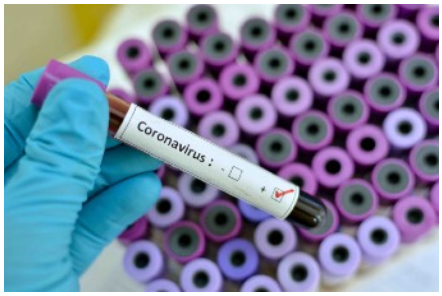
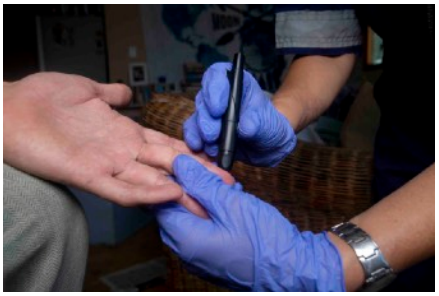
SUPPLYING THE EU MARKET WITH COVID-19 SELF TESTING KITS
a guide by QServe and ProductIP

Getting involved with self testing kits is complex. It may not be your everyday product compliance process. It involves paperwork, time, money, patience. There are no quick routes to the market.



Lockdowns are step-by-step lifted. Governments are increasing the number of tests. At the same time the market for self-tests is growing quickly; consumers want to know if they have it or not. And they want to check this regularly. So, they are looking for tests they can buy, that are easy to use, and that provide a high level of accuracy.

Which types of self-tests are currently available in the market?

There are two main categories of tests;

1. tests to tell you have the virus, the so-called **antigen-tests.** They detect (parts of) the virus itself

2. tests that tell you, you have had the virus and you have antibodies to the virus, the so-called **antibody-tests.** It is hoped that these antibodies will protect you in future from reinfection but at present there is no data on how effective this is or how long the immunity will last.

   The body does not immediately produce large quantities of antibodies, so they are not a good marker of active infection and you may have to wait for there to be enough antibodies to measure. You could compare this to a pregnancy test, the body does not start to make pregnancy hormone immediately you have to wait till there is enough pregnancy hormone to measure.

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Besides self-tests testing services may also be offered. A sample collection kit is sold, and the patient sends the sample to a professional laboratory who then send you back the result. This sort of service raises questions about the risks of mailing infectious material and no COVID-19 tests of this kind are available at present.

Besides different types of tests there are also different ways to take a sample such as:
- Finger prick using a lancet
- Swab test
- Saliva test

Sampling kits may contain separate items. Most likely these are also considered medical devices and have to have all proper markings, including CE, as well.

What is the accuracy rate of the various types of test kits?

The accuracy of tests varies considerably and also depend on the sample being taken correctly and the test run according to the instructions. There are 2 important measures,

Sensitivity – what is the smallest amount and therefore the earliest you can detect either the virus antigen or the virus antibody depending on the type of test

Specificity – There are different types of the virus and this is a measure of how well the test correctly identifies all the different virus types

The performance of home test technology was initially very poor. The test only give correct results 60% of the time. This is due to the fact that the virus is so new, materials used in the tests have to be cultured/ grown. Compare this to creating a new breed of plant. It takes time to grow and select the right materials. Once the right materials have been created they can eventually be mass produced.

The performance has already started to improve but at this point they are still considered poor. A best of class test is probably correct 80-90% of the time, when used correctly. Home tests are therefore not a replacement for professional tests. A professional test for active infection is correct 98% of the time.

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Self-tests may provide useful information; however, if you are taking a test before visiting an at-risk family member you should understand that they are not fool proof. This is a rapidly improving area and some hospitals are performing independent testing and publishing the results. The FindDx website (www.finddx.org) is a useful resource

Which types of tests can detect asymptomatic patients?

It is becoming apparent that some patients who have not shown any significant symptoms may have (had) the virus. These are so-called **asymptomatic** patients. Both antigen- and antibody-tests will work, even if you do not have symptoms. Are you in the early stages of infection a self-test may not pick it up. A professional test will and thus is important before visiting anyone who is vulnerable.

By whom is the COVID-19 Self Tester used?

Many people are curious to know whether the cough they had in February was COVID-19 or just a regular cold. These tests can help answer this curiosity; however, it is important to consider the reliability of the result and the impact it can have. For example; if you have a false positive antibody test you may think you have immunity where in fact you do not. A false negative antigen result could mean that you continue to spread the virus. This is why **some countries have currently banned the sale of self-test devices**. For more details check the ProductIO Covid-19 blog on https://www.productip.com/corona-timeline/

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Regulation

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What is the route to market?

