

Responding to the COVID-19 Pandemic: the Diagnostic Industry Angle

May 2020

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Introduction

As the healthcare situation caused by COVID-19 starts to evolve, countries are looking for safe exit strategies from confinement measures. Most deconfinement strategies identify a crucial component in testing — a lot of testing, a lot of the time.

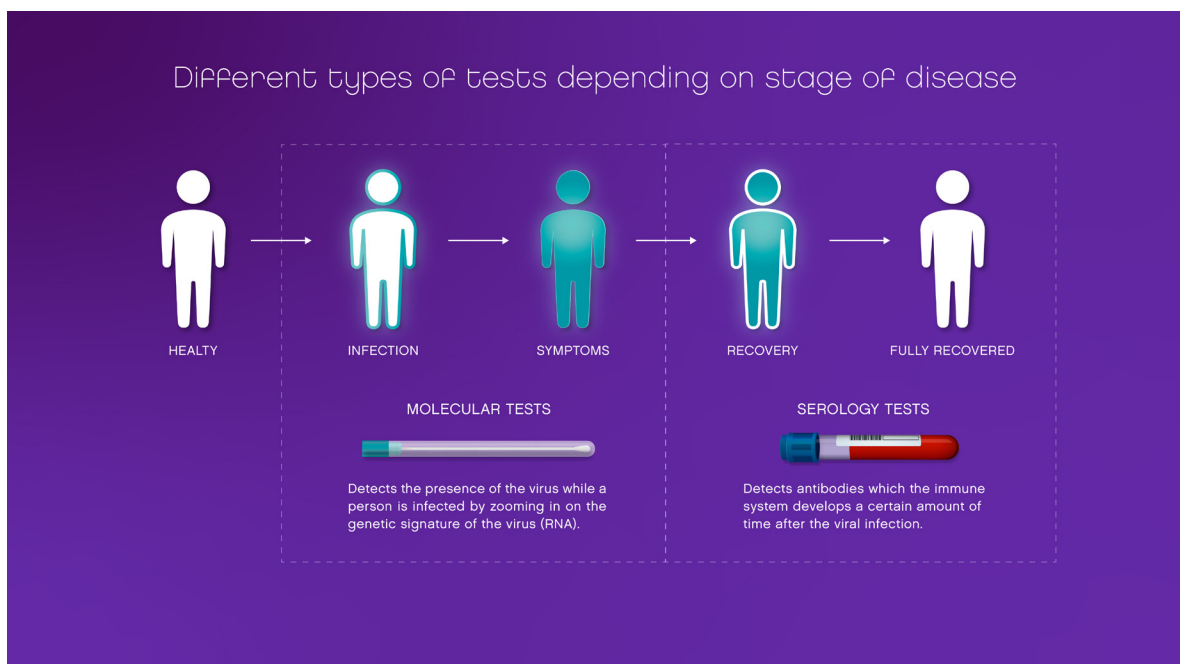
Anyone seeking to understand possible paths out of the lockdowns could be asking the following COVID-19 testing-related questions: why are different tests needed for different situations? Why does it matter which test is chosen? What has been achieved so far? What are the learnings from the past weeks for the way forward?

This document aims to provide some answers drawn from the experience of developers and producers of tests and their related components. In this global health emergency, the diagnostics industry plays a crucial role, and is committed to doing its part so that life can move forward to a new kind of normal.

What does COVID-19 testing mean?

First off, COVID-19 is the disease caused by the novel virus called SARS-Cov-2. There are two broad categories of tests, and they are relevant at different points in the progression of the disease:

- The first type of test detects the presence of the virus itself while a person is actually infected:
 - Almost all of these tests zoom in on the genetic signature of the virus (RNA).
 - Work is also being done on developing reliable tests that detect antigens (viral proteins).
- The second type of test detects antibodies against SARS-CoV-2, which the immune system develops a certain amount of time after the initial infection with the virus.



