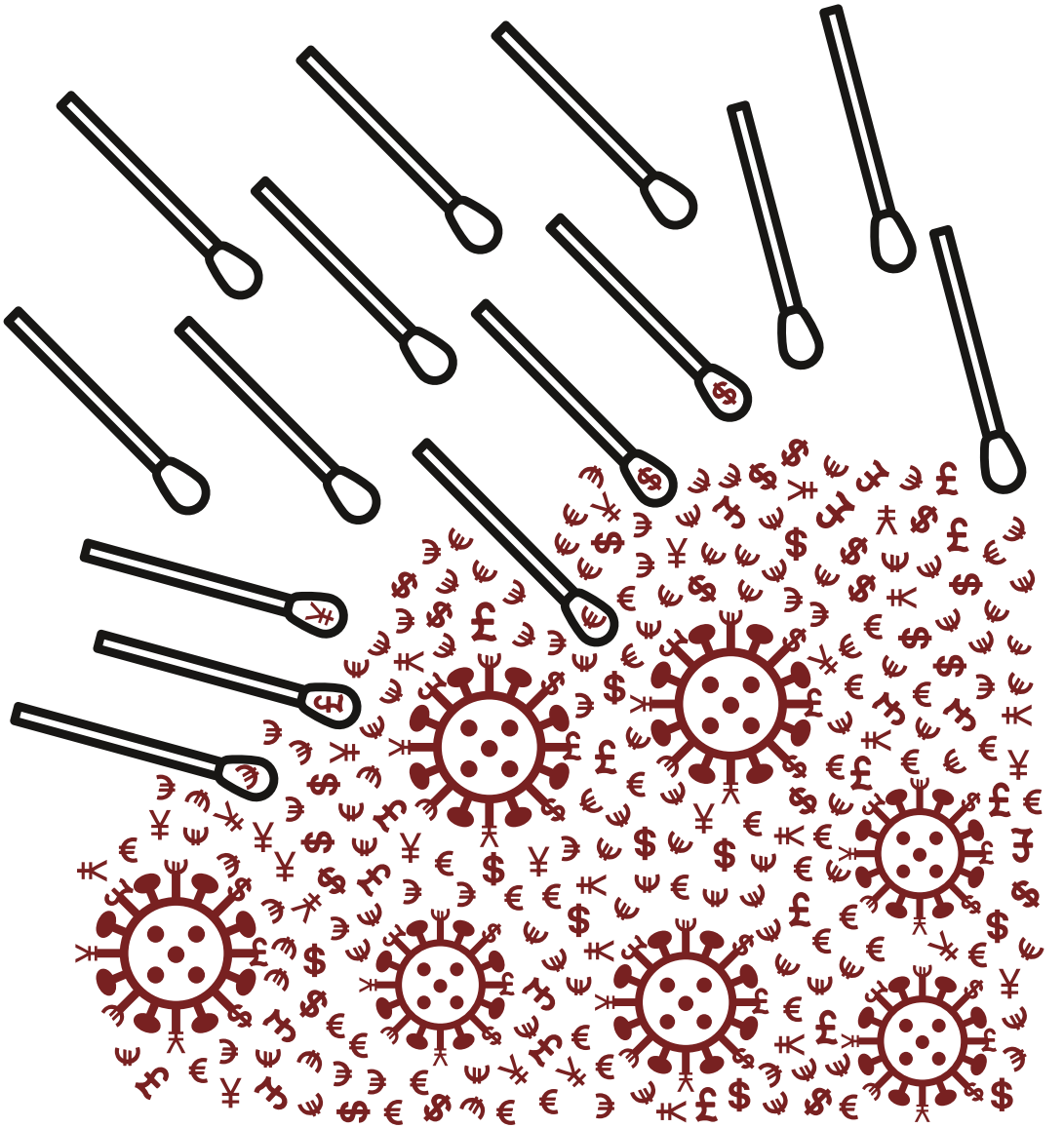
ILLA

The PCR Disaster

Genesis and Evolution of the »Drosten Test«



The PCR Disaster

Genesis and Evolution of the »Drosten Test«

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The PCR Disaster

Genesis and Evolution of the »Drosten Test«

by Illa
with a contribution from Prof. Ulrike Kämmerer

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Introduction

This booklet exposes a cornerstone of the Corona narrative—testing based on *Polymerase Chain Reaction*, PCR for short. It has emerged from a series of longer articles from the blog www.corodok.de that have appeared over the past few months.

The author of the following pages, Illa, wants to remain anonymous. But the sources she uncovers and her analytical mind emerge all the more clearly for it. Illa reveals patterns that also reach before the Corona year 2020. She also reveals a subtle web of actors and institutions that profit from society's fear of an invisible enemy.

Attached is the authorised transcript of Prof. Ulrike Kämmerer's hearing before the Corona Committee on 5 February 2021, in which she discusses the unusual genesis of the article in the journal *Eurosurveillance* that was written by the Drosten Group. The end of this story is still open; however, it is already becoming apparent that »science« is not immune to the grip of economic interests, even if it pretends to be.

The volume concludes with a glossary to help all those who can no longer see the wood for the trees.

2021 threatens to become another Corona year. The publisher and editor agree that it does no good to remain in shock like a rabbit in front of a snake. The booklet is therefore the beginning of a series that examines the structural framework of the Corona crisis from different angles.

Editorial note: All links were checked on 9.2.2021. Author's emphases are blue. Quotes from other languages than English were translated. The titles of quoted texts were preserved in footnotes whilst adding a translation in square brackets.

With PCR, if you do it well, you can find almost anything in anybody—it starts making you believe in the, sort of, buddhist notion that everything is contained in everything else. I mean, if you amplify one single molecule up to something you can really measure—which PCR can do—then there's just very few molecules that you don't have at least one single one of in your body…

It allows you to take a very minuscule amount of anything and make it measurable and then talk about in meetings and stuff like it is important. See, that's not a misuse that's just sort of a misinterpretation…

Those tests are all based on things that are invisible, and the results are inferred, in a sense. PCR is separate from that, it's just a process that's used to make a whole lot of something out of something. It doesn't tell you that you're sick and it doesn't tell you that the thing you ended up with was really going to hurt you or anything like that.

Kary Mullis
Inventor of PCR and Nobel Prize laureate (1944–2019)

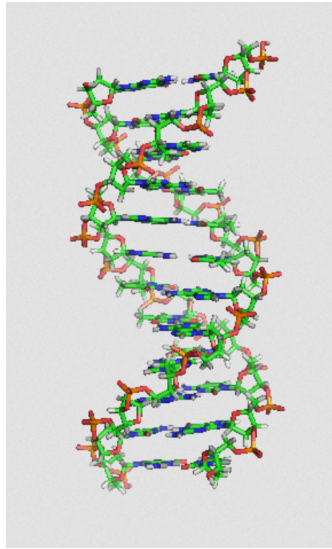
Cycling and Recycling of SARS-CoV-PCR

The test that forms the basis for COVID-19 and all of its consequences is the *polymerase chain reaction.* This method was invented by the US-American biochemist Kary Mullis, who told his story like this:

