COVID19 PCR Tests are Scientifically Meaningless

by

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on

Off Guardian



Though the whole world relies on RT-PCR to "diagnose" Sars-Cov-2 infection, the science is clear they are not fit for purpose.

Lockdowns and hygienic measures around the world are based on numbers of cases and mortality rates created by the so-called SARS-CoV-2 RT-PCR tests used to identify "positive" patients, whereby "positive" is usually equated with "infected."

But looking closely at the facts, the conclusion is that these PCR tests are meaningless as a diagnostic tool to determine an alleged infection by a supposedly new virus called SARS-CoV-2.

Unfounded "Test, test, test..." mantra

At the <u>media briefing on COVID-19 on March 16, 2020</u>, the WHO Director General Dr Tedros Adhanom Ghebreyesus said:

We have a simple message for all countries: test, test, test.

The message was spread through headlines around the world, for instance by Reuters and the BBC.

Still on the 3 of May, the moderator of the heute journal — one of the most important news magazines on German television— was passing the mantra of the corona dogma on to his audience with the admonishing words:

Test, test, test—that is the credo at the moment, and it is the only way to really understand how much the coronavirus is spreading.

This indicates that the belief in the validity of the PCR tests is so strong that it equals a religion that tolerates virtually no contradiction.

But it is well known that religions are about faith and not about scientific facts. And as Walter Lippmann, the two-time Pulitzer Prize winner and perhaps the most influential journalist of the 20th century said: "Where all think alike, no one thinks very much."

So to start, it is very remarkable that Kary Mullis himself, the inventor of the Polymerase Chain Reaction (PCR) technology, did not think alike. His invention got him the Nobel prize in chemistry in 1993.

Unfortunately, Mullis passed away last year at the age of 74, but there is no doubt that the biochemist regarded the <u>PCR as inappropriate to detect a viral infection</u>.

The reason is that the intended use of the PCR was, and still is, to apply it as a manufacturing technique, being able to replicate DNA sequences millions and billions of times, and not as a diagnostic tool to detect viruses.

How declaring virus pandemics based on PCR tests can end in disaster was described by Gina Kolata in her 2007 New York Times article <u>Faith in Quick Test Leads to Epidemic That Wasn't</u>.

Lack of a valid gold standard

Moreover, it is worth mentioning that the PCR tests used to identify so-called COVID-19 patients presumably infected by what is called SARS-CoV-2 do not have a valid gold standard to compare them with.

This is a fundamental point. Tests need to be evaluated to determine their preciseness — strictly speaking their "sensitivity" (1) and "specificity" — by comparison with a "gold standard," meaning the most accurate method available.

As an example, for a pregnancy test the gold standard would be the pregnancy itself. But as Australian infectious diseases specialist Sanjaya Senanayake, for example, stated in an <u>ABC TV interview</u> in an answer to the question "How accurate is the [COVID-19] testing?":

If we had a new test for picking up [the bacterium] golden staph in blood, we've already got blood cultures, that's our gold standard we've been using for decades, and we could match this new test against that. But for COVID-19 we don't have a gold standard test.

Jessica C. Watson from Bristol University confirms this. In her paper "Interpreting a COVID-19 test result", published recently in *The British Medical Journal*, she writes that there is a "*lack of such a clear-cut 'gold-standard*" for COVID-19 testing."

But instead of classifying the tests as unsuitable for SARS-CoV-2 detection and COVID-19 diagnosis, or instead of pointing out that only a virus, proven through isolation and purification, can be a solid gold standard, Watson claims in all seriousness that, "pragmatically" COVID-19 diagnosis itself, remarkably including PCR testing itself, "may be the best available 'gold standard'." But this is not scientifically sound.

Apart from the fact that it is downright absurd to take the PCR test itself as part of the gold standard to evaluate the PCR test, there are no distinctive specific symptoms for COVID-19, as even people such as Thomas Löscher, former head of the Department of Infection and Tropical Medicine at the University of Munich and member of the Federal Association of German Internists, conceded to us (2).