Both types of tests are essential elements of an effective, situational, comprehensive and staged response to the outbreak. Beyond decisions for the individual, at the population level they allow for informed decisions on whether further confinement restrictions are necessary, or if it is possible to ease or lift lockdowns. By quickly identifying those who are infected, effective quarantines can be implemented to break the chain of contagion. By learning who has been ill in the past, it is possible to both understand the virus better and, more importantly, identify those people at lower risk of future infections. This last part comes with a question mark still, as it is not yet precisely understood whether a past infection grants future immunity or for how long.

Now - how easy is it to quickly develop such a test for a new emerging virus, and produce it to a high standard? Not that easy. Whilst rapid response is critical during a pandemic, delivering tests of the highest quality is the top priority that needs to be guaranteed.



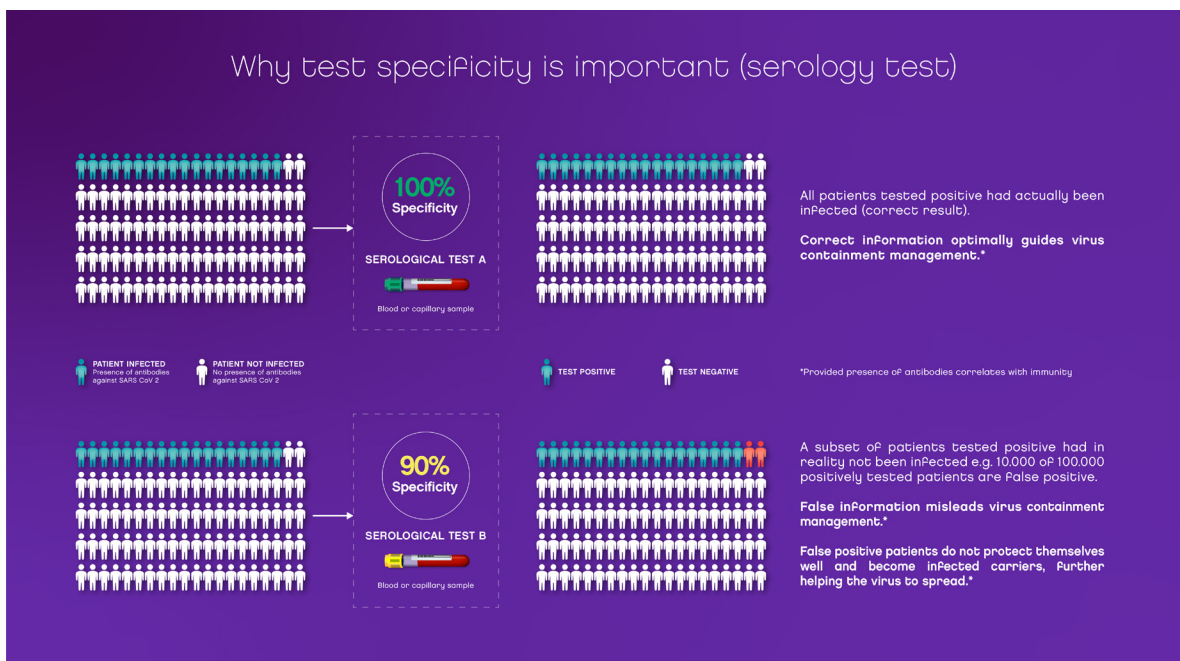
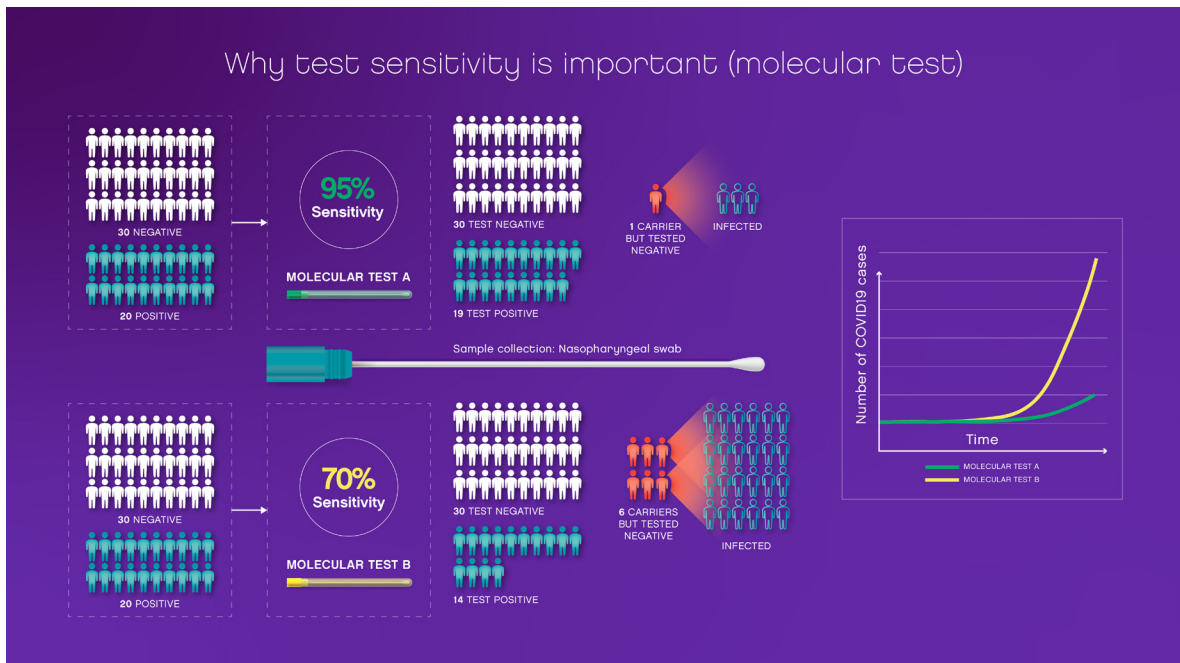
Nataša Reisch, Project Leader at Roche, was involved in the development of a molecular test that responded to the pandemic: "Like many other diagnostic companies, we had a highly engaged team working practically day and night on developing a COVID-19 test: highly knowledgeable people from research, development and manufacturing, specialists in their areas, some with decades of experience. As an industry, we managed to come up with solutions in just a few weeks, all while making sure the tests did exactly what they were supposed to do—reliably detecting the virus causing COVID-19."

