

Unmasking myths about COVID-19 diagnostic tests



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Introduction

On 11 March 2020, the World Health Organisation declared the epidemic caused by the SARS-CoV-2 outbreak a global pandemic.

We have learned a lot since then, and we have increasingly become aware of the risks of the virus and of the solutions available to keep the infection curve under control.

We know that vaccines remain the most powerful weapon to protect us from hospitalisation following infection. However, diagnostic testing is an effective tool to measure the spread of the pandemic.

The range of diagnostic methods has increased in recent years. Nowadays, home test kits are available at pharmacies for a small fee.

But myths about the pandemic and diagnostic tests still circulate, fuelled by a constant flow of information generated by news articles and social media, which have made it difficult for people to separate truth from falsehood.

In this “Unmasking myths about COVID-19 diagnostic tests” guide we debunk some of the most common misconceptions which have circulated during the pandemic.

To stay informed about the latest in diagnostic test research, follow the CORONADX website and our social media channels.

Regards

The CORONADX team

Does “rapid” mean “less accurate” for coronavirus tests?



Myth: *Rapid coronavirus tests are less accurate.*

Fact: *Rapid tests can be as accurate as standard ones. Accuracy does not necessarily depend on speed.*

WHAT IS A “RAPID” TEST FOR THE CORONAVIRUS?

The word “rapid” defines any method which is significantly faster than the ones we use today to detect SARS-Cov-2 (the coronavirus that causes COVID-19).

The gold standard test for SARS-CoV-2 is based on a technology called RT-PCR. The sample must be sent to a qualified laboratory and takes several hours to give a result. Rapid tests take less than an hour or even a few minutes. They are often performed at the Point of Care (POC), meaning that the samples are not taken to a laboratory but instead are processed on-site. This is faster and cheaper.

Faster and more widespread tests will be key to controlling the COVID-19 pandemic and limiting lockdowns. With rapid tests, more people can be checked at work or during travel. Carriers can be detected earlier and quarantines can be shortened for those who test negative.

Myth: *A reliable test is 100% accurate.*

Fact: *Virtually every test has a degree of error. Therefore, it’s important to balance specificity and sensitivity.*

WHAT MAKES FOR AN ACCURATE TEST?

The accuracy of a diagnostic test is defined by two statistical measures: sensitivity and specificity.

Sensitivity is the ability to detect the virus in carriers. 100% sensitivity means that a test will identify all the individuals carrying the virus, while 98% sensitivity means that the test will miss 2% of carriers, and so on. Specificity is the ability to correctly exclude the individuals who are not carriers. In a test that is 100% specific, no one without the virus will test positive. If the specificity is 98%, then 2 out of 100 of those who tested positive are not carriers and therefore are called false positives. A perfect test would have a 100% sensitivity and specificity, of course. However, this is rarely the case in real applications. Most tests have a degree of error, and therefore their accuracy is not perfect. And there is typically a trade-off where you can’t improve sensitivity without losing specificity and vice-versa.

IS SPEED RELATED TO ACCURACY?

The sensitivity and specificity of a test do not necessarily depend on its speed of execution. Instead, these parameters depend on the technology used and many

other variables. In principle, a faster test can be as accurate, or even more accurate, than a slower one. On the other hand, faster and cheaper tests often involve technologies that are newer than the gold standard and therefore need more work to assess and improve accuracy.

WHAT IS THE ACCEPTABLE ACCURACY FOR A TEST?

The accuracy of a new test is usually expected to be comparable to or better than the gold standard. However, there isn't a fixed threshold to determine whether a test is accurate enough. Since sensitivity and specificity are often a trade-off, the choice may depend on the situation.

When screening travellers at an airport, for example, it may be more useful to identify as many carriers as possible with a first-line test (higher sensitivity and lower specificity) and eventually rule out the false positives with a second-line test which is less sensitive and more specific.

The sensitivity and specificity of a test must be properly measured and validated statistically. Validation is essential for making a new test and critical for ensuring reliability.

Different methods are useful for different testing strategies.

That is why the CORONADX project is developing and validating three rapid methods with different speeds, costs and accuracy that will hopefully fit various real-life situations.

How useful are rapid COVID-19 tests?



Myth: *The best-performing test is always the best choice.*

Fact: *When it comes to containing epidemics, the speed and availability of tests can be important too.*

WHAT ARE THE PROS AND CONS OF RAPID ANTIGEN TESTS?

Laboratory tests for the detection of the COVID-19 coronavirus are based on molecular methods such as RT-PCR, which detect the viral genetic material. Rapid antigen tests (RATs), instead, detect one or more proteins (called antigens) that are specific to the Coronavirus.