And if there are no distinctive specific symptoms for COVID-19, COVID-19 diagnosis — contrary to Watson's statement — cannot be suitable for serving as a valid gold standard.

In addition, "experts" such as Watson overlook the fact that only virus isolation, i.e. an unequivocal virus proof, can be the gold standard.

That is why I asked Watson how COVID-19 diagnosis "may be the best available gold standard," if there are no distinctive specific symptoms for COVID-19, and also whether the virus itself, that is virus isolation, wouldn't be the best available/possible gold standard. But she hasn't answered hese questions yet - despite multiple requests. And she has not yet responded to our rapid response post on her article in which we address exactly the same points, either, though she wrote us on June 2nd: "I will try to post a reply later this week when I have a chance."

No proof for the RNA being of viral origin

Now the question is: What is required first for virus isolation/proof? We need to know where the RNA for which the PCR tests are calibrated comes from.

As textbooks (e.g., White/Fenner. Medical Virology, 1986, p. 9) as well as leading virus researchers such as <u>Luc Montagnier or Dominic Dwyer state</u>, particle purification — i.e. the separation of an object from everything else that is not that object, as for instance Nobel laureate Marie Curie purified 100 mg of radium chloride in 1898 by extracting it from tons of pitchblende — is an essential prerequisite for proving the existence of a virus, and thus to prove that the RNA from the particle in question comes from a new virus.

The reason for this is that PCR is extremely sensitive, which means it can detect even the smallest pieces of DNA or RNA — but it cannot determine where these particles came from. That has to be determined beforehand.

And because the PCR tests are calibrated for gene sequences (in this case RNA sequences because SARS-CoV-2 is believed to be a RNA virus), we have to know that these gene snippets are part of the looked-for virus. And to know that, correct isolation and purification of the presumed virus has to be executed.

Hence, we have asked the science teams of the relevant papers which are referred to in the context of SARS-CoV-2 for proof whether the electron-microscopic shots depicted in their in vitro experiments show purified viruses.

But not a single team could answer that question with "yes" — and NB., nobody said purification was not a necessary step. We only got answers like "No, we did not obtain an electron micrograph showing the degree of purification" (see below).

We asked several study authors "Do your electron micrographs show the purified virus?", they gave the following responses:

Study 1: Leo L. M. Poon; Malik Peiris. "Emergence of a novel human coronavirus threatening human health" *Nature Medicine*, March 2020

Replying Author: Malik Peiris

Date: May 12, 2020



Answer: "The image is the virus budding from an infected cell. It is not purified virus."

Study 2: Myung-Guk Han et al. "Identification of Coronavirus Isolated from a Patient in Korea with COVID-19", *Osong Public Health and Research Perspectives*, February 2020

Replying Author: Myung-Guk Han

Date: May 6, 2020

Answer: "We could not estimate the degree of purification because we do not purify and concentrate the virus cultured in cells."

Study 3: Wan Beom Park et al. "Virus Isolation from the First Patient with SARS-CoV-2 in Korea", *Journal of Korean Medical Science*, February 24, 2020

Replying Author: Wan Beom Park

Date: March 19, 2020

Answer: "We did not obtain an electron micrograph showing the degree of purification."

Study 4: Na Zhu et al., "A Novel Coronavirus from Patients with Pneumonia in China", 2019, *New England Journal of Medicine*, February 20, 2020

Replying Author: Wenjie Tan

Date: March 18, 2020

Answer: "[We show] an image of sedimented virus particles, not purified ones."

Regarding the mentioned papers it is clear that what is shown in the electron micrographs (EMs) is the end result of the experiment, meaning there is no other result that they could have made EMs from.

That is to say, if the authors of these studies concede that their published EMs do not show purified particles, then they definitely do not possess purified particles claimed to be viral. (In this context, it has to be remarked that some researchers use the term "isolation" in their papers, but the procedures described therein do not represent a proper isolation (purification) process. Consequently, in this context the term "isolation" is misused).

