding the safety and performance of the device. This must cover a wide range of elements stipulated by Directive 98/79/EC[10], such as a general description of the product, the documentation of the quality system, detailed design information, the results of a risk analysis, adequate performance evaluation data, stability studies, labels, instructions for use *etc*.

The manufacturer has to apply specific conformity assessment procedures to place the device on the market. The applicable procedures depend on the kind of device and are described in Article 9 of Directive 98/79/EC.

For COVID-19 IVDs, the procedures depend on the intended user. They are different for tests for professional use, which are intended to be used by healthcare professionals, and for self-tests that are intended to be used by lay persons.

- For a COVID-19 device that is intended to be used by professionals, the manufacturer must draw up the EC declaration of conformity. They may then affix the CE marking to the device and place it on the market (these tests are frequently referred to as “self-declared” tests, although this term is not mentioned in the Directive).
- For COVID-19 devices that are intended to be used by lay persons (self-tests to be used at home), in addition to the above a third-party assessment body (a notified body) is involved. The notified body will ensure that the device design and the information provided for its use are suitable for non-professional users, and will issue the corresponding certificate (more information in **question 15**).

[10] See Annex III (3) of Directive 98/79/EC.

A manufacturer located outside the EU must designate an authorised representative within the EU (see also **question 16**).

Manufacturers, or their authorised representatives (see **question 16**), are obliged to notify the competent authorities of the Member State in which they have their registered place of business of the address of this place of business and of basic information on the device[11]. The competent authorities are not required to perform any verification of the device at this stage, and the notification does not constitute any "market approval" or similar (see also **question 8**). Notification is required under Directive 98/79/EC only for the Member State where manufacturers or authorised representatives have their registered place of business, i.e. Directive 98/79/EC does not impose notification of the device in every country where the device is sold. However, there may be additional national notification or registration requirements for market operators, such as registration of importers and distributors.

In addition to these rules, some specific national requirements can also exist, such as language requirements for the information accompanying the device (for example, of the labelling and instructions for use). For further information please contact the relevant competent authority. The contact details of national competent authorities may be found on the European Commission's webpage.

More information on legitimate conformity documents can be found in the European Commission guidance document How to check if medical devices and PPE can be lawfully placed on the EU market in the COVID-19 context.

8. Do national competent authorities, the European Commission or any EU agency approve or authorise COVID-19 tests?

National competent authorities do not approve or authorise COVID-19 tests before they are placed on the market. There is also no central approval or authorisation for COVID-19 tests by European Union institutions, such as the European Commission, nor by any EU agency (for example neither the European Medicines Agency nor the European Centre for Disease Prevention and Control).

The legally mandatory procedures the manufacturer must follow to place a test on the market are summarised in **question 7**, including the notification of tests to national competent authorities. For more information about the role of the competent authorities, see **question 14**.

Under Directive 98/79/EC, manufacturers may place COVID-19 tests on the market without any explicit permission from authorities after they have declared the compliance of the product with the legislation and affixed the CE marking on the product themselves. For self-tests, the situation is different. A notified body must confirm that the device design and the information provided for its use is suitable for non-professional users and issue the corresponding certificate. This is an additional requirement before the manufacturer can draw up the EC declaration of conformity (see **questions 7** and **15** for

[11] See Article 10 of Directive 98/79/EC.

more information). The EC declaration of conformity issued by the manufacturer is always a prerequisite to place a device on the market, regardless whether it is a self-test or not.

Therefore, statements that a manufacturer has "received", "obtained" or "was granted" the CE marking, "EU/CE/CE-IVD approval/authorisation", "permission for market access" or similar, are incorrect and should not be used for COVID-19 tests placed on the EU market under Directive 98/79/EC.