> »Sometimes a good idea comes to you when you are not looking for it. Through an improbable combination of coincidences, naiveté and lucky mistakes, such a revelation came to me one Friday night in April, 1983, as I gripped the steering wheel of my car and snaked along a moonlit mountain road into northern California's redwood country. That was how I stumbled across a process that could make unlimited numbers of copies of genes, a process now known as the polymerase chain reaction (PCR).
>
> Beginning with a single molecule of the genetic material DNA, the PCR can generate 100 billion similar molecules in an afternoon. The reaction is easy to execute: it requires no more than a testtube, a few simple reagents and a source of heat. The DNA sample that one wishes to copy can be pure, or it can be a minute part of an extremely complex mixture of biological materials. The DNA may come from a hospital tissue specimen, from a single human hair, from a drop of dried blood at the scene of a crime, from the tissues of a mummified brain or from a 40,000-year-old woolly mammoth frozen in a glacier.«[1]

Essential characteristics of PCR are mentioned in one single sentence of this story: All that is needed is a minimum of material in the beginning; the method is a formidable amplification machine. In short, it can be used to find the proverbial needle in a haystack, specifically a single molecule in a sample. In a few hours, this molecule can be multiplied by a factor of 100,000,000,000—to be precise, it is a molecule section from which the presence of the whole molecule is deduced. Kary Mullis received a Nobel Prize for his stroke of genius in 1993.

[1] Kary B. Mullis: The Unusual Origin of the Polymerase Chain Reaction (Scientific American April 1990). Online: https://cs.brown.edu/courses/csci1810/resources/pcr%20origin.pdf.



Structural model of a DNA helix in B conformation. The nucleic bases containing nitrogen (blue) lie horizontally between two backbone strands, which are very rich in oxygen (red). Carbon atoms are shown in green. Hydrogen: white, phosphorus: orange.

PCR and the importance of cycles

The hereditary substance DNA is present in the cell nuclei of animals, plants and fungi as a spirally twisted double strand. This double helix, whose discovery was also awarded a Nobel Prize, can be seen schematically in the illustration.[2] It is the material basis of genes and contains all the information about an organism. DNA is the abbreviation of ***d****eoxyribo****n****ucleic* ***a****cid* which is a »nuclear acid« (from Latin *nucleus*) with the sugar deoxyribose.

The decisive factor here is the arrangement of four building blocks, the nucleotides (in the illustration with blue part horizontally between the two backbone strands). They are lined up next to each

[2] »Strukturmodell einer DNA-Helix in B-Konformation (Animation)«. Online: https://commons.wikimedia.org/wiki/File:DNA_orbit_animated.gif by Richard Wheeler (Zephyris), (CC BY-SA 3.0).

other on the backbone strand and each nucleotide connects with another nucleotide on the opposite strand. The only possible connection is: adenine with thymine, guanine with cytosine.

These nucleotides abbreviated with A, T, G, C are organised in sections—the genes—and specify which proteins are finally formed from them: for example, enzymes for metabolism, antibodies for the immune response, structural proteins such as collagen for connective tissue or hair. By the way, you are synthesizing various proteins as you are reading this text.

(When PCR is used to search SARS-CoV-2, an additional preparatory step is required. The genetic material of the virus does not consist of DNA, but of a similar substance, RNA = ribonucleic acid. However, since the polymerase only works with DNA, the viral RNA must first be »transcribed« into DNA, then PCR can start).

For cell reproduction by division—your cells are also dividing just as you are reading—the DNA double strand opens and is duplicated by the enzyme polymerase which attaches the corresponding counterparts to the nucleotides of each strand: C to G, G to C, A to T, T to A. This creates two identical double strands, one of which migrates into each of the two newly formed cells.

The polymerase also duplicates the DNA when PCR is carried out; it enables the polymerase chain reaction, which takes place in cycles (C). In this process, the double-stranded DNA is first separated into two single strands by heating it to over 90°C. If the polymerase and the four nucleotides are then present in sufficient quantities as building material, the base pairs C-G and A-T join when the temperature is lowered to below 60°C, resulting in the duplication of the starting material.

However, since it is not possible to amplify a whole gene with PCR, but only a section of a gene, one chooses a section of interest within the gene. In order to let the polymerase start at exactly this section, one defines the starting point by setting the »primer« and carries out the reaction in a device called thermocycler: Heating, cooling, heating, cooling … The resulting DNA is not seen directly, but via a fluorescent dye whose intensity is measured.

The DNA in the sample is doubled in each step, the increase is exponential. If you start from a single gene segment, after one cycle

you already have two of them, and since doubling continues in each cycle, you receive:

10 cycles = 1.024 = approx. 1 thousand
20 cycles = 1.048.576 = approx. 1 million
30 cycles = 1.073.741.824 = approx. 1 billion
35 cycles = 34.359.738.368
40 cycles = 1.099.511.627.776 = approx. 1 trillion
45 cycles = 35.184.372.088.832
50 cycles = 1.125.899.906.842.624 = approx. 1 quadrillion

The crucial question is: When do you stop? PCR does not deliver delimited results in YES or NO, but there is first a range without reaction in which no fluorescence is measured yet, then there is an intermediate range in which more or less the increase of the fluorescence can be observed until the curve reaches a plateau sooner or later.

It has to be justified which number of cycles generates a meaningful result that does not fall into the measurement range with interfering signals and unspecific reactions for technical reasons, i. e. intrinsically false-positive results. Additionally, there must be a reference to clinical relevance, and this cannot be about the meaningless finding of the »needle in the haystack«. Mere determination not sufficient but must be determined in a comprehensible way, so the justification for the upper limit must be reasonable and binding. The Canadian David Crowe summed up the problem like this:

> »So, if you cut off at 20, everybody would be negative. If you cut off a[t] 50, you might have everybody positive.«[3]

45 Cycles: Drosten and the World Health Organization

The maximum upper limit of 45 cycles can be found with Christian Drosten (Charité) and Olfert Landt (*TIB Molbiol*), both situated in

[3] Quote from David Crowe in Celia Farber: The Corona Simulation Machine: Why the Inventor of The »Corona Test« Would Have Warned Us Not To Use It To Detect A Virus (7.4.2020). Online: https://uncoverdc.com/2020/04/07/was-the-covid-19-test-meant-to-detect-a-virus/.

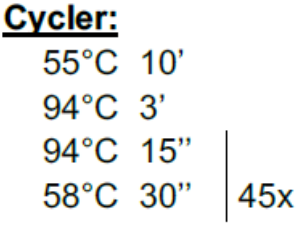
Berlin. This is of particular importance because they developed the test and perform or produce it. But above all because they, together with some other authors, wrote the PCR instructions that were adopted by the *World Health Organization* (WHO).

The »workflow« as a template for the whole world originated from them; they put it together at the speed of light, made possible by virology without a virus and even without a gene sequence:

> »In the first week of January, reports emerged that a mysterious new form of pneumonia had affected dozens of people in China. […]
>
> Thousands of miles away in Berlin, German scientist Olfert Landt was already on alert. For 30 years, he had worked on diagnosing emerging diseases, including severe acute respiratory syndrome (SARS). He wanted to make a test kit to help doctors diagnose the disease—and he wanted to do it fast.
>
> Virologists usually wait until the genetic material of a new virus is sequenced to start working on a test. This time, Landt and his 30-strong company TIB Molbiol got started early. By January 9 they had designed their first test kit using SARS and other known coronaviruses as references. Along with scientists from a local university hospital, he designed three kits, meaning once the sequence was published, they could pick the one that worked best.
>
> On January 11, Landt sent his kit to Taiwan's Centers for Disease Control and diagnostic company Roche in Hong Kong. He didn't know for certain that it would work, and he hadn't even prepared instructions.
>
> Over the weekend, he worked up a manual and emailed it over. ›We said, listen, you have six tubes without any instructions,‹ he recalls. ›Give them to the test laboratory, you can test patients with this.‹
>
> In the end, the test he sent over was perfect, he said. On January 17, the World Health Organization (WHO) published Landt's protocol online, making it the first test to be shared by the organization.«[4]

[4] Julia Hollingsworth: A coronavirus test can be developed in 24 hours. So why are some countries still struggling to diagnose? (CNN 25.3.2020). Online: https://edition.cnn.com/2020/03/24/asia/testing-coronavirus-science-intl-hnk/index.html.