Thus, the authors of four of the principal, early 2020 papers claiming discovery of a new coronavirus concede they had no proof that the origin of the virus genome was viral-like particles or cellular debris, pure or impure, or particles of any kind. In other words, the existence of SARS-CoV-2 RNA is based on faith, not fact.

We have also contacted Dr Charles Calisher, who is a seasoned virologist. In 2001, *Science* published an "*impassioned plea...to the younger generation*" from several veteran virologists, among them Calisher, saying that:

(modern virus detection methods like) sleek polymerase chain reaction (...) tell little or nothing about how a virus multiplies, which animals carry it, (or) how it makes people sick. (It is) like trying to say whether somebody has bad breath by looking at his fingerprint.[3]

And that's why we asked Dr Calisher whether he knows one single paper in which SARS-CoV-2 has been isolated and finally really purified. His answer:

I know of no such a publication. I have kept an eye out for one.[4]

This actually means that one cannot conclude that the RNA gene sequences, which the scientists took from the tissue samples prepared in the mentioned in vitro trials and for which the PCR tests are finally being "calibrated," belong to a specific virus — in this case SARS-CoV-2.

In addition, there is no scientific proof that those RNA sequences are the causative agent of what is called COVID-19.

In order to establish a causal connection, one way or the other, i.e. beyond virus isolation and purification, it would have been absolutely necessary to carry out an experiment that satisfies the four Koch's postulates. But there is no such experiment, as Amory Devereux and Rosemary Frei recently revealed for OffGuardian.

The necessity to fulfill these postulates regarding SARS-CoV-2 is demonstrated not least by the fact that attempts have been made to fulfill them. But even researchers claiming they have done it, in reality, did not succeed.

One example is a study <u>published in *Nature* on May 7</u>. This trial, besides other procedures which render the study invalid, did not meet any of the postulates.

For instance, the alleged "infected" laboratory mice **did not show any relevant clinical symptoms** clearly attributable to pneumonia, which according to the third postulate should actually occur if a dangerous and potentially deadly virus was really at work there. And the slight bristles and weight loss, which were observed temporarily in the animals are negligible, not only because they could have been caused by the procedure itself, but also because the weight went back to normal again.

Also, **no animal died except those they killed to perform the autopsies**. And let's not forget: These experiments should have been done *before* developing a test, which is not the case.

Revealingly, none of the leading German representatives of the official theory about SARS-Cov-2/COVID-19 — the Robert Koch-Institute (RKI), Alexander S. Kekulé (University of Halle), Hartmut Hengel and Ralf Bartenschlager (German Society for Virology), the aforementioned Thomas Löscher, Ulrich Dirnagl (Charité Berlin) or Georg Bornkamm (virologist and professor emeritus at the Helmholtz-Zentrum Munich) — could answer the following question I have sent them:

If the particles that are claimed to be to be SARS-CoV-2 have not been purified, how do you want to be sure that the RNA gene sequences of these particles belong to a specific new virus?

Particularly, if there are studies showing that substances such as antibiotics that are added to the test tubes in the in vitro experiments carried out for virus detection can "stress" the cell culture in a way that new gene sequences are being formed that were not previously detectable — an aspect that Nobel laureate Barbara McClintock already drew attention to in her Nobel Lecture back in 1983.

It should not go unmentioned that we finally got the Charité - the employer of Christian Drosten, Germany's most influential virologist in respect of COVID-19, advisor to the German government and co-developer of the PCR test which was the first to be "accepted" (not validated!) by the WHO worldwide - to answer questions on the topic.

But we didn't get answers until June 18, 2020, after months of non-response. In the end, we achieved it only with the help of Berlin lawyer Viviane Fischer.

Regarding our question "Has the Charité convinced itself that appropriate particle purification was carried out?," the Charité concedes that they didn't use purified particles.

And although they claim "virologists at the Charité are sure that they are testing for the virus," in their paper (Corman et al.) they state:

RNA was extracted from clinical samples with the MagNA Pure 96 system (Roche, Penzberg, Germany) and from cell culture supernatants with the viral RNA mini kit (QIAGEN, Hilden, Germany)

Which means they just assumed the RNA was viral.