9. Is there an emergency market access procedure in the EU under the current legislation?

Directive 98/79/EC foresees the possibility of granting a national derogation from conformity assessment procedure(s), if the use of individual devices is in the interest of protection of health[12]. Such a derogation can be issued by the competent authority of a Member State and is valid only in that Member State, i.e. it does not grant access to the EU market. The derogation would mean that the manufacturer can make the device available before completing all the conformity assessment procedures and CE-marking the device, e.g. before all the necessary safety testing took place. According to national requirements, such early market access is usually temporary until the manufacturer has fulfilled all conformity assessment requirements. After this, only the CE-marked version of the device can be marketed.

Granting a derogation must be carefully considered by the national competent authority to ensure that the risks are outweighed by the benefit of having the device available for use and that this action is indeed in the interest of protection of health.

An emergency use authorisation granted by the Food and Drug Administration of the United States of America is not valid in the EU.

10. What legislation is applicable to swabs and lancets?

Swabs for obtaining a sample of nasal secretions or lancets for obtaining a sample of blood are intended for direct contact with the human body. They are also invasive devices, i.e. they penetrate the body either through a body orifice or through the surface of the body. The applicable legislation has been explained in a guidance document endorsed by the competent authorities[13]. Such products are medical devices but not *in vitro* diagnostics, i.e. they fall in the scope of Directive 93/42/EEC and not Directive 98/79/EC (see also **question 1**). They must satisfy the requirements of Directive 93/42/EEC and bear CE marking according to that Directive.

[12] See Article 9(12) of Directive 98/79/EC.
[13] MEDDEV 2.14/1 rev. 2 here

11. What legislation is applicable to combinations of swabs and lancets and COVID-19 tests?

A test package could consist of e.g. a swab or a lancet, reagents and equipment to process the sample and obtain the result. Such a combination of several components that are made available together would constitute a kit, as mentioned in the definition of an IVD in Directive 98/79/EC[14] and explained in a guidance document endorsed by the IVD competent authorities[13]. If the intended purpose of the kit falls under the definition of an IVD, the whole kit must be CE-marked according to Directive 98/79/EC. However, the swab or the lancet, which is a medical device but not an *in vitro* diagnostic, must be CE-marked according to Directive 93/42/EEC (see also **question 1** and **10**) even if it is a component of the IVD kit.

12. Where can I obtain further guidance on complying with Directive 98/79/EC on *in vitro* diagnostic medical devices?

First of all it is essential to examine the text of the Directive 98/79/EC carefully to determine which legal requirements are applicable in your particular case.

Secondly, a number of guidance documents endorsed by the EU competent authorities are available on the European Commission's webpage. General guidance documents for the Directives are called MEDDEVs. They cover a variety of topics from borderline (determining whether a product is an IVD or not) to details of instructions for use. There are also several COVID-19-specific guidance documents issued by the Commission, notably:

- Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context
- How to check if medical devices and PPE can be lawfully placed on the EU market in the COVID-19 context
- Guidance on COVID-19 in vitro diagnostic tests and their performance

Please check the website regularly as further guidance may be published.

There may also be additional national legal obligations, and guidelines at national level may also be available. You are strongly advised to research these and check the website of the relevant national competent authority. The details of the national competent authorities may be found on the European Commission's webpage.

In the case of devices that need to be assessed by a notified body, further information may be available on the website of the notified body.

It is the responsibility of the manufacturer to determine exactly which steps must be taken to ensure that their device complies with the requirements of Directive 98/79/EC. While notified bodies,

[14] See Article 1 (2) (b) of Directive 98/79/EC

competent authorities and the European Commission may provide general information, they do not provide consultancy services to manufacturers to assist with compliance of their devices.