The WHO and officials from China announced on 9 January that the cause of the illness was a new coronavirus, by which time the test kit was ready. Over the weekend of 11–12 January, as Landt's package was en route to Asia, the RNA sequence of the virus was announced by Chinese health officials.[5] At that time, however, there were no patients in Taiwan and Hong Kong to be tested with the Drosten/Landt test, as the first ones were not reported until 21 and 22 January, respectively.[6,7]



Since speed is emphasised in the report, it is even stranger that the first version of the Drosten/Landt protocol on PCR for diagnostic detection »of Wuhan coronavirus 2019«, posted online by WHO on 13 January, went unmentioned. In this protocol there was guidance for gene segments from the E gene as well as the RdRp and N genes.[8] It was succeded on 17 January by a modified version for diagnostic detection »of 2019-nCoV« this time using the E gene and two sections of the RdRp gene. And always 45 cycles are provided for each step.[9]

[5] Whole genome of novel coronavirus, 2019-nCoV, sequenced (Insitut Pasteur 31.1.2020). Online: https://www.sciencedaily.com/releases/2020/01/200131114748.htm.

[6] Erster Coronavirus-Fall in Taiwan bestätigt [*First coronavirus case confirmed in Taiwan*] (Der Standard 21.1.2020). Online: https://www.derstandard.de/story/2000113562179/erster-coronavirus-fall-in-taiwan-bestaetigt.

[7] Coronavirus: Erster Infektionsfall in Hongkong bestätigt [*Coronavirus: First case of infection confirmed in Hong Kong*] (Kurier 22.1.2020). Online: https://kurier.at/wissen/gesundheit/corona-virus-bereits-neun-tote-440-menschen-infiziert/400732881.

[8] Victor Corman et al: Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR protocol and preliminary evaluation as of Jan 13, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf?sfvrsn=d381fc88_2.

[9] Victor Corman et al: Diagnostic detection of 2019-nCoV by real-time RT-PCR

40 Cycles: The Inventor and the Standard

In the opening quote, Kary Mullis spoke of »100 billion similar molecules« that could be created from »a single molecule of the genetic material DNA« by PCR within one afternoon—which corresponds to about 37 PCR cycles. For him, 40 cycles was the maximum:

> »**Cycle Number**
> The optimal number of cycles will depend mainly upon the starting concentration of target DNA when other parameters are optimized. A common mistake is to execute too many cycles. To quote Kary Mullis, ›If you have to go more than 40 cycles to amplify a single-copy gene, there is something seriously wrong with your PCR.‹ Too many cycles can increse the amount and complexity of nonspecific background products (see Plateau Effect).«[10]

The »MIQE Guidelines« (*Minimum Information for Publication of Quantitative Real-Time PCR Experiments*) by Stephen Bustin et al. are available for the proper performance and evaluation:

> C_q values > 40 [i. e. more than 40 cycles] are suspect because of the implied low efficiency and generally should not be reported; however, the use of such arbitrary C_q cutoffs is not ideal, because they may be either too low (eliminating valid results) or too high (increasing false-positive results).[11]

In an interview with David Crowe, Bustin went even further, saying »that cycles should probably be limited to 35.«[12]

-Protocol and preliminary evaluationas of Jan 17, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

[10] PCR Protocols. A Guide to Methods and Applications. Edited by Michael A. Innis et al., Academic Press, London (1990: 8f.). Online: https://books.google.de/books?id=Z5jwZ2rbVe8C&pg=PA8&lpg=PA8&dq#v=onepage&q&f=false.

[11] Stephen A. Bustin: The MIQE Guidelines: Minimum Information for Publication of Quantitative Real-Time PCR Experiments. Clinical Chemistry 55:4 611–622 (2009). Online: https://www.gene-quantification.de/miqe-bustin-et-al-clin-chem-2009.pdf.

[12] David Crowe: Flaws in Coronavirus Pandemic Theory (version 8.5. of 6.6.2020). Online: https://theinfectiousmyth.com/book/CoronavirusPanic.pdf. As the author died in July 2020, the long-term availability of his articles may be uncertain. If you are interested in this text or other of his publications such as

The main issue: Being positive?

45 cycles compared to the generally valid—and probably not even optimal—upper limit of 40 means the production of 35 trillion instead of 1 trillion copies at a starting point of one gene. Of course, the authors of the WHO guidelines from January know these statements and regulations, at least Christian Drosten and Olfert Landt certainly do, because these form the basis of their work. But why did they decide to disregard these guidelines?

Possibly they did not want the problems of SARS 2003—i. e. the direct precursor of COVID-19—to be repeated: too few positives. This led to doubts expressed publicly and even internationally at the time:

> »They have so far been able to find the new coronavirus only in 40 per cent of all suspected SARS patients. However, they did manage to detect the virus in some healthy people from the control group. In another group of 250 patients, they found an antibody to the coronavirus in 20 per cent of the samples. In light of these findings the head of the Canadian research group Frank Plummer said he was ›surprised‹ and raised doubts about whether the new coronavirus was really the cause of SARS.«[13]

Frank Plummer was director of Canada's *National Microbiology Laboratory* in Winnipeg. This laboratory was one of eleven research labs that were part of WHO's SARS network.

> »Canada is the Western country hardest hit by SARS […]. It has seen 190 SARS cases, in two waves, and 11 deaths […] ›Of course, the case definition of SARS is a little loose,‹ said Plummer, ›but many of the Toronto cases are epidemiologically linked, and we are finding some of the best-characterized cases are negative. So it's puzzling. As is the fact the amounts of virus we are finding, when we find it, are very small – only detectable by very sensitive

his started book on the SARS panic he witnessed in Canada in 2003, you may need to hurry.

[13] Kanadische Wissenschaftler können den SARS-Erreger nicht in allen Patienten nachweisen [*Canadian scientists cannot detect SARS agent in all patients*] (Deutschlandfunk 25.4.2003). Online: https://www.deutschlandfunk.de/meldungen-liste-forschung-aktuell.1508.de.html?drn:news_id=75613.

