The covid-19 testing lottery

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During our pandemic times, it happens very frequently that somebody decides whether somebody else is infect. At the time of the first wave, you could only require the services of the testers if you manifested some symptoms - the sort of evidence that one associates with the plain flu of the good old days. Since the autumn of 2020, the concept was brought to the public that so-called *asymptomatic* infections existed, that were marketed as being even more dangerous than the ones with symptoms.

The verdict that the testers provide is definitive. Either you are, or you are not, infected. If you happen to receive a positive result, your personal freedom runs the risk of being limited even more radically than what happens with us who remain presumably healthy. The consequences can be so serious that we would expect the procedures to be *very carefully* designed, so as to make as few errors as possible.

Ideally, since there is just one question to answer (whether I am infected with SARS-CoV-2 or not), we would expect there to be just **one** method available to provide it.

Instead, you have a multiplicity of ways.

There are two main categories:

- Rapid antigen test
- Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) test

The two categories are very different. For the first one, the test takes place in 15-30 minutes, and tries to find the antigens of the Covid-19 virus in the goo that is taken from your nose. The stuff is smeared onto a piece of plastic with some other special stuff on it, and after a short wait, a coloured band either appears or dœs not appear on the piece of plastic.

See for example the instructions for use of one of these kits, that contain an interestingly informative introduction:

http://www.bodinco.nl/wp-content/uploads/2021/01/Instructions-for-Use-COVID-Rapid-Antigen.pdf

Many millions of these tests are performed each day around the world. They are relatively cheap (although apparently more expensive than a vaccine shot!), and if you obtain a negative result you will gain the privilege of being accepted (for a limited time only!) into the elite of the officially immune.

In passing, I'd like you to give a thought to the **enormous** quantity of plastic that adds to the already staggering amount of pollution that we humans already produce, thanks to these kits and to the ubiquitous, all-plastic face masks that are imposed upon us, regardless of their limited practical usefulness.

After having been used, these kits even have to be destroyed as potentially infective waste. That is certainly *not* an eco-friendly process.

Experiments have been made that tributed a verdict of infectiousness to innocent stuff, like the juice of fresh fruit, that is really not expected to contain the Covid-19 antigen.

Another story is known about these tests - see here for example

https://www.cnbc.com/2020/11/13/musk-says-took-four-covid-19-tests-two-were-positive-two-negative.html

Elon Musk is said to have undergone four of these tests in the same day. Two resulted positive and the other two negative.

I, for one, do not trust this kind of test too much.

If you pick the lucky number and your result is negative, you can go back to your *relatively* normal life. If you did not get a winning ticket, chances are that you will have to submit to one or more tests of the second type. It is better for you to keep your doubts about the validity of the previous one to yourself: it is not polite to doubt official science.

Polymerase chain reaction

Polymerase chain reaction, or PCR, is a technique invented in the early 80's that, by way of cycles of heating and cooling at precise temperatures and for precise lengths of time, is able to duplicate at each cycle the genetic material contained in samples of organic stuff (in this case, again, goo from your nose), and detect in it the presence of specific short sequences of DNA bases.

This test is also non-quantitative. It returns a positive result if the sequences searched for were found, and a negative result otherwise, but it will have nothing to say about the relative abundance of the searched-for sequences in the sample. The quasi-quantitative aspect of it is given by considering the progressive cycle number at which the first detection takes place. The lower the number, the easier it has been to locate the sequences, and thus one can *presume* that the amount of what is being sought for is higher.

If the number of cycles being performed is large, it becomes more and more probable that what is being detected is not the complete organism that was searched for, but just stray fragments of genetic material that do not have the ability to replicate. Thus, at every cycle the probability to return a false positive result increases. There is a threshold after which you are practically certain that your test will return a false positive.

Dr. Anthony Fauci is on record (episode #641 of podcast "This week in virology", aired July 16th 2020, at minute 04:26, https://asm.org/Podcasts/TWiV/Episodes/COVID-19-with-Dr-Anthony-Fauci-TWiV-641) with the following statement:

"What is now sort-of evolving into a little bit of a standard is that if you get a cycle threshold of 35 or more, the chances of there being replication-competence are minuscule. We have patients, and it is very frustrating for the patients as well as for the physicians... Somebody comes in and they repeat their PCR, and it is like 37 cycle threshold, but you never, you almost never can culture viruses from a 37 threshold cycle. So I think if somebody dœs come with a 37, 38, even 36, you got to say, you know, it's just dead nucleotides, period."