13. Directive 98/79/EC is being replaced by Regulation (EU) 2017/746. What changes will it bring?

Regulation (EU) 2017/746 will come into application on 26 May 2022. It will significantly change the regulatory framework for IVDs in the EU. For example, it introduces a risk-based device classification system, replacing the simple list of high-risk devices under Directive 98/79/EC. COVID-19 IVDs will generally be classified in the highest risk class, class D[15]. The Regulation introduces assessment by third-party bodies independent from the manufacturer (the notified bodies) for the vast majority of IVDs, including COVID-19 devices. It lays down extensive and stringent requirements for device performance, for the studies that the manufacturer must perform and for the evidence he must furnish to show that the device is safe and performant. Novel devices will be further assessed by an independent panel of experts. Under the Regulation the Commission may designate EU reference laboratories to verify the performance of the devices. Importantly, the Regulation allows development of legally binding EU-wide rules on device performance (the common specifications).

The Commission, Member States and stakeholders are currently engaged in intensive work to implement Regulation (EU) 2017/746. Please consult the European Commission's medical device page for regular updates.

Actors and their roles

14. What is a national competent authority and what is their role for COVID-19 tests?

A competent authority is a government body in a given country entrusted with the implementation and enforcement of the law in a particular sector, for example in the field of *in vitro* diagnostic medical devices. It may be a government department or an agency legally entrusted by the government to perform this function. The contact details of national competent authorities for medical devices may be found on the European Commission's webpage. The European Commission facilitates cooperation and coordination among the competent authorities of the Member States.

According to Directive 98/79/EC, Member State competent authorities do not assess files of individual devices before they are placed on the market. Manufacturers and authorised representatives (see **question 17**) do need to contact the national competent authorities to notify their devices and other basic information prior to placing them on the market.

[15] The classification depends on the intended purpose as stated by the manufacturer, see Annex VIII of the Regulation.

The role of the competent authorities also includes designation and oversight of notified bodies involved in assessment of COVID-19 self-tests (see **questions 7** and **16**).

The national competent authorities have the duty to engage in surveillance of devices already made available on the market[16]. As part of this, they may request the manufacturer to provide the full technical documentation or conduct testing of devices. The national authorities are empowered to take actions concerning non-compliant medical devices, which may include restriction, prohibition or withdrawal of products from the market.

The authorities are also engaged in vigilance, i.e. the central recording and evaluation of serious incidents reported by manufacturers, medical practitioners etc. according to national rules. This could be e.g. a failure of a device which may lead to serious deterioration of a person's health. The competent authorities may take appropriate measures in such cases to protect health and safety of patients, users or other persons.

15. Who is a manufacturer of a COVID-19 test?

According to Directive 98/79/EC, a manufacturer of an *in vitro* diagnostic medical device is the natural or legal person responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market in their own name. This is regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The manufacturer defines the intended purpose of the device, is responsible for following the legally prescribed conformity assessment procedures and for ensuring that the device is safe and indeed performs as intended.

The Directive's requirements for manufacturers also apply to persons who assemble, package, process, fully refurbish and/or label one or more ready-made products and/or assign them their intended purpose as devices to place them on the market in their own name. Please refer also to the European Commission services' interpretative document on own brand labelling.

16. What is a notified body and what do they do for COVID-19 tests?

A notified body is a conformity assessment body, i.e. it is an organisation that carries out legally prescribed conformity assessment procedures for certain products (e.g. assessment of technical documentation, assessment of the performance evaluation report, assessment of quality management systems, etc.) as a service for manufacturers. They are public or private organisations, independent from manufacturers. Notified bodies are designated by the relevant national authority to carry out such activities under a specific piece of legislation and are subject to constant surveillance by the designating authorities. Notified bodies are designated for the type of product to be certified. The

[16] Such market surveillance activities are not in the remit of the European Commission or other EU institutions.

current list of notified bodies under Directive 98/79/EC, including the types of devices they can certify, can be consulted in the European Commission's NANDO database here.

The precise role of notified bodies for different types of products is described in the relevant legislation. For IVDs under Directive 98/79/EC, they are involved in the assessment of self-tests (intended for lay users) and certain high-risk devices listed in Annex II of Directive 98/79/EC[17]. For COVID-19 tests, notified bodies are not involved in conformity assessment of tests intended for professional use, as these are not listed in Annex II. However, they do have a role for COVID-19 self-tests (i.e. those intended for lay users). For these tests, the manufacturer must submit an application to a notified body for the assessment of the design of the device, e.g. the suitability, for the lay user, of handling and information included on the label and instructions for use. Following a positive assessment, the notified body will then issue an EC design-examination certificate[18]. The assessment is usually by document review and not by physical testing of the device.