In a global crisis where days can feel like weeks and weeks like months, several weeks can seem long. But compared to the usual development time of around one and a half year, this was 'fast-paced science', all while making sure that results can be trusted.

"A wrong test result can have potentially devastating consequences," says Mark Miller, Chief Medical Officer of bioMérieux. "For all member companies of MedTech Europe, the quality and performance of the tests are a key priority at every step of the development process. Imagine someone tests negative for the virus, goes home to their family and maybe, feeling reassured, even visits their elderly parents. Then it turns out the test result was wrong, and our initial patient has passed the virus on to all their loved ones. When it comes to serological assays (tests which say whether people have been previously infected), false-positive results may also result in serious consequences as they provide false information on the extent and progression of the outbreak, and can erroneously convince a susceptible person that they are immune. Due to several technical and biological reasons, no diagnostic test can ever be 100%. However, the duty of responsible diagnostic companies is to develop highly reliable and accurate diagnostic tests, with performances as close to 100% as possible."



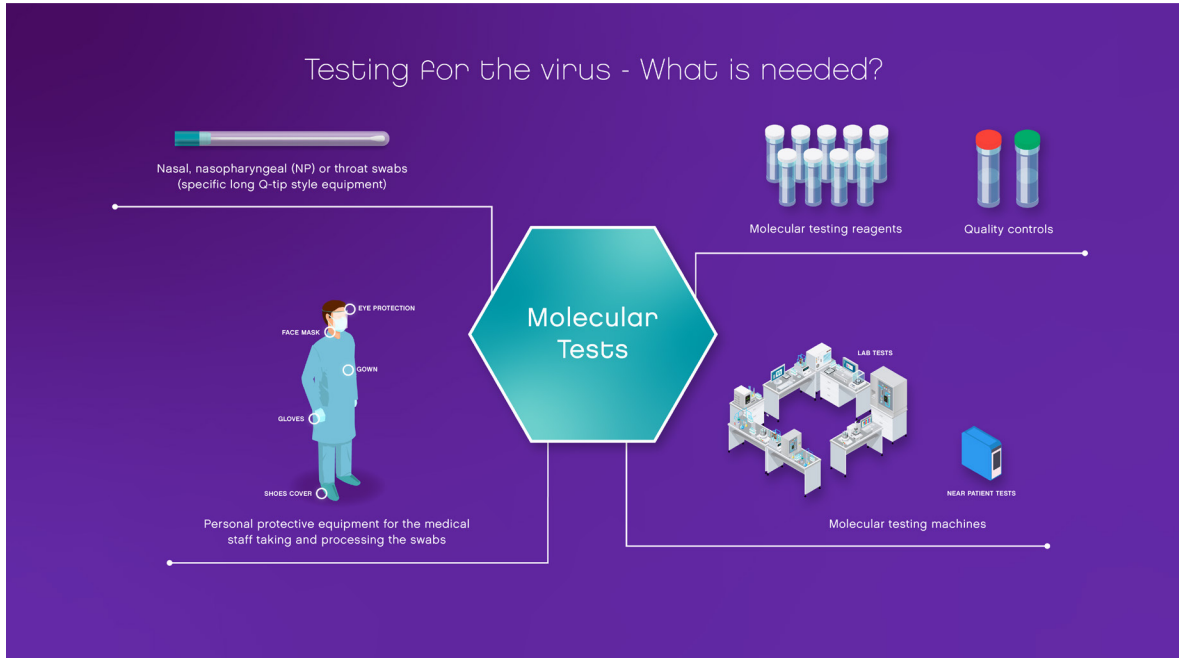
The reliability of diagnosis depends on a complex chain that assigns specific but essential roles to each player, including industry, but also the patient himself, the medical doctor, the laboratory, basic science, and regulatory authorities. When it comes to the test itself, inaccurate results can have devastating effects on patients - and in the case of a pandemic - on the whole population. Some tests, developed without sufficient quality controls, came onto the market and failed in detecting significant numbers of active viral infections. Fortunately, healthcare systems quickly identified them and abandoned them.