> PCR. […] Coronavirus could be the etiology; but I'm not impressed‹ he said. On the basis of the Canadian data ›the chances of having SARS if you have this virus are increased by about a factor of two – compared with if you don't.‹«[14]

This serious concern was presented in April 2003 by a renowned scientist who was directly involved. The data situation in Germany was similar. In 2003, Herbert Schmitz was a professor at the Bernhard Nocht Institute for Tropical Medicine (BNI) in Hamburg, Drosten's place of work at the time:

> »In Canada, doctors have actually found the virus in only 40 percent of cases. Now one wonders about the rest. In Hong Kong, for example, there is currently an influenza that causes exactly the same symptoms. It's not being kept apart properly. […] All the figures are very shaky and need to be cleaned up urgently. Example: There have been seven cases of SARS reported in Germany so far. But we have only been able to detect the Corona virus in three of them. Something is not adding up. The main reason is that the SARS definition is very vague, whereas the Corona laboratory diagnostics are very strict.«[15]

And no matter how much the data offered a reason for considerable doubt about the test as well, the BNI decided to take a different view from Plummer, perhaps also because Drosten's PCR was a stroke of luck for the institute and the associated *artus GmbH*.[16] In any case, the causal role of SARS-CoV-1, as it is now called, had already been decided on in March: not only by Drosten and the BNI, but also the

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[14] Robert Walgate: Cause of SARS disputed (The Scientist 10.4.2003). Online: https://www.the-scientist.com/news-analysis/cause-of-sars-disputed-51794.

[15] Haben Sie SARS unterschätzt, Herr Schmitz? [*Did you underestimate SARS, Mr. Schmitz?*] (Welt 29.4.2003). Online: https://www.welt.de/print-welt/article691304/Haben-Sie-SARS-unterschaetzt-Herr-Schmitz.html.

[16] Studie zum SARS-assoziierten Coronavirus veröffentlicht – Protokoll einer Spurensuche [*Study of SARS-associated coronavirus published—protocol of a forensic investigation*]. Online: https://www.bnitm.de/en/news/communications/132-studie-zum-sars-assoziierten-coronavirus-veroeffentlicht/.

US *Centers for Disease Control and Prevention* (*CDC*) and the WHO, among others. Besides, SARS was over in May 2003.[17]

This SARS PCR was the beginning of an extremely profitable collaboration for Drosten and Landt that has lasted to this day; the two have been involved in every influenza scare since then (bird flu, swine flu) and in several smaller events such as MERS and Zika.[18] Landt was able to build up a corporate empire worth millions, which consists to a considerable part of real estate.[19] Drosten received various prizes from the pharmaceutical industry for SARS as well as the Federal Cross of Merit, became a professor without habilitation and possibly without formally obtaining a doctorate.[20] But that was nothing compared to 2020.

PCR-Recycling

In January 2020, Drosten and Landt retrieved their old SARS-CoV-1 data rapidly; without a virus at hand they made a test out of it and sent the instructions with the 45 cycles to the WHO. A few days later, the protocol was modified a little, but this test for SARS-CoV-2 is so much SARS-CoV-1 that its viral RNA can even be used as a positive control.[8,9]

With such a high degree of similarity between these two viruses, it is surprising that they should behave so differently from a biological point of view, as Jonas Schmidt-Chanasit from the BNI described:

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17 SARS, COVID-19 und die Macht der Definition [*SARS, COVID-19 and the power of definition*]. Online: https://www.corodok.de/sars-covid-definition/.

18 Drosten-Landt-Connection: Geld scheffeln mit Pandemien (I–III) [*Drosten-Landt-Connection: Reaping money with pandemics*]. Online: https://www.corodok.de/drosten-landt-connection-1/; https://www.corodok.de/drosten-landt-connection-2/; https://www.corodok.de/drosten-landt-connection-3/.

19 Millionenschweres Netzwerk des Charité-Partners Olfert Landt [*Million-dollar network of Charité partner Olfert Landt*]. Online: https://www.corodok.de/millionenschweres-netzwerk-charite/; Landts besseres Büro auf dem Kudamm – und wieder Fragen… [*Landts better office on the Kudamm—and more questions….*]. Online: https://www.corodok.de/landts-buero-kudamm/.

20 Was stimmt eigentlich am akademischen Lebenslauf von C. Drosten? [*What is actually true about C. Drosten's academic resume?*] Online: https://www.corodok.de/drosten-lebenslauf-was-stimmt/; Diss & das [*Diss & that*]. Online: https://www.corodok.de/diss-das/. Cf. in principle: https://www.corodok.de/tag/dissertation/.

> »You know that the virus is very, very closely related to the old SARS virus. But the old SARS virus has a completely different dynamic, so to speak, in terms of spreading. It was, after all, only transmitted from sick people in hospitals in the end, which means a much easier way of containment. This is just different with the new SARS coronavirus, although it is very closely related to the old SARS virus. It is very fascinating to me that two closely related viruses have completely different spreading dynamics, pre-symptomatic or asymptomatic transmission plays a significant role in the new SARS coronavirus. This is the decisive factor that has led to a pandemic in the first place, precisely this silent spread. It is a silent pandemic, so to speak, a cancer that is slowly spreading, also in Germany. That is why we now have the cases that are increasingly taking place in the countryside, that is precisely the critical point.«[21]

Before guessing around on this level for a long time without results, it is better to look elsewhere. Then you will realise that it is the definition combined with the test that makes the difference. In 2003, there was an event that limited itself by the completely different definition and finally ended—an epidemiological link was required and there were no test-positives without symptoms, because symptomless people were not tested. So only a very small group of people were eligible for a test, and without symptomless test-positives, no asymptomatic transmission could then be construed.[22] In 2020, on the other hand, there are no corresponding preconditions for testing, so now everybody is a potential PCR candidate, possibly even several times.

Moreover, it is now the positive test alone that makes one a case by definition, with matching, mismatching, missing, unknown symptoms.[17] Now the test is the sole criterion, whereas in 2003 it only played a subordinate role in the definition later on. Presumably,

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[21] Virologe Jonas Schmidt-Chanasit – Gesellschaftliche Sprengkraft von COVID-19-Virus ist gewaltig [*Virologist Jonas Schmidt-Chanasit—The disruptive social power of COVID-19 virus is enormous*] (Deutschlandfunk 7.8.2020). Online: https://www.deutschlandfunk.de/virologe-jonas-schmidt-chanasit-gesellschaftliche.694.de.html?dram:article_id=481940.

[22] Die Legende von der asymptomatischen Übertragung [*The myth of asymptomatic transmission*]. Online: https://www.corodok.de/die-legende-uebertragung/.

the current pandemic would have been over long ago if the WHO definition of 2003 with its completely different emphasis was still in place. Instead, about 42 million tests were carried out in Germany by calendar week 5/2021, the vast majority on asymptomatic people, i. e. healthy people who can become a »case« just by a positive PCR.

There is no official information on the proportion of false-positive results in these tests, and the *Robert Koch Institute* (RKI) which is responsible for disease surveillance in Germany only gives very evasive answers to enquiries, while the German Ministry of Health does not answer at all, considerably exceeding the deadline for enquiries.[23] Thus, only educated guesses can be made: with a good specificity of 99 %, it would be about 400,000.[24]

Unfortunately, the question must remain unanswered as to what Plummer would have said about the current situation because he died in February 2020. Another question is: How could such a non-standard »workflow« be accepted at the WHO, knowing that this is the invitation for false-positive results?

35 or 30 cycles—or 20?