RATs are less sensitive than RT-PCR. While RT-PCR can detect even a few viral particles, RATs will give a positive result only in patients with a higher viral load. On the other hand, RATs are cheaper and provide results in about 10-15 minutes, while with RT-PCR it usually takes one or more days to get the results back from a laboratory.

WHAT TYPES OF COVID-19 TESTS CAN WE DO AT HOME?

The available at-home tests for COVID-19 are RATs that can be self-administered by anyone, even without training. Depending on the version, these tests are done on a nasal swab or a saliva sample.

Myth: *A patient with a positive RT-PCR is always contagious.*

Fact: *RT-PCR can be positive also in people who are not (yet) contagious.*

HOW ACCURATE ARE RATs IN IDENTIFYING AND ISOLATING INFECTIOUS PEOPLE?

Early identification of infectious people depends on the sensitivity of the test. Soon after an infection, the viral load in patients is low: at this stage, it can be detected only with RT-PCR – which is more sensitive – and not with an antigen test. However, most patients are not yet contagious at this time. Later on, the viral load increases and patients become contagious. When the viral load is high enough to be contagious, state-of-the-art RATs are usually able to detect the virus, just like RT-PCR, and they provide an immediate answer. Therefore, these tests can be used to screen for contagious people before they can infect others, even if they are less sensitive than RT-PCR.

More generally, RT-PCR answers the question: “does a patient have the virus?” and gives a positive result even with low viral loads, while RATs will light up only when a patient has enough virus to be contagious.

WHERE ARE RATs MORE USEFUL?

Which test is the more suitable will depend on the circumstances. RT-PCR is the gold standard for the diagnosis and confirmation of COVID-19 and it's considered the best option when time is not essential. Self-administered RATs, which are faster and relatively inexpensive, can be a very practical tool for monitoring families, communities, students and workplaces and they break the transmission chains, especially when repeated regularly. Therefore, some countries offer free at-home test and promote their widespread use. With at-home, inexpensive kits, more people can get tested more often than they would be with molecular tests alone.

Are we able to detect all coronavirus variants?



Myth: Tests do not work with the new coronavirus variants.

Fact: Most tests are still able to detect the emerging variants.

WHAT IS A “VARIANT” OF A VIRUS?

Random mutations occur in the genome of viruses, just like in other organisms. This process creates the so-called variants. Each is a slightly different version of the same virus, carrying a distinct set of mutations.

Variants occur spontaneously during epidemics and mark the evolution of the virus. The longer and faster a virus circulates in a population, the more subtypes are likely to emerge.

Myth: Mutations always make a virus more or less infectious.

Fact: Mutations and their effects occur randomly.

IS IT TRUE THAT SOME NEW VARIANTS ARE MORE INFECTIOUS?

Yes, although viruses do not evolve with the purpose of being more or less infectious or dangerous: it is just natural selection at work. New random variants occur continuously and most of them are neutral or make the virus less infectious. But the few variants that are more infectious, or become resistant to the immune system, spread more rapidly by definition, and therefore may become prevalent in the population. By reading the genome of many viral samples and using specialized software, researchers can monitor the emergence of variants and recognize those of particular concern.

WHAT IS THE PROBLEM WITH COVID-19 TESTS AND NEW VARIANTS?

Tests for the COVID-19 coronavirus work by detecting specific targets of the viral genome (molecular tests) or specific viral proteins (antigenic tests). A mutation that changes the target may therefore affect their sensitivity. The tests available on the market are designed to detect different parts of the virus. Therefore, a variant may affect one or a few tests while the others would still work.

ARE CURRENT TESTS ABLE TO DETECT THE EMERGING VARIANTS?

Manufacturers often validate their kits against the most common variants. By knowing the target of a test, it is possible to predict whether a kit’s performance may be affected by a specific variant. Some molecular tests also detect multiple targets at the same time, making them more reliable with different variants. That said, it is always possible, in theory, that a new variant could go undetected for some time. Health authorities and diagnostic networks need to keep abreast of emerging variants and verify the efficacy of the different tests against them.



Together for a safer future

Rapid testing is crucial for tracking and isolating people at risk of transmitting the virus, even when they don't show any symptoms.

CORONADX develops three portable and easy-to-use kits to rapidly detect COVID-19.

Main CORONADX objectives:

- provide tools for surveillance and testing in the field by minimally trained people;
- foster innovation in point-of-care diagnostics;
- sustain economic and societal resilience through the analysis of the COVID-19 impacts on economy and society;
- ensure an effective public health response to the pandemic with timely, affordable and widespread testing.

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