Incidentally, the Corman et al. paper, published on January 23, 2020 **didn't even go through** a **proper peer review process**, nor were the procedures outlined therein accompanied by controls — although it is only through these two things that scientific work becomes really solid.

Irrational test results

It is also certain that we cannot know the false positive rate of the PCR tests without widespread testing of people who certainly do not have the virus, proven by a method which is independent of the test (having a solid gold standard).

Therefore, it is hardly surprising that there are several papers illustrating irrational test results.

For example, already in February the health authority in China's Guangdong province reported that people have fully recovered from illness blamed on COVID-19, started to test "negative," and then tested "positive" again.

A month later, a paper published in the *Journal of Medical Virology* showed that 29 out of 610 patients at a hospital in Wuhan had 3 to 6 test results that flipped between "negative", "positive" and "dubious".

A third example is a study from Singapore in which tests were carried out almost daily on 18 patients and the majority went from "positive" to "negative" back to "positive" at least once, and up to five times in one patient.

Even Wang Chen, president of the Chinese Academy of Medical Sciences, conceded in February that the PCR tests are <u>"only 30 to 50 per cent accurate"</u>; while Sin Hang Lee from the Milford Molecular Diagnostics Laboratory sent a <u>letter to the WHO's coronavirus response</u> team and to Anthony S. Fauci on March 22, 2020, saying that:

It has been widely reported in the social media that the RT-qPCR [Reverse Transcriptase quantitative PCR] test kits used to detect SARSCoV-2 RNA in human specimens are generating many false positive results and are not sensitive enough to detect some real positive cases.

In other words, even if we theoretically assume that these PCR tests can really detect a viral infection, the tests would be practically worthless, and would only cause an unfounded scare among the "positive" people tested.

This becomes also evident considering the positive predictive value (PPV).

The PPV indicates the probability that a person with a positive test result is truly "positive" (ie. has the supposed virus), and it depends on two factors: the prevalence of the virus in the general population and the specificity of the test, that is the percentage of people without disease in whom the test is correctly "negative" (a test with a specificity of 95% incorrectly gives a positive result in 5 out of 100 non-infected people).

With the same specificity, the higher the prevalence, the higher the PPV.

In this context, on June 12 2020, the journal *Deutsches Ärzteblatt* published an article in which the PPV has been calculated with three different prevalence scenarios.

The results must, of course, be viewed very critically, first because it is not possible to calculate

the specificity without a solid gold standard, as outlined, and second because the calculations in the article are based on the specificity determined in the study by Jessica Watson, which is potentially worthless, as also mentioned.

But if you abstract from it, assuming that the underlying specificity of 95% is correct and that we know the prevalence, even the mainstream medical journal Deutsches Ärzteblatt reports that the so-called SARS-CoV-2 RT-PCR tests may have "a shockingly low" PPV.

In one of the three scenarios, figuring with an assumed prevalence of 3%, the PPV was only 30 percent, which means **that 70 percent of the people tested "positive" are not "positive" at all**. Yet "they are prescribed quarantine," as even the Ärzteblatt notes critically.

In a second scenario of the journal's article, a prevalence of rate of 20 percent is assumed. In this case they generate a PPV of 78 percent, meaning that **22 percent of the "positive" tests are false "positives".**

That would mean: If we take the around 9 million people who are currently considered "positive" worldwide — supposing that the true "positives" really have a viral infection — we would get almost 2 million false "positives."

All this fits with the fact that the CDC and the FDA, for instance, concede in their files that the so-called "SARS-CoV-2 RT-PCR tests" are not suitable for SARS-CoV-2 diagnosis.

In the <u>"CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel"</u> file from March 30, 2020, for example, it says:

Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms

And:

This test cannot rule out diseases caused by other bacterial or viral pathogens.

And the FDA admits that:

positive results (...) do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Remarkably, in the instruction manuals of PCR tests we can also read that they are not intended as a diagnostic test, as for instance in those by <u>Altona Diagnostics</u> and Creative Diagnostics[[url=#5]5[/url]].