In August 2020, an article appeared in the *New York Times* in which the problem of the number of cycles was finally at least addressed to a broad public, even if it was not sufficiently analysed. Statements like the following were made by one virologist: »Any test with a cycle threshold above 35 is too sensitive. […] ›I'm shocked that people would think that 40 could represent a positive‹ […] A more reasonable cutoff would be 30 to 35, she added.« An epidemiologist said, »he would set the figure at 30, or even less.«[25]

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[23] https://fragdenstaat.de/anfrage/fallzahlen-r-wert-zweite-welle-durch-falsch-positve-pcr/ and https://fragdenstaat.de/anfrage/bitte-um-beantwortung-von-fragen-zu-tests-auf-sars-cov-2/. The questions are reproduced in the appendix. www.fragdenstaat.de is a platform that facilitates information requests towards government entities in Germany.

[24] PCR-Spezifität: Auswirkungen auf Fallzahlen und R-Wert [*PCR specificity: impact on case numbers and R-value*]. Online: https://www.corodok.de/pcr-spezifitaet-auswirkungen/.

[25] Apoorva Mandavilli: Your Coronavirus Test Is Positive. Maybe It Shouldn't Be. (New York Times 29.8.2020). Online: https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html.

Several tests were approved in the USA in the course of an Emergency Use Authorization (EUA, the Drosten/Landt test is not included). For the tests with an upper cycle limit, the specifications cover this range:

> »One manufacturer each recommended 30 cycles, 31, 35, 36, 37, 38 and 39. 40 cycles was most popular, chosen by 12 manufacturers, and two recommended 43 and 45«[26]

The impact of different ciycle numbers on test results and those tested is shown by two examinations that were absolutely overdue:

> »Officials at the Wadsworth Center, New York's state lab, have access to C.T. values from tests they have processed, and analyzed their numbers at The Times's request. In July, the lab identified 872 positive tests, based on a threshold of 40 cycles.
>
> With a cutoff of 35, about 43 percent of those tests would no longer qualify as positive. About 63 percent would no longer be judged positive if the cycles were limited to 30.
>
> In Massachusetts, from 85 to 90 percent of people who tested positive in July with a cycle threshold of 40 would have been deemed negative if the threshold were 30 cycles, Dr. Mina said. ›I would say that none of those people should be contact-traced, not one,‹ he said.«[25]

Even though so much astonishment is being put on display now: all this was known beforehand. They closed their eyes and kept their mouths shut and let the catastrophe based on this test happen. For Germany, using figures for the fifth week of 2021, this means: at 50 %, 1.2 mio. of the current 2 mio. RKI cases would remain, and at 90 % there would be only about 200,000—which would be the cumulative values for the entire pandemic!

> »... if you cut off at 20, everybody would be negative ...«[27]

[26] David Crowe: The Incredible and Scary Truth about COVID-19 Tests (26.4.2020 Version 2). Online: https://theinfectiousmyth.com/coronavirus/FDATestSummary.pdf. Please note the comment placed under footnote 12.

[27] More precisely, with such a low number of cycles, *almost* everyone would be negative. However, this pointed quotation from David Crowe should be left as he wrote it and as it was used in the text to illustrate the problem.

PCR technology between the pharmaceutical industry and virology

PCR (polymerase chain reaction) is a now widely known laboratory method routinely used to »diagnose« COVID-19. Technically, it is a precise tool for immensely multiplying the genetic material DNA from a barely available starting material—from a single section of a molecule it can make billions of copies within hours. Tragically, this method has fallen into bad company: it was first appropriated by the pharmaceutical giant *Hoffmann-La Roche* and then by clinical virology.

This association emerged at the end of the last century and forms the core of our current situation, because without the PCR test with its enormous number of false-positive results,[1] many of them in asymptomatic[2]—aka healthy—people, a return to normality would have been possible from June 2020 at the latest.[3] PCR itself mercilessly amplifies any DNA in a sample that fits certain specifications (primers): it can be the object sought for, or any other cross-reacting virus; but a possible reason can also be some kind of impurity (which can get into the sample in the course of the process, which also includes a multi-stage preparation). And even if the object sought for is actually detected, PCR cannot say anything about its condition (fragments, lack of ability to multiply) and not necessarily anything

[1] PCR-Spezifität: Auswirkungen auf Fallzahlen und R-Wert [*PCR specificity: impact on case numbers and R-value*]. Online: https://www.corodok.de/pcr-spezifitaet-auswirkungen/. Von Epidemien und Pseudo-Epidemien [*Of epidemics and pseudo-epidemics*]. Online: https://www.corodok.de/von-epidemien-und-pseudo-epidemien/.

[2] Die Legende von der asymptomatischen Übertragung [*The myth of asymptomatic transmission*]. Online: https://www.corodok.de/die-legende-uebertragung/. »Wunder von Haiti« statt »maximaler Katastrophe« [*»Miracle of Haiti« instead of »maximum disaster«*]. Online: https://www.corodok.de/wunder-haiti-katastrophe/.

[3] Ein Gespenst geht um in Europa: die »Falldemie« [*A spectre is haunting Europe: the »casedemic«*]. Online: https://www.corodok.de/ein-gespenst-europa/.

about its concentration being sufficient for infectivity.[4] You get a result, but realistically you don't know what it means in the context of a disease.

A positive test result could and should urgently be routinely checked, but there is little interest in this at best. One can safely assume that the »case numbers«—aka positive PCR results—published daily by the Robert Koch Institute (RKI) would shrink considerably through a thorough review, which in turn would deprive everything that follows of justification. And one would have to think consistently further and admit that PCR methodologically cannot answer the question at all whether a person is ill with COVID-19 or not, and furthermore whether a person actually ill with COVID-19 can infect others or not—which of course applies in principle to other infectious diseases, too. However, this is not the fault of PCR, but the mistake is made by those who ask the wrong question. The fact that they have persistently done so for decades is not only based on incompetence, but above all on a very banal mixture of greed for profit and careerism.

Mullis, Cetus and Roche

The US biochemist Kary Mullis invented PCR in 1983 as an employee of the Californian biotechnology company *Cetus Corporation.* Mullis was compensated with US$ 10.000. The other members of the laboratory received a symbolic dollar and *Cetus* sold the patents to the Swiss pharmaceutical company *Hoffmann-La Roche*[5]—currently the world's largest pharmaceutical company with a dominant diagnostics division and known simply as *Roche*—for US$ 300 million. The majority of the company is owned by the founding family, but for some years its rival company *Novartis* from Switzerland has held

[4] See the preceding chapter »Cycling and Recycling of SARS-CoV-PCR«. Also online in German: https://www.corodok.de/cycling-recycling-sars/.

[5] Joe Fore Jr, Ilse R Wiechers, Robert Cook-Deegan: The effects of business practices, licensing, and intellectual property on development and dissemination of the polymerase chain reaction: case study (Journal of Biomedical Discovery and Collaboration 3.7.2006). Online: https://www.researchgate.net/publication/6966905_The_effects_of_business_practices_licensing_and_intellectual_property_on_development_and_dissemination_of_the_polymerase_chain_reaction_Case_study/link/0f611bb33829848d99d0f113/download.

a stake of just under a third.[6] Concerning the highly problematic company history, only a few search engine suggestions should suffice at this point: *Seveso/Dioxin*, *Vitamin Cartel*, *Roaccutane*, *Lariam*, *Tamiflu*.