Notified bodies are not responsible for affixing the CE marking on the device, as this is the duty of the manufacturer. Notified bodies only issue the certificate for the specific activity that they have carried out. For a COVID-19 self-test, the manufacturer will not be able to affix the CE marking until the notified body has issued the relevant EC design-examination certificate. More information on legitimate conformity documents can be found in the Commission services' guidance document How to check if medical devices and PPE can be lawfully placed on the EU market in the COVID-19 context.

Notified bodies are not to be confused with authorised representatives (see **question 17**) or competent authorities (see **question 14**).

17. How can a non-EU manufacturer place a test on the EU market, and who is the authorised representative?

Any manufacturer may place devices in the EU market if they are compliant with Directive 98/79/EC. Manufacturers with a registered place of business located outside the EU must fulfil the same requirements as those based in the EU. In addition, they are required to designate an authorised representative established in the EU, who will represent the manufacturer to authorities and bodies in the EU[19].

An authorised representative is not to be confused with a notified body (see **question 16**). Unlike a notified body, they do not assess the manufacturer's documentation nor issue any certificates.

One of the duties of the authorised representative is notifying the device to the relevant competent authority as described in **question 7**.

[17] The notified bodies' role for COVID-19 tests will be much broader under Regulation (EU) 2017/746, e.g. they will be responsible for certifying not only self-tests but also devices for professional use.
[18] See Annex III(6) of Directive 98/79/EC.
[19] See Article 1(2)(c) of Directive 98/79/EC for the formal definition.

18. Who are importers and distributors and what are their duties?

Importers and distributors are economic operators involved in the supply chain of the device. Importers are natural or legal persons established in the EU that import devices from outside the EU and place them on the market. Distributors are natural or legal persons, other than the manufacturer or the importer, that make a device available on the market. Directive 98/79/EC does not lay down specific duties for importers and distributors[20]. However, there are usually national requirements applicable to them. Importers and distributors should therefore make themselves aware of the national requirements and if needed consult the competent authorities of the Member States where they intend to operate. The contact details of national competent authorities may be found on the European Commission's webpage.

19. What is the European Commission doing in the field of COVID-19 tests and their performance?

Work related to COVID-19 tests is part of the European Commission's comprehensive response to the COVID-19 pandemic. Extensive information on this is available on the Commission's coronavirus response page. Some examples are organisation of joint procurement of tests and lab equipment among Member States, facilitating exchange of information on testing strategies, matching supply and demand as part of the COVID-19 Clearing House and funding research projects on innovative tests.

Concerning placement of COVID-19 *in vitro* diagnostic tests on the market, the European Commission chairs a forum of the EU competent authorities called the Medical Device Coordination Group (MDCG). It has a dedicated subgroup on *in vitro* diagnostic medical devices. This group oversees the implementation and application of EU legislation on *in vitro* diagnostics (Directive 98/79/EC and Regulation (EU) 2017/746) and issues corresponding guidance. The Commission may also adopt more specific legally binding measures to implement the above legislation, with the approval of the Member States. Please consult the European Commission's medical device page regularly for updates.

In addition to the above work with the competent authorities, on 16 April 2020, the Commission services have published a working document Current performance of COVID-19 test methods and devices and proposed performance criteria with an overview of test performance as of 6 April 2020 and proposed performance criteria for different types of test, intended as temporary emergency guidance and input to the discussion on the topic by regulators and stakeholders.