The PCR protocol(s) in use

A multiplicity of types of PCR kits for detecting the Covid virus are available. This page from Public Health England:

www.gov.uk/government/publications/covid-19-phe-laboratory-assessments-of-molecular-tests

lists 17 of them, that the UK entity has assessed. There are many more. Each of them is different, even to the point of checking on different DNA sequences. and yet we must consider their outputs as having the same diagnostic value. We are not entitled to choose which test will be used on the samples we provide.

What happens is that each laboratory is equipped with whatever PCR equipment it has purchased[1], and chooses whatever detection kit it prefers among those that are compatible with its testing equipment. The normality is for laboratories to return to the subject being tested a yes/no verdict. The laboratory is simply requested to strictly follow the instructions for use of the testing device and of the kit. The instructions almost always contain a suggested threshold value, most often between 40 and 42.

Keep in mind what Dr. Fauci said: results above 35 are to be considered as reporting "just dead nucleotides."

If you want to read a bit about the meaning of the assays and their realiability, I warmly suggest you to study the contents of this site:

https://cormandrostenreview.com/

It has been set up to keep record of the proceedings connected with the request that has been made last December by a large group of respectable scientists to retract a published paper. The paper is entitled "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR," and was published by the scientific journal *Eurosurveillance* on January 23rd, 2020. It contains the first published tentative description of a PCR procedure to use on the SARS-CoV-2 virus, at the time still called 2019-nCoV.

The paper has been peer-reviewed in an unusually short time - just two days - and has been very quickly adopted by the WHO; it has been used as a reference for the design of the currently existing detection kits, although some of the kits now available diverge from the recommendations. It specifies the DNA sequences to use in the PCR process

[1] These devices are not cheap: for example, it seems that the cost of a used tabletop *Biorad CFX96* device may hover around US$35,000.

in order to detect the Covid virus. The paper was published, as the authors admit, *"in absence of available virus isolates or original patient specimens."* The design of the test was "enabled by the close genetic relatedness to the 2003 SARS-CoV."

It is reported that there exist serious conflicts of interest attributable to some of the authors of the paper.

The request of retraction has been sadly turned down, without offering convincing confutations for the 10 flaws that the review had denounced. The material collected in the site offers much food for thought to an enquiring mind who will want to try and understand a bit more on this subject.

Two early studies

Two studies published in spring 2020 tried to correlate the cycle threshold value (*Ct*) and contagiousness. They did this by trying to infect a cell culture with real-life samples that resulted positive from PCR testing at various *Ct* values.

On April 27th, 2020, the *European Journal of Clinical Microbiology & Infectious Diseases* published the article you can find here:

https://link.springer.com/article/10.1007/s10096-020-03913-9

This article concluded that:

"Correlation between successful isolation of virus in cell culture and Ct value of quantitative RT-PCR targeting E gene suggests that patients with Ct above 33–34 using our RT-PCR system are not contagious and thus can be discharged from hospital care or strict confinement for non-hospitalized patients."

This even lowers Fauci's limit.

May 20th, 2020 saw the publication by Oxford's *Clinical infectious diseases* journal by a team of Canadian researchers:

https://academic.oup.com/cid/article/71/10/2663/5842165

The title of the paper is: **Predicting Infectious Severe Acute Respiratory Syndrome Coronavirus 2 From Diagnostic Samples.**

This is the conclusion the authors reached:

"These results demonstrate that infectivity (as defined by growth in cell culture), is significantly reduced when RT-PCR Ct values are greater than 24. For every 1 unit increase in Ct, the odds ratio for infectivity decreased by 32%."

I could not find papers that contradicted these conclusions. Nevertheless, laboratories worldwide are still running tests at cycle thresholds of 40-42. The Corman-Drosten paper mentioned above even proposes 45 cycles. This translates to the generation of **a sizeable percentage of false positive results,** that individuals have no way to correctly assess, since those who are tested positive are not informed about the threshold at which their positive verdict was obtained.

What does the WHO say?

The World Health Organization has been lightning-fast to endorse the PCR-based testing procedure based on the Corman-Drosten paper, but waited until Dec. 7th, 2020 to make a public statement about the topic of *Ct* cycles.

On that date, they published a so-called *medical product alert*. They described the problem they were addressing with these words:

> WHO has received user feedback on an elevated risk for false SARS-CoV-2 results when testing specimens using RT-PCR reagents on open systems.

I, as a world citizen, am very interested in the implementation of any measure that may be taken to curb this risk. Could it be that the WHO is caught proposing guidelines that act in favour of citizens and not of the pharmaceutical companies?