This huge investment in PCR had to pay off for *Roche*, and as quickly as possible, since key components of the patents would expire in the USA in 2005 and in Europe in 2006.[7] The group described its goals as follows:

> »1) expand and encourage the use of the technology;
> 2) receive financial returns from the use of the technology by others;
> 3) preserve the value of the intellectual property and patents granted on it;«

The two-part licence for users was divided into the purchase of a thermal cycler (the device in which the PCR takes place) from an authorised distributor and the use of the licensed reagents. The cost was, in the words of one researcher, »among the highest royalties I've personally dealt with« and earned *Roche* up to US$ 2 billion.[5]

Its use was also subject to licensing, and subsequently »Roche expanded the potential uses of the technology by licensing it in paternity testing and infectious disease diagnostics, two fields for which the company had previously denied granting rights.«[5] This is how PCR entered AIDS research in the 1990s and, by extension, clinical virology. Mullis, who had received the Nobel Prize for his invention in 1993, did not agree with this at all:

> »PCR made it easier to see that certain people are infected with HIV […] and some of those people came down with symptoms of AIDS. But that doesn't begin even to answer the question, ›Does HIV cause it?‹ […] The mystery of that damn virus […] has been generated by the $2 billion a year they spend on it. You take any

[6] https://www.roche.com/de/investors/faq-investors/major_shareholders.htm.

[7] Die Patente der Polymerase-Kettenreaktion: EINFÜHRUNG [*The patents of the polymerase chain reaction: INTRODUCTION*]. Online: https://www.westfalenpatent.de/wp-content/uploads/2019/12/Die-Patente-der-Polymerase-Kettenreaktion.pdf.

other virus, and you spend $2 billion, and you can make up some great mysteries about it too.«[8]

LightCycler® and LightMix®

Roche has been offering a PCR device called *LightCycler* since 1998. It's still sold with various enhancements and is used for routinely used Real-Time PCR. It was developed through a collaboration between a US university, a reference laboratory and a small company; the patent was sold to *Boehringer Mannheim*, more specifically to the Bahamas-based holding company *Corange* which owned the diagnostics company.[9] Its owner »has sold the family firm Boehringer Mannheim (BM), including its holding company and foreign holdings, to the Basel-based pharmaceutical company *Roche*. For eleven billion dollars, 27 times BM's consolidated profits, the Swiss are buying the top position in the diagnostics industry.«[10] This is what happened in 1997, and for the sake of completeness the »tax saving models« gaining the old owners billions of euros and the new owners are noteworthy.[11]

The company which is based in Mannheim, Germany, kept its location after the sale and became part of *Roche Diagnostics*. It provided *Roche* with the patent for the *LightCycler* after analysts estimated that the group had already invested more than US$ 1 billion »to develop automated accessories and additional products. Despite the superior sensitivity and reliability of PCR-based tests, it had been difficult to convince customers such as blood banks to replace tests with a cost factor of a few cents with those that cost a few US$

[8] Celia Farber: Was the COVID-19 Test Meant to Detect a Virus? (7.4.2020). Online: https://uncoverdc.com/2020/04/07/was-the-covid-19-test-meant-to-detect-a-virus/.

[9] Elaine Lyon, Carl T. Wittwer: LightCycler Technology in Molecular Diagnostics (Journal of Molecular Diagnostics March 2009). Online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665858/.

[10] Unternehmer »Wir neigen zum Geiz« [*Entrepreneur »We tend to be stingy«*] (Spiegel 2.6.1997). Online: https://magazin.spiegel.de/EpubDelivery/spiegel/pdf/8720167.

[11] Steuerhinterziehung in Milliardenhöhe – legal und illegal [*Tax evasion worth billions—legal and illegal*] (16.11.2017). Online: https://kommunalinfo-mannheim.de/2017/11/16/steuerhinterziehung-in-milliardenhoehe-legal-und-illegal/.

per test. Boehringer Mannheim's strength is in the high-volume segment of the diagnostics industry, the so-called clinical chemistry systems that churn out thousands of tests a day in huge hospital laboratories.«[12] The new thermal cycler and access to the large laboratory sector opened up new perspectives for the dissemination of PCR to *Roche*.

In this context, the controversial dissertation[13] by Christian Drosten should be briefly mentioned, whose research object he himself describes as follows: »I took my first steps at the Institute for Transfusion Medicine at the University Hospital Frankfurt, where blood donations were already being tested for HCV, HIV-1 and HBV by PCR in the 1990s. Setting up the first test systems for HIV-1 and HBV in a high-throughput procedure was my doctoral thesis.«[14] As pioneers of PCR application, the Frankfurt group around Drosten's doctoral supervisor (without Drosten) was honoured for their work published in *Lancet* in 1999 on »Feasibility and efficiency of routine PCR screening of blood donations for hepatitis C virus, hepatitis B virus and HIV-1 in a blood bank«.[15]

When *Boehringer Mannheim* was still a patent owner, the *LightCycler* was presented to potential customers. One of them was Olfert Landt, founder and owner of the Berlin biotechnology company *TIB Molbiol*:

> »With the introduction of Real-Time PCR (1997), TIB MOLBIOL immediately focused on the young technology. The exploration of new approaches was pushed while experimenting with different technical formats.
>
> In 1998, Boehringer Mannheim (now Roche) introduced the LightCycler® real-time PCR instrument. Based on the novel detection format […] the instrument revolutionised real-time PCR. On

[12] Stephen D. Moore and Margaret Studer: Roche Holding to Buy Corange, Making It No. 1 in Diagnostics (Wallstreet Journal 26.5.1997). Online: https://www.wsj.com/articles/SB864639230274970500.

[13] https://www.corodok.de/tag/dissertation/

[14] https://virologie-ccm.charite.de/forschung/labor_drosten/.

[15] Verleihungen [*Awards*] (Deutsches Ärzteblatt 28.1.2000). Online: https://www.aerzteblatt.de/archiv/20981/Verleihungen.

> the one hand, the processes could be accelerated, on the other hand, the experimental application possibilities gained in versatility.
>
> TIB MOLBIOL […] started a cooperation with Boehringer Mannheim. Together they tried to increase the application horizon and the attractiveness of the instrument. Accordingly, the company invested its most valuable resources: knowledge, experimental curiosity as well as a willingness to take risks«[16]

Landt's connection to *Boehringer Mannheim* had come about via *LightCycler* and continued after the sale of the company to *Roche*, as documented in a PowerPoint presentation by *TIB Molbiol*.[17] Landt wrote this article in the series »Roche Technical Note« together with his employee Andreas Nitsche, who went from *TIB Molbiol* to the *Robert Koch Institute* (*RKI*) in 2002, where he is currently head of the department of highly pathogenic viruses, i. e. also responsible for SARS-CoV-2.[18] Nitsche habilitated at the Charité in 2010, his first examiner was Drosten[19] who was a professor in Bonn at the time, but unlike his examinee, he did not have to habilitate.

The connection between *Roche* and *TIB Molbiol* was further strengthened in 2005 when Landt invented »the LightMix® Kits (licensed from *Roche Diagnostics*)« to go with the *LightCycler*, each containing the primers needed. Not only the proprietary name fits the instrument perfectly: »TIB MOLBIOL's kits have been designed, developed and evaluated specifically for and on the LightCycler® instrumentation.«[16]

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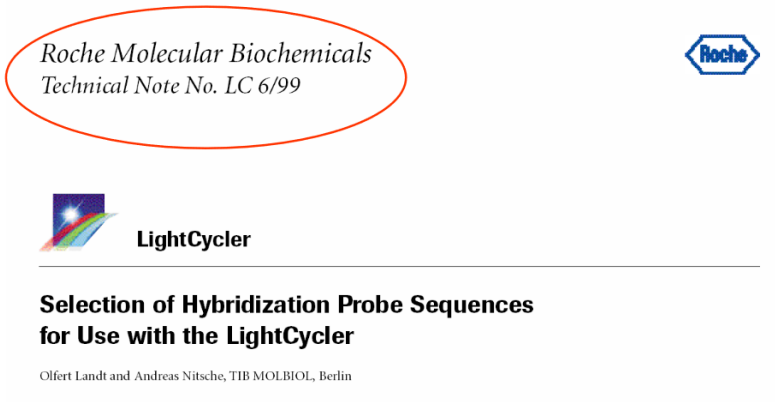
[16] http://web.archive.org/web/20200819043634/https://www.tib-molbiol.de/de/company/index.html.