On 15 April 2020, the European Commission adopted a Communication titled Guidance on in vitro diagnostic tests and their performance. The Communication identifies a number of further actions needed in this area. The Commission is currently actively engaging in the follow-up of these actions by:

- facilitating regular exchanges of information between national competent authorities on regulatory issues;

[20] This is in contrast to Regulation (EU) 2017/746, which does lay down requirements for importers and distributors.

- assisting Member States in coordinating the crisis response through the Health Security Committee;
- engaging with the relevant stakeholders;
- supporting international cooperation, especially in the fight against counterfeit devices;
- publishing a number of guidance documents, also dedicated specifically to COVID-19 which can be found on the European Commission's medical device page;
- working closely with the European Centre for Disease Prevention and Control (ECDC) to make use of the agency's epidemiological expertise;
- establishing and maintaining a centralised overview of devices and their performance;
- supporting the work of EUnetHTA, the European network of health technology assessment bodies;
- supporting research and innovation in the field of diagnostics, for example via the ERAvsCORONA action plan;
- developing tools such as reference materials;
- coordination of supply and demand via the specially created structure of the COVID-19 Clearing House and via EU instruments such as joint procurement, rescEU and the Emergency Support Instrument.

Regarding the use of tests, on 28 October 2020 the Commission adopted a Recommendation (EU) on COVID-19 testing strategies, including the use of rapid antigen tests. On 18 November, this was followed by the Commission Recommendation on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection. On 18 December 2020, the Commission adopted a Proposal for a Council Recommendation on a common framework for the use, validation and mutual recognition of COVID-19 rapid antigen tests in the EU. The proposal was adopted by the Council on 21 January 2020 with text in EU languages available in the Official Journal.

Please consult the Commission's coronavirus response page and Commission's medical device page regularly for updates.

20. Do competent authorities have an overview of the devices that are placed on the market in their Member State?

Manufacturers, or their authorised representatives (see **question 17**), are obliged by Directive 98/79/EC to notify the competent authorities of the Member State in which they have their registered place of business of the address of this place of business and of basic information on the device[21]. The competent authorities are not required to perform any verification of the device at this stage, and the notification does not constitute any "market approval" or similar (see also **question 8**).

Please note that Directive 98/79/EC does not impose notification of the device in every country where the device is sold. However, there may be additional national notification or registration requirements for market operators, such as registration of importers and distributors.

[21] See Article 10 of Directive 98/79/EC.

Moreover, competent authorities engage in market surveillance and vigilance activities for devices present on the market (see **question 14**).

21. How do I know who is the manufacturer, authorised representative and, if applicable, the notified body of a COVID-19 test?

The complete name and address of the manufacturer are included on the label and in the instructions for use of the device. If applicable, the name and address of the authorised representative is included on the label, outer packaging or in the instructions for use of the device.

If a device has been assessed by a notified body, which must be the case for COVID-19 self-tests intended for lay users, the CE marking will be accompanied by a four-digit number. This is the identification number of the notified body. You can find the details of the notified body in the European Commission's NANDO database using the number.

22. Who is responsible for ensuring that COVID-19 tests comply with legal requirements?

The manufacturer has the responsibility to ensure that the device is safe, performs as intended and has up-to-date and complete technical documentation. The national competent authorities have the duty to engage in surveillance of devices already made available on the market[22]. As part of this, they may request the manufacturer to provide the full technical documentation or conduct testing of devices. The national authorities are empowered to take actions concerning non-compliant medical devices, which may include restriction, prohibition or withdrawal of products from the market.

Besides the requirements for CE marking laid down by the Directive 98/79/EC, for clinical laboratory practice, many laboratories validate the devices they use against the manufacturer's specifications and/or national requirements. There may be national legislation or restrictions for clinical laboratories and/or restrictions from public health authorities on what tests are used to provide COVID-19 testing for the public in that country.

23. Has the sale of any COVID-19 testing kits been revoked in the EU?

Actions against manufacturers are in the remit of national competent authorities. Several Member States have taken enforcement action to prohibit the making available of some devices, in particular certain rapid antibody tests, on their territory. Some devices were also refused registration (and therefore cannot be marketed) due to insufficient or incorrect documentation.