The document was originally available from this URL:

`https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users`

This is not he case anymore. Just over a month after the document appeared, the WHO has removed the original version, and published a second one, that you can find here:

`https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05`

This second version mentions that its purpose is to *"clarify information previously provided by WHO. This notice supersedes WHO Information Notice for In Vitro Diagnostic Medical Device (IVD[2]) Users 2020/05 version 1, issued 14 December 2020."* The WHO does not consider it appropriate to give you access to the version that was in need of clarification. I was able to obtain a copy thanks to **the wayback machine**, that stores the history of a sizeable part of the internet. For each document in its archive, the site contains all past versions that have been published along time.

This is how you must proceed if you wish to obtain your own copy of the old version:

- Visit this site: `http://web.archive.org/`.
- Insert this link in the field that appears on the page:

  https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users

- Select year **2020** in the years bar.
- Select the date of Dec. 14th, the day of publishing, and then the only available snapshot from that date.

The second version is a rewrite of the first one. It contains roughly the same material as the first one, but a few important differences can be spotted. Among them:

[2] IVD's are devices that test bodily specimens after they have been extracted from the body that originally contained them.

- While the original document specifically mentions *user feedback on an elevated risk for false SARS-CoV-2 results* in its declared motivation and purpose, the stated purpose of the second version has been reduced to these words:

  > WHO requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology.

  The scope of the document is now equivalent to a mere reminder for laboratory personnel to follow the instructions that test kits provide.

- One item disappears from the concluding itemized list of *Actions to be taken by IVD users*. This is the only proposed action that refers to the *elevated risk for false SARS-CoV-2 results* that the first version of the document mentions, and the second one decides to drop from its stated purpose. The item reads:

  > "Consider any positive result (SARS-CoV-2 detected) or negative results (SARS-CoV-2 not detected) in combination with specimen type, clinical observations, patient history, and epidemiological information."

  A similar suggestion is included in the new version, but it is removed from the concluding list of recommended actions. I believe that this list, evidenced in **bold**, is the only part of the document, together with the declared purpose, that is considered by the intended receivers of this document (the legislators of the various countries that belong to the WHO) when deciding whether to consider it at the moment of defining their countries' official policies.

The result of the rewrite is that focus is removed from *elevated risk for false SARS-CoV-2 results,* that was so prominent in the first version. The text now boils down to a bland reminder to lab technicians to acritically adhere to the instructions that come with the test kits. This makes the problem worse, if we keep in mind that dozens of kits exist, each with its specific characteristics. It is difficult to understand how heach of them wll manage to give **the** precise, unequivocal answer to one and the same question.

The advice to consider test results together with a wider-angle picture of each single patient would certainly contribute to results that could be better trusted. Sadly, this eventuality is in strong contrast with the current usage of test results: they are intended as a currency of uncontestable value that is obtained and acted upon quickly. Sadly, it may have the consequence for basic freedoms to fall into the meat-grinder.

it is interesting to notice that both documents recommend to:

> "Provide the Ct value in the report to the requesting health care provider."

This is the least applied of all suggestions. Governments seem not to be interested in receiving and redistributing *Ct* threshold values.

If the cycle threshold value were required to be an official part of the test verdict *(to be also forwarded to the subject being tested!!)*, not only would the receiver have the possibility to better asses the gravity of his or her condition, but wise legislators would also be able to:

- impose a threshold to equate positive tests with a higher *Ct* to negative ones. From all the material I have read on this topic, I would adopt a value of **30**, that should greatly reduce the number of false positives.
- provide to the public, along with the customary daily bulletin of deaths and infections, an average of the current *Ct* thresholds, that would be a useful indicator of the intensity of the pandemic at a given time.

A welcome side effect with a *Ct* limit of 30, would be that governments would most probably not be able to sustain the level of induced fear that mainstream media has imposed on the peoples of the world for almost two years now.

Conclusions

I wrote this text as an aid to reach my own conclusions about the level of confidence I was to tribute to Covid-19 test results, in case I was ever forced to submit to one.

I am now reasonably certain that to submit to a test is analogous to picking a lottery number. Since the medical sector, for more than one reason, is more interested in limiting false negatives than false positives, it is only to be expected that established practices will be biased accordingly. I am not surprised to discover that odds seem to be strongly unbalanced towards a false positive result, and this adds to the fact that you do not need to show any symptom to receive a guilty verdict.

If I am to receive a negative result, I will thank my lucky star and go on with my life. Otherwise, I will face what comes, keeping in mind that it is better to banish fear from life. What is certain is that I will harbour doubts about the face value of the sentence that is passed on me.

Nevertheless, the planet is in a very sad state. Shame on the (medical and political) bureaucrats. Shame on the media.