[17] Excerpt from: Eduardo Thuroff: The Potential of Multiplex Real-time PCR – A Modular Approach, Toronto 2016. Online: http://nmgroup.ca/Document/2016/2016_06.pdf.

[18] Andreas Nitsche, Robert Koch Insitute [*sic*] (RKI), Germany. Online: https://www.globalmicrobialidentifier.org/people/steering-committee/andreas-nitsche-germany.

[19] Title of the thesis: Aus dem Robert Koch-Institut in Berlin Zentrum für Biologische Sicherheit: Untersuchungen zur Diagnostik und Risikobewertung von emerging und re-emerging Orthopockenviren in Deutschland / zur Erlangung der Lehrbefähigung für das Fach Virologie / vorgelegt dem Fakultätsrat der Medizinischen Fakultät Charité-Universitätsmedizin Berlin von Dr. rer. nat. Andreas Nitsche / Eingereicht: Dezember 2010. Online: https://edoc.rki.de/bitstream/handle/176904/5350/nitsche.pdf?sequence=1&isAllowed=y.


Roche Molecular Biochemicals
Technical Note No. LC 6/99

Roche

LightCycler

Selection of Hybridization Probe Sequences for Use with the LightCycler

Olfert Landt and Andreas Nitsche, TIB MOLBIOL, Berlin

TIB Molbiol with its symbiotic connection to the pharmaceutical giant *Roche* is thus much more than the courageous family business with the modest prices, as Landt presented it repeatedly in the media, especially in connection with COVID-19.[20] On the contrary, Landt owns a company network worth millions, which in the meantime consists to a considerable extent of real estate.[21]

Of viruses, diseases and tests

The new century has brought new and lucrative fields of activity for all those involved, their skills and their products: before COVID-19, SARS, MERS as well as avian and swine flu, among others, were added. Like AIDS, they are all traced back to RNA viruses and tested with PCR, although, as mentioned beofre, no infection can be detected with this technique. They all also have in common that they were worked on by Drosten and Landt. After his time in Frankfurt, Drosten worked as a clinical virologist first from the Bernhard Nocht Institute for Tropical Medicine (BNITM) in Hamburg, then from the

[20] home stories über das Gespann Christian Drosten – Olfert Landt [*home stories about the team Christian Drosten—Olfert Landt*]. Online: https://www.corodok.de/home-stories-drosten-landt/.

[21] Millionenschweres Netzwerk des Charité-Partners Olfert Landt [*Million-dollar network of Charité partner Olfert Landt*]. Online: https://www.corodok.de/millionenschweres-netzwerk-charite/. Landts besseres Büro auf dem Kudamm – und wieder Fragen… [*Landts better office on the Kudamm—and more questions…..*] Online: https://www.corodok.de/landts-buero-kudamm/.

Virological Institute in Bonn and finally came to the Charité in Berlin, while Landt was permanently involved with his Berlin company *TIB Molbiol*. Through Landt's company, *Roche* in turn was involved from the beginning, both before and after the patent expired. Landt's company description states this about the new fields of activity:

> »The long experience with Real-Time PCR and cooperation with well-known scientists have enabled TIB MOLBIOL to develop a range of low-cost products. […]
>
> In addition to TIB MOLBIOL Syntheselabor GmbH's 4,000m² headquarters in Berlin, the company has subsidiaries and production facilities in the USA, Italy, Spain and Poland. The company's presence in different countries has facilitated customer proximity and cooperation. Furthermore, the distribution of the branches enables the company to act quickly in the event of critical biological threats. As a result, TIB MOLBIOL has always been one of the first to make important diagnostic contributions when SARS, anthrax, H5N1 avian flu or the new H1N1 swine flu occurred.«[16]

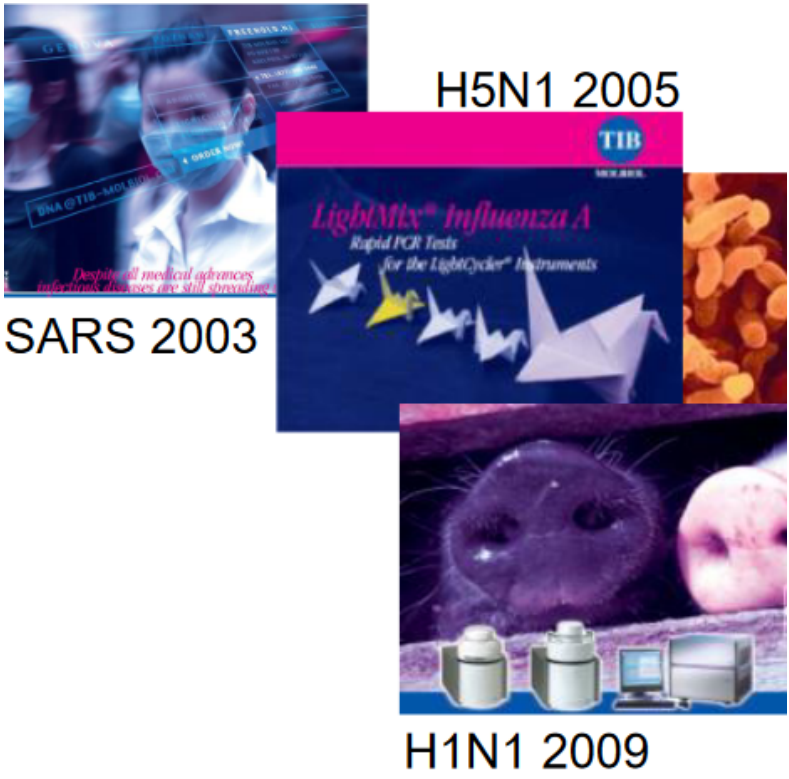
This is summarised in a PowerPoint presentation in which they present themselves as *Quick Responders in Emergencies*.[17]

SARS was the beginning of the collaboration between *TIB Molbiol* and Drosten, who was working at the Hamburg BNITM at the time. Whether Drosten has held a doctorate since 2003 is disputed, but SARS has been inextricably linked with his name since that year, and apart from his first Federal Cross of Merit in 2005, he also received several prizes from the pharmaceutical industry in 2004: from *GlaxoSmithKline*, *Abbott*, *bioMérieux*.[22]

The excitement about SARS was mainly media-related. Contrary to high estimates, a total of 8,096 people fell ill and 774 deaths were counted[23] and the evidence was also extremely poor, as the disease had no defined symptoms and tests were positive in only a minority

[22] Abbott Award: https://www.escv.eu/awards/the-abbott-diagnostic-award/. bioMérieux: https://www.dghm.org/startseite/dghm-stiftung/voraussetzungen-und-ehemalige-preistraeger-innen/biomerieux-diagnostikpreis/. GlaxoSmithKline: https://www.cducsu.de/veranstaltungen/referenten/prof-dr-christian-drosten.