To quote another one, in the product announcement of the LightMix Modular Assays produced by TIB Molbiol — which were developed using the Corman et al. protocol — and <u>distributed by Roche</u> we can read:

These assays are not intended for use as an aid in the diagnosis of coronavirus infection

And:

For research use only. Not for use in diagnostic procedures.

Where is the evidence that the tests can measure the "viral load"?

There is also reason to conclude that the PCR test from Roche and others cannot even detect the <u>targeted genes</u>.

Moreover, in the product descriptions of the RT-qPCR tests for SARS-COV-2 it says they are

"qualitative" tests, contrary to the fact that the "q" in "qPCR" stands for "quantitative." And if these tests are not "quantitative" tests, they don't show how many viral particles are in the body.

That is crucial because, in order to even begin talking about actual illness in the real world not only in a laboratory, the patient would need to have millions and millions of viral particles actively replicating in their body.

That is to say, the CDC, the WHO, the FDA or the RKI may assert that the tests can measure the so-called <u>"viral load,"</u> i.e. how many viral particles are in the body. "*But this has never been proven.* That is an enormous scandal," as the journalist <u>lon Rappoport points out</u>.

This is not only because the term "viral load" is deception. If you put the question "what is viral load?" at a dinner party, people take it to mean viruses circulating in the bloodstream. They're surprised to learn it's actually RNA molecules.

Also, to prove beyond any doubt that the PCR can measure how much a person is "burdened" with a disease-causing virus, the following experiment would have had to be carried out (which has not yet happened):

You take, let's say, a few hundred or even thousand people and remove tissue samples from them. Make sure the people who take the samples do not perform the test. The testers will never know who the patients are and what condition they're in. The testers run their PCR on the tissue samples. In each case, they say which virus they found and how much of it they found. Then, for example, in patients 29, 86, 199, 272, and 293 they found a great deal of what they claim is a virus. Now we un-blind those patients. They should all be sick, because they have so much virus replicating in their bodies. But are they really sick — or are they fit as a fiddle?

With the help of the aforementioned lawyer Viviane Fischer, I finally got the Charité to also answer the question of whether the test developed by Corman et al. — the so-called "Drosten PCR test" — is a quantitative test.

But the Charité was not willing to answer this question "yes". Instead, the Charité wrote:

If real-time RT-PCR is involved, to the knowledge of the Charité in most cases these are (...) limited to qualitative detection.

Furthermore, the "Drosten PCR test" uses the unspecific E-gene assay as <u>preliminary assay</u>, while the Institut Pasteur uses the same assay as <u>confirmatory assay</u>.

According to Corman et al., the E-gene assay is **likely to detect all Asian viruses**, while the other assays in both tests are supposed to be more specific for sequences labelled "SARS-CoV-2".

Besides the questionable purpose of having either a preliminary or a confirmatory test that is likely to detect all Asian viruses, at the beginning of April the WHO changed the algorithm, recommending that from then on a test can be regarded as "positive" even if just the E-gene assay (which is likely to detect **all Asian viruses!**) gives a "positive" result.

This means that a confirmed unspecific test result is officially sold as specific.

That change of algorithm increased the "case" numbers. Tests using the E-gene assay are produced for example by Roche, TIB Molbiol and R-Biopharm.

High Cq values make the test results even more meaningless

Another essential problem is that many PCR tests have a "cycle quantification" (Cq) value of over 35, and some, including the "Drosten PCR test", even have a Cq of 45.

The Cq value specifies how many cycles of DNA replication are required to detect a real signal from



biological samples.

"Cq values higher than 40 are suspect because of the implied low efficiency and generally should not be reported", as it says in the MIQE guidelines.

MIQE is stands for "Minimum Information for Publication of Quantitative Real-Time PCR Experiments", a set of guidelines that describe the minimum information necessary for evaluating publications on Real-Time PCR, also called quantitative PCR, or qPCR.

The inventor himself, Kary Mullis, agreed, when he stated:

If you have to go more than 40 cycles to amplify a single-copy gene, there is something seriously wrong with your PCR.