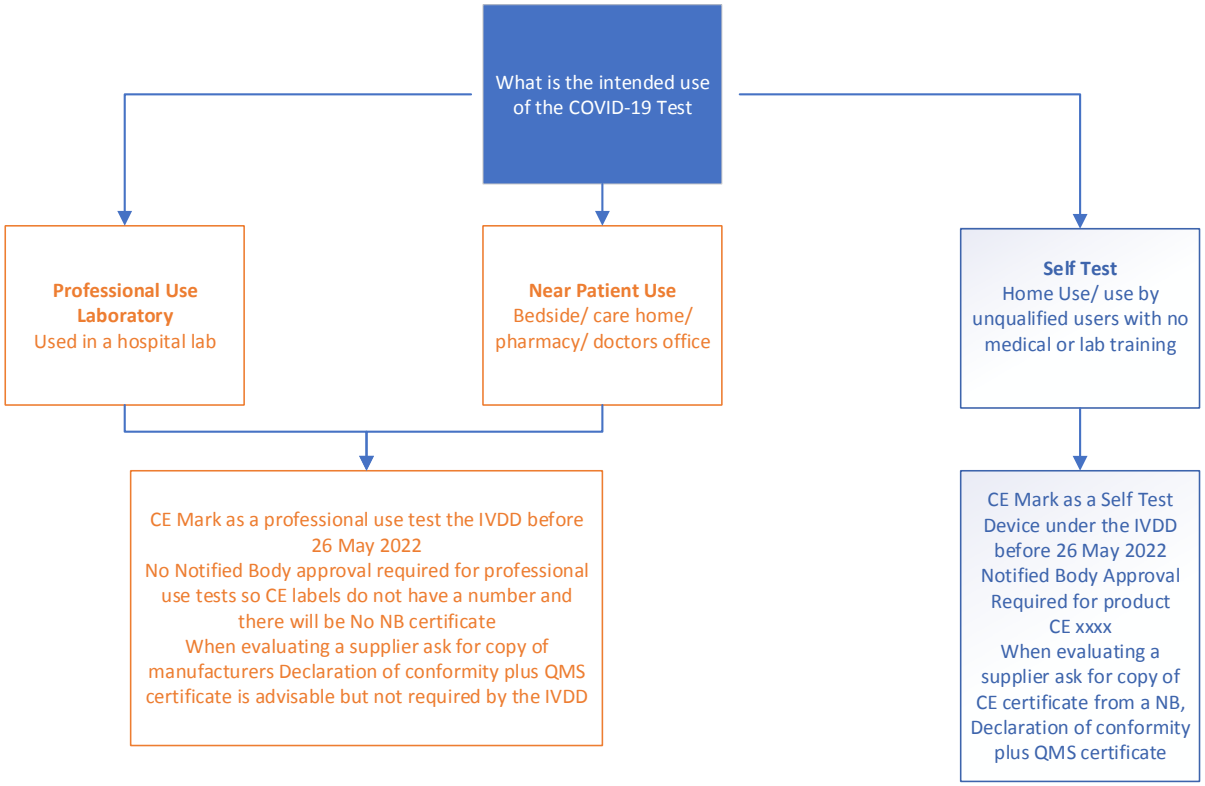
First there are 2 key questions when considering whether to supply a COVID-19 test:

1. Who do you intend to sell the test to?

2. Who did the manufacturer intend the test to be used by?

This is important because there is an increased level of regulatory oversight required for tests to be used by home users to ensure they can use it safely.

These tests are not covered by self-certification, a product review by a **Notified Body** is mandatory. A Notified Body (NB) is an independent third party who assesses the requirements to the European Directives and Regulations and issues a mandatory CE Certificate. In case of a Self-Test, the manufacturer also needs at least a valid ISO 13485 quality management system certificate (QMS).



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The manufacturer is required to specifically state whether a test is intended for self-testing by a lay nonprofessional user (a consumer) and if it is, they should have the appropriate Notified Body approval and certificates.

If the manufacturer intends the test to be used by professionals, which could include near patient tests to be used at the bedside or in the doctor's office by someone with medical training, but you decide to sell it directly to the general public, you have made it into a self-test.

Approval documents for a test for professional use SHALL NOT be used to support sales of self-test device to consumers!

What about so-called "rapid-tests"?

Some suppliers may offer, "rapid-tests". Rapid tests often use lateral flow technology and may look a little like a home pregnancy test. Unfortunately, just because it looks like a home test does not mean it is intended for home use.

What to do with claims and warnings?
Claims are based on the approval results, verified by the Notified Body.

https://www.alcoline.nl/product/covid-19-corona-bloedtest/
claiming 90,19% accuracy

https://www.prodiag.nl/store/corona-virus-sars-cov-2-antigen-rapid-test-swab-25-pieces/
claiming positive coincidence rates of 83.33%, negative coincidence rates of 100%, and a total coincidence rate of 92%

https://www.wbez.org/stories/stick-this-swab-up-your-nose-and-twirl-it-covid-19-self-tests-are-on-the-rise/708d79b3-f684-483e-957f-9330fef82613

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Regulatory requirements (status May 26, 2022)

There are multiple aspects to consider looking at the regulatory requirements before selling a Covid-19 self-test in Europe.

1. Economical Operators (supply chain)

The first thing to consider is the whole supply chain from manufacturing to distribution to the final user, what role each party in the supply chain has and what their regulatory obligations are.