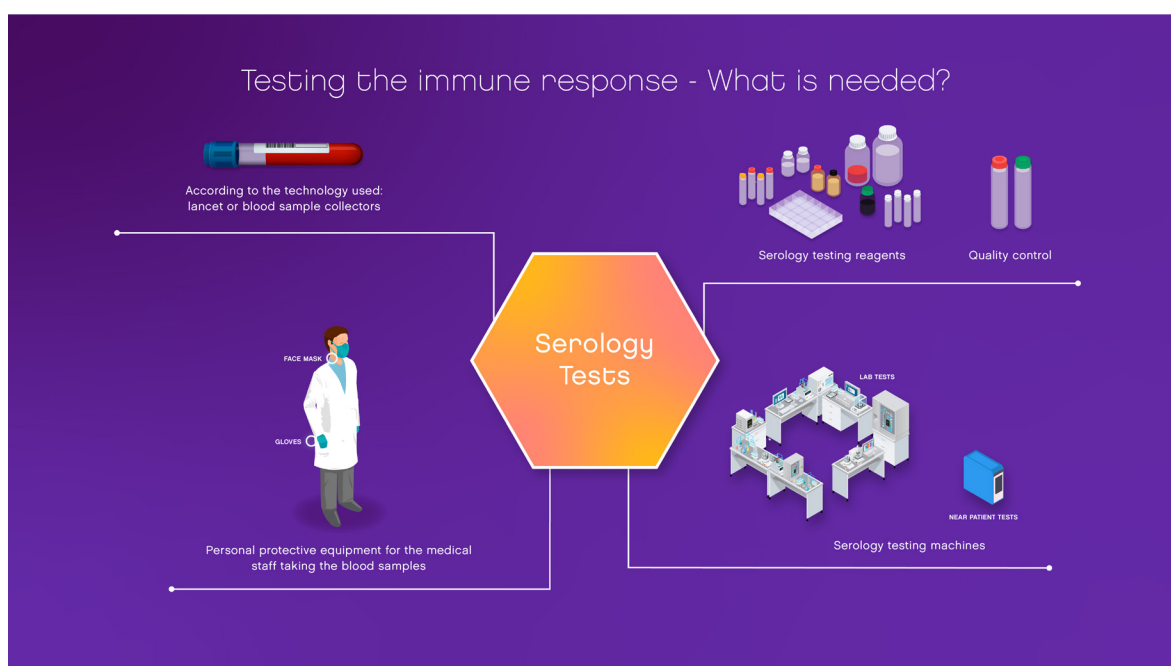




“When people hear ‘diagnostic,’” explains Katharine Qiu, Vice President, Infectious Disease R&D, Developed Markets, Rapid Diagnostics, Abbott, “many think of something like a pregnancy test, or something which is easy to reproduce quickly. However all diagnostic tests aren’t just a little package you can buy over the counter or online. They are composed of many different parts that fit together like a complex 3D puzzle, and you can’t get the full picture if the pieces don’t match or even a wrong picture.”

Testing typically requires three things: a sample of a person, a set of necessary reagents and components, which are both put in an instrument that can run the test. The concept is similar yet vastly more complex than what is needed for printing documents, where you take a piece of paper, and the ink provided in a cartridge, and both are fed into a printer. For every test, dozens of different components and fluidics must combine perfectly in order to provide correct test results. Here is an example of what this can look like:





The reliability of the final test partly depends on the reliability of its various components. If a single component fails, patients may receive incorrect results that will force them to either needlessly quarantine themselves even though they are healthy, or could lead them to neglect necessary caution as they are not aware they are infected. In addition, the safety of lab workers needs to be preserved by protecting them from faulty components. To prevent problems like these, manufacturers carry out in-depth quality assurance studies during the test development, and strict quality controls and audits of component vendors. Part of the process for ensuring the performance of the IVD tests includes:

- **Validation** – As part of the development process, all assays are validated and carried out by confirming their performance against available samples – this is done by all manufacturers.
- **Batch Release** – Individual batch performance is verified by manufacturers for every batch before the tests are shipped out.
- **Verification** – Before laboratories begin to deliver results to patients, they verify that the stated performance can be met to ensure the reliability of the information provided by the test.

These measures together work to ensure the reliability of tests by confirming the performance of the valid tests and eliminating those tests which are not able to deliver reliable results.



“Our member companies are actively developing new tests for COVID-19,” says [Serge Bernasconi, Chief Executive Officer of MedTech Europe](#), “and are committed to producing high-quality tests, which reliably guide patient management decisions and can be highly impactful in managing this pandemic. A lot of experience and resources are needed to make this happen, especially if time is of the essence like it is right now, when we are still learning more about the virus. Healthcare system strategies are evolving as we speak, and the diagnostics industry response has and will continue to evolve and adapt accordingly.”

An exponentially growing demand

Quality is just one side of the equation – the other is quantity. This is a pandemic, with exponential growth of patient numbers in some places, slowing growth in others, and decreasing numbers of new infections elsewhere. Even with countries being more and more in control of their rates of COVID-19 infections today, demand for testing is still increasing, be it for tests to identify active cases of the disease, or for tests that reveal past infections and the associated response of the immune system.

“This has been a historically unmatched experience for our industry,” states [Christopher DeAngelis, Functional Lead, Roche Operations](#). “Responding this quickly, on such a scale, to a novel pathogen, is unlike anything that we as an industry have seen before. Companies prioritised the development of COVID-19 RNA detection tests over any other activity in early January, and we have since ramped up production to the point where we now manage to deliver more in a single week than we delivered in the entire prior month.”



Massive upscale in production goes hand in hand with adjusting logistics chains to ensure around-the-clock delivery across the world – working 24/7, while facing the challenge of upholding and upscaling the sourcing of raw materials from around the globe. Managing closed borders, of limited supplier stocks, of cancelled flights and lengthening custom procedures can pose additional roadblocks as well on distribution. It also includes sending company experts to labs and other healthcare facilities to help install machines needed to run tests, and training lab personnel in how to do so. At the same time, companies need to protect the health of their own employees and to make sure that routine testing for all other patients can still happen.