The MIQE guidelines have been developed under the aegis of <u>Stephen A. Bustin</u>, Professor of Molecular Medicine, a world-renowned expert on quantitative PCR and author of the book *A-Z* of *Quantitative PCR* which has been called <u>"the bible of aPCR."</u>

In a recent podcast interview Bustin points out that "the use of such arbitrary Cq cut-offs is not ideal, because they may be either too low (eliminating valid results) or too high (increasing false "positive" results)."

https://www.podbean.com/media/player/znrvk-d932a7?from=usersite&vjs=1&skin=1&fonts=Helvetica&auto=0&download=1

And, according to him, a Cq of 20 to 30 should be aimed at, and there is concern regarding the reliability of the results for any Cq over 35.

If the Cq value gets too high, it becomes difficult to distinguish real signal from background, for example due to reactions of primers and fluorescent probes, and hence there is a higher probability of false positives.

Moreover, among other factors that can alter the result, before starting with the actual PCR, in case you are looking for presumed RNA viruses such as SARS-CoV-2, the RNA must be converted to complementary DNA (cDNA) with the enzyme Reverse Transcriptase—hence the "RT" at the beginning of "PCR" or "qPCR."

But this transformation process is "widely recognized as inefficient and variable," as Jessica Schwaber from the Centre for Commercialization of Regenerative Medicine in Toronto and two research colleagues pointed out in a 2019 paper.

Stephen A. Bustin acknowledges problems with PCR in a comparable way.

For example, he pointed to the problem that in the course of the conversion process (RNA to cDNA) the amount of DNA obtained with the same RNA base material can vary widely, even by a factor of 10 (see above interview).

Considering that the DNA sequences get doubled at every cycle, even a slight variation becomes magnified and can thus alter the result, annihilating the test's reliable informative value.

So how can it be that those who claim the PCR tests are highly meaningful for so-called COVID-19 diagnosis blind out the fundamental inadequacies of these tests—even if they are confronted with questions regarding their validity?

Certainly, the apologists of the novel coronavirus hypothesis should have dealt with these questions before throwing the tests on the market and putting basically the whole world under lockdown, not least because these are questions that come to mind immediately for anyone with even a spark of scientific understanding.

Thus, the thought inevitably emerges that financial and political interests play a decisive role for this ignorance about scientific obligations. NB, the WHO, for example has financial ties with drug companies, as the *British Medical Journal* showed in 2010.

And <u>experts criticize</u> "that the notorious corruption and conflicts of interest at WHO have continued, even grown" since then. The CDC as well, to take another big player, is obviously <u>no better off</u>.

Finally, the reasons and possible motives remain speculative, and many involved surely act in good faith; but the science is clear: The numbers generated by these RT-PCR tests do not in the least justify frightening people who have been tested "positive" and imposing lockdown measures that plunge countless people into poverty and despair or even drive them to suicide.

And a "positive" result may have serious consequences for the patients as well, because then all non-viral factors are excluded from the diagnosis and the patients are treated with highly toxic drugs and invasive intubations. Especially for elderly people and patients with pre-existing conditions such a treatment can be fatal, as we have outlined in the article "Fatal Therapie".

Without doubt eventual excess mortality rates are caused by the therapy and by the lockdown measures, while the "COVID-19" death statistics comprise also patients who died of a variety of diseases, redefined as COVID-19 only because of a "positive" test result whose value could not be more doubtful.

NOTES:

- 1. [1] Sensitivity is defined as the proportion of patients with disease in whom the test is positive; and specificity is defined as the proportion of patients without disease in whom the test is negative.
- 2. [2] E-mail von Prof. Thomas Löscher from March 6, 2020
- 3. [3] Martin Enserink. Virology. Old guard urges virologists to go back to basics, Science, July 6, 2001, p. 24
- 4. [4] E-mail from Charles Calisher from May 10, 2020
- 5. [5] Creative Diagnostics, SARS-CoV-2 Coronavirus Multiplex RT-qPCR Kit