Producer
This is the party that actually produces and delivers the product. He may be a contact manufacturer who produces the product based on specifications he receives from another party. Or he may be the owner of the design and IP and then probably controls all the technical specifications and test reports. In case of a Self-Test, he needs at least have a valid ISO 13485 quality system certificate.

Manufacturer
This is the party who labels the product with his name and address and is therefore the person responsible for product liability. He is responsible that all the regulatory requirements are met before he places a product on the European market with his name and address. Also, if you are not the producer but label the product as your own (Private Labelling or Own Brand Labelling), you are considered the Manufacturer. At all times, the Manufacturer must have the full technical documentation in his possession. In case of a Self-Test, he must also have a valid ISO 13485 quality system certificate and a valid CE certificate covering the product.

Importer
If the Manufacturer of the product has his address outside the European Union, he must have an importer in the EU. The importer is the party who imports the product into the EU. Under the current IVDD legislation, the importer must be identified as part of the registration process in certain Member States, but otherwise has little regulatory requirements to fulfil. There may be different importers in the EU for a product, for instance in different Member States.

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Distributor
The distributor is the party who distributes the product to the end user (hospital, healthcare professional, consumer). There may be different sequential distributors in a chain between importer and end user. Under the current IVDD legislation, the distributor may need to be identified as part of the registration process in certain Member States, but otherwise has little regulatory requirements to fulfil.

EU Authorized Representative
If the Manufacturer of the product has his address outside the European Union, he must have an EU Authorized Representative. This is a company with an address in the European Union who is the legal representative of the Manufacturer. The name and address of the EU Authorized Representative must be on the label of the product in addition to the name and address of the Manufacturer. In addition, the EU Authorized Representative must be registered in databases of Member States.

Note. Qserve is EU Authorized Representative for many medical device and in-vitro diagnostic medical device manufacturers outside Europe.

It is very important to consider which role you are playing in the supply chain and based on that, which regulatory requirements apply to you. This is especially the case when you intend to private-label a product and hence become by default the legal Manufacturer. In contrast, if you are only distributing a product of a Manufacturer, your regulatory obligations are limited under current legislation.

2. Requirements before applying CE Marking on the product

When you have a COVID-19 Test for professional use or near-patient use, then the Manufacturer needs to meet the following requirements:

- Have full technical documentation for the product. This comprises of product specifications, a risk management report, verification and validation test reports, a usability report and a clinical performance report. If you private label the product and hence are considered the Manufacturer, you need to ensure that you obtain the full technical documentation from the Producer.
- If you contract the production out, you need to have a regulatory contract in place with the Producer in which certain obligations for both parties are defined.
- If you are a Manufacturer outside the EU, then you need to establish a contract with an Importer in the EU and with an EU Authorized Representative.
- You then issue a Declaration of Conformity (self-declaration) and may apply the CE Mark on the product.

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When you have a COVID-19 Self-Test, then the Manufacturer needs to meet the following additional requirements:

- Have a quality system compliant to the the IVD Directive, preferably to the ISO 13485 standard.
- Have a Notified Body who audits the quality system of the Manufacturer and the technical documentation, and upon successful completion of that issues a CE Certificate.

Finding a Notified Body and going through the required assessments until receiving a CE Certificate is a lengthy process that may take a year.

If you intend to private label a product and hence are yourself the legal Manufacturer but not the producer and that product has already the appropriate CE Certificate from the original Manufacturer, it may speed up things, provided they will give you the complete documentation and allow your Notified Body access for audits. However, this still requires considerable time.

3. Registrations in Member States of the European Union

Once you have applied the CE Marking and the appropriate CE Certificates if required, you need to register the product in databases in certain Member States. Each Member State has a different process to go through and slightly different requirements.

Qserve has experience with the registration of medical devices in the various Member States and can carry out this activity for you.

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Relevant links

Regulatory updates from Qserve on COVID-19 tests
European Commission guidelines on COVID-19 IVD tests and their performance
In Vitro Diagnostics Directive (IVDD) (applicable until 26 May 2022)
In Vitro Diagnostics Regulation (IVDR) (applicable from 26 May 2022)
List of Notified Bodies designated for the IVD Directive
List of Notified Bodies designated for the IVD Regulation
Dutch Health Inspectorate IGJ – warning on self-tests
UK health authority MHRA – how tests for COVID-19 work
French health authority ANSM – information on COVID-19 tests

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How can ProductIP help?

Via our web-based solution you can instantly create a comprehensive regulatory checklist for non-food consumer products. This checklist is the core of a so-called technical file. Invited suppliers can upload the compliance evidence directly into this technical file. You sign off the references in the regulatory checklist with the uploaded information; certificates, test reports, declarations, bill of materials, etc. When relevant for the product you can create a CE declaration with a mouse click.

These technical files enable you to demonstrate to authorities, consumers, other stakeholders, that you are in control of product compliance in a way that is in line with the regulatory framework.

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