For further information, please contact the relevant competent authority. The contact details of national competent authorities may be found on the European Commission's webpage.

[22] Such market surveillance activities are not in the remit of the European Commission or other EU institutions.

Performance of COVID-19 tests

24. Does the EU legislation lay down any minimum levels of sensitivity and specificity of COVID-19 tests?

Directive 98/79/EC obliges the manufacturers to evaluate the performance of their devices prior to placing them on the market and to report the performance parameters in the technical documentation and in the instructions for use. This includes analytical and diagnostic sensitivity and specificity, alongside a number of other parameters. The parameters must be adequate for the intended purpose of the device, as described by the manufacturer.

Devices listed in Annex II of Directive 98/79/EC must also comply with common technical specifications[23], which list some specific requirements on sensitivity and specificity for certain kinds of devices. These are legally binding. However, COVID-19 devices are NOT listed in Annex II, therefore there are currently no quantitative EU-level legally binding minimum requirements for sensitivity or specificity of these tests. However, the basic requirement that the performance of the device must be adequate for the intended purpose still applies – it is up to the manufacturer to demonstrate that this is the case.

The EU Member States may have more specific national requirements and you are advised to contact the relevant national competent authorities for more information. The contact details of national competent authorities may be found on the European Commission's webpage.

25. Is there any specific guidance applicable to performance of CE-marked COVID-19 tests?

There are legal requirements for performance of tests laid down in Directive 98/79/EC, in particular Article 3 and Annexes I and III.

In addition, on 15 April 2020, the Commission adopted a Communication titled Guidance on COVID-19 *in vitro* diagnostic tests and their performance. It includes considerations on device performance and validating that performance. It provides elements to be considered by Member States in defining national strategies, and by economic operators in placing devices on the market, with the objective of ensuring that safe and effective devices for COVID-19-related testing are available in the EU. In this

[23] 2002/364/EC: Commission Decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (Text with EEA relevance) (notified under document number C(2002) 1344) *OJ L 131, 16.5.2002, p. 17–30.* Amended by Commission Decision 2009/886/EC - OJ L318/25 of 14 December 2009, Corrigendum to Commission Decision 2009/886/EC - OJ L 348/94 of 29 December 2009, Commission Decision 2011/869/EU - OJ L341/63 of 22 December 2011, Commission Implementing Decision 2019/1244/EU - OJ L193/1 of 19 July 2019 and Commission Implementing Decision (EU) 2020/350 - OJ L 63 of 3 March 2020.

and other documents listed in **question 18**, the Commission recommends validation of the devices by the Member States and cooperation between Member States in efficient use of resources and establishment of a common framework for such validation activities.

On 16 April, the Commission services published a working document Current performance of COVID-19 test methods and devices and proposed performance criteria with an overview of test performance as of 6 April 2020 and proposed performance criteria for different types of test, intended as temporary emergency guidance and input to the discussion on the topic by regulators and stakeholders.

Further guidance may be issued by the Commission or by the dedicated subgroup of the Medical Device Coordination Group (MDCG), the coordination forum of EU competent authorities chaired by the Commission. Please consult the Commission's medical device page regularly for updates.

The European Centre for Disease Prevention and Control (ECDC) also issues epidemiological guidance on testing, such as the Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK. Please consult their webpage for more information.

The Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU, of 21 January 2021, recommends that the Member States should apply minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity for this type of test.

As the follow-up to the Council Recommendation, on 18 February 2021, the EU Member States in the Health Security Committee agreed on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates. These three deliverables will be continuously reviewed and updated, and eventually available on the Commission's COVID-19 *in vitro* diagnostic devices and test methods database referred to in **question 5**.

The Member State competent authorities may also issue guidance at national level. Please consult the relevant webpages or contact the relevant authorities. The contact details of national competent authorities are available on the European Commission's webpage.