In other words, the diagnostic industry finds itself on the frontline of a global health emergency that forced countries, healthcare systems and entire populations to abandon normal routines, and move into uncharted territory - a territory where testing plays an essential role, and demand is at unprecedented levels. In response, the diagnostic industry needed to repurpose production lines, invest in new facilities, and find creative solutions to deal with the unforeseen level of demand.



Barthold Piening leading QIAGEN Global operations: "From the very first days of the novel coronavirus outbreak, we have developed tests to specifically target SARS-CoV-2. Our dedicated global teams have been working around the clock to ensure availability of existing testing solutions. Companies have dramatically scaled-up production, moving to 24 hour, seven-day-a week operations at our manufacturing sites, and are investing in additional equipment capacity. Ultimately, we aim to ensure an unprecedented response to this once-in-a-generation public health challenge."

Essential partners in this pandemic are also the many laboratories in hospitals, medical schools and private labs that are performing the tests on patient samples. They are the ones to perform high-quality diagnosis and reporting of test results, and therefore our guides as we seek a way out of this crisis. Just like for diagnostics developers and manufacturers, this is a challenging time for them, faced with an unprecedented demand for tests while simultaneously having to reorganise or implement new processes to protect their employees and cope with the situation: put in place special COVID-19 testing teams, work in three shifts or set up drive-in test centres.

“What the test manufacturing diagnostic industry has done in such a short time is enormous,” acknowledges [Frank Exner](#), COO Bioscientia Group & Chief Procurement Officer, Sonic. “The testing demand for COVID-19 has exploded in such a short time, and we barely knew how to cope with that. And sure, there still aren’t always as many tests available as we’d like, but this is an exceptional situation, and we see that the industry is working incredibly hard. I’d also like to point out that the quality of the test matters, and even if it takes a little longer, it’s worth it. If you get a test even faster, but it gives you wrong results and maybe you don’t even know -this would be a disaster.”



Exit strategies needs to take testing capacity into consideration

This is where we have to sound a note of caution: there is no realistic strategy to end a lockdown that relies on high numbers of tests that are not available. Besides all that has already been achieved, and the diagnostic industry is deeply committed to being a partner in this journey, there is a limit to how fast the production of reliable tests can be increased to meet the exponentially growing demand.

“No single company,” acknowledges [Serge Bernasconi](#), “could come close to fulfilling the enormous need for tests – not just here in Europe, but around the world. We are in discussions with numerous partners about ways to further increase production. Nevertheless, the complexity of the consumables and reagents can limit how quickly our members can expand production while keeping tests reliable, which is paramount. We need to find a balance. We have a global responsibility to distribute our tests in a way that takes into account most importantly the health impact and it doesn’t leave anyone stranded.”

Countries that plan their exit strategies need to assess their desire for widespread testing against what is actually realistic both in terms of availability of tests and associated components, and in terms of their infrastructure and personnel. That way, they can focus available testing capacity on where it will have the biggest impact on the health of the population. This has shown success in containing the spread of infection, and can be combined with other well-considered measures such as continued physical distancing in certain public places, applications that track infections, or targeted measures such as the recommendation to wear masks in some situations.

“We consider COVID-19 tests, and thus the industry sector providing them, to be an important pillar of any coherent exit strategy,” says [Serge Bernasconi](#), “and we are proud of that. We are proud of how we managed to ramp up production on a massive scale, and we are proud of the incredible work our people have done in research and development, in production, in logistics, – all across the sector, all intending to get these tests produced and delivered.”

Conclusion

The COVID-19 outbreak has created an unprecedented public health crisis at global level. Diagnostic tests will remain a central pillar in the phase of the deconfinement and societal adjustments and beyond. Providing background about how the diagnostic industry operates and how COVID-19 tests are developed and produced in needed large scales is meant to unlock the full potential of diagnostic tests and to support the decision making during this pandemic.

Within MedTech Europe, its diagnostic company members are working relentlessly to produce high quality and accurate COVID-19 related tests as fast and at as high volumes as possible.

As the world continues to fight the pandemic, the diagnostic sector is committed to contribute and collaborate with policymakers and other stakeholders to play its part in ensuring that people's lives and health can be protected.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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