[23] SARS, COVID-19 und die Macht der Definition [*SARS, COVID-19 and the power of definition*]. Online: https://www.corodok.de/sars-covid-definition/.



of cases. »They have so far only been able to find the new coronavirus in 40 per cent of all suspected SARS patients. However, they did manage to detect the virus in some healthy people from the control group. […] In view of these results, the head of the Canadian research group, Frank Plummer, said he was ›surprised‹ and expressed doubts as to whether the new coronavirus is really the cause of SARS.«[24]

Another milestone was the avian flu (H5N1) in 2005. It remained largely invisible, despite reports like this one, citing virologist and epidemiologist Klaus Stöhr: »The World Health Organization (WHO) considers a cataclysmic Avian Influenza pandemic to be inevitable.

[24] Kanadische Wissenschaftler können den SARS-Erreger nicht in allen Patienten nachweisen [*Canadian scientists cannot detect SARS agent in all patients*]. (Deutschlandfunk 25.4.2003). Online: https://www.deutschlandfunk.de/meldungen-liste-forschung-aktuell.1508.de.html?drn:news_id=75613.

When the worldwide epidemic will break out is only a question of time. Even in the best-case scenario, two to seven million deaths are to be expected.«[25] Since it was essentially about birds, Drosten was less involved, but for Landt it was the start of his *LightMix* series[26] and the strengthening of the collaboration with *Roche*: »›The close collaboration with Roche Diagnostics allows us to reach customers worldwide,‹ said Olfert Landt, CEO of TIB MOLBIOL.«[27]

The tests, in turn, enabled *Roche* not only to make direct profits through PCR, but also to acquire customers.

> »It was a direct hit for the researchers in the Roche laboratories: introduced ten years ago, Tamiflu became a blockbuster for the pharmaceutical company just a few years later. While sales in 2001 were only CHF 97 million and the drug was only the 14th best-selling Roche product in 2004, the global fear of bird flu catapulted sales of the pill sharply upwards: in 2005, sales increased by 370 %, and the following year they rose by 68 % to CHF 2.6 billion—fourth place on Roche's best-seller list.
>
> In total, between 2005 and 2008 alone, the drug flushed around CHF 6.9 billion into the coffers of the Basel SMI member. Most of this money came from government budgets as a result of stockpiling Tamiflu. Fearing the consequences of a possible pandemic caused by the bird flu virus, governments around the world ordered and stockpiled hundreds of millions of treatment units from the Basle-based company.
>
> However, the drug has hardly been used so far. This is because the spread of the deadly virus has so far remained within narrow limits. According to the current July report of the World Health Organization (WHO), there were only 436 confirmed cases of infection with the bird flu virus worldwide between 2003 and June

[25] Millionen Tote / WHO hält globale Seuche für unvermeidbar [*Millions dead / WHO considers global epidemic inevitable*] (Spiegel 26.11.2004). Online: https://www.spiegel.de/wissenschaft/mensch/millionen-tote-who-haelt-globale-seuche-fuer-unvermeidbar-a-329741.html.

[26] The first LightMix: for the detection of Avian Influenza A Virus (Subtype Asia) H5. Online: http://web.archive.org/web/20160806132031/http://tib-molbiol.de/download/25Manual_LMx_219_InfA_H5_vers_060412.pdf.

[27] Ultrafast Test for Inlfuenza [*sic*] A for Research Use. Online: http://web.archive.org/web/20060316091552/http://www.tib-molbiol.com/download/21Influenza_Pressemitteilung_TIB_2005_11_09_en.pdf.

> 2009, 262 of which resulted in death. After the initial excitement about the virus had passed, it became quiet about Tamiflu. Last year, sales were cut in half to CHF 609 million.«[28]

Tamiflu was invented by the US pharmaceutical company *Gilead*, from which *Roche* received a license in the 1990s. Due to a lack of efficacy combined with severe side effects, the drug was only approved after various interventions by *Roche*. In order to generate the desired sales, a meta-analysis was published in 2003 in which the team, consisting mainly of *Roche* employees (some of whom did not even know of their alleged involvement), »referred to ten efficacy studies conducted or paid for by Roche itself and concluded that Tamiflu worked«.[29] This reference was successfully used by *Roche* to claim efficacy against avian flu, which was in the interests of both pharmaceutical companies, because »Gilead had accused Roche of not being sufficiently committed to the marketing of Tamiflu and of not putting the drug on sale in some countries despite approval.«[30] And Klaus Stöhr moved from WHO to *Novartis* in 2007.[31]

Then swine flu H1N1 appeared in 2009/2010 and was received with enthusiasm—at least by *Roche*—and also for *TIB Molbiol* it was a fantastic business year. Objectively, however, it was a disaster.

Case study swine flu (H1N1)

After equally horrendous predictions of victims and hysteria in the media—in other words, in a situation that is very similar to our current one—the hangover came at the beginning of 2010:

> »Do you still remember? A few weeks ago there was only one word on our lips: swine flu. And today, nobody cares two hoots about it.

[28] Georg Pröbstl: Roche und Novartis profitieren von H1N1 [*Roche and Novartis profit from H1N1*] (HZ 4.8.2009). Online: https://www.handelszeitung.ch/unternehmen/roche-und-novartis-profitieren-von-h1n1.

[29] Andreas Item: Der Tamiflu-Skandal – Wie man mit einem Hauch von Nichts Milliarden verdient. Online: https://www.agstg.ch/magazin/magazin-archiv/61-/albatros-35/307-der-tamiflu-skandal-wie-man-millarden-verdient.html.

[30] Roche und Gilead einigen sich über Tamiflu [*Roche and Gilead reach agreement on Tamiflu*] (16.11.2005). https://www.swissinfo.ch/ger/roche-und-gilead-einigen-sich-ueber-tamiflu/4848688.

[31] https://www.nature.com/articles/nj7140-112a.

What has become of it? A few more cases of the disease, probably in February, and then it passed us by. There was no pandemic. All the precautions, the millions of euros spent on vaccinations, a joint effort by health authorities, ministries, health insurance companies and manufacturers, by the federal and state governments, proved to be unnecessary. […]

The handling of the epidemic that was not an epidemic is a debacle for the World Health Organization WHO, the German ministries and epidemic institutions. Note: Those who want to do good should think twice and not stir up hysteria. It is a prime example of how formal justifications and hedging fears create a reality called Absurdistan. In the end, it was the common sense of the population not to surrender to this vaccination whirlpool after all.

Swine flu has turned an important basic medical rule on its head. Normally, sneezing, coughing, aching limbs, headaches, eye pain and perhaps fever always cause fear: Is there an allergy, pneumonia, influenza A or B, malaria, dengue fever, SARS? Against such irritations, the physician knows a reassuringly down-to-earth formula: The rare is rare, and the common is common. In most cases, there is just a common germ in the nose. It is all the more astonishing that in the past four months, among the eight billion citizens of the world, it was always the handful of people who were found to be suffering from swine flu rather than the common cold—even after no one had been officially counted and tests for the virus were no longer offered to everyone.

Suddenly, every sore throat was attributed to the swine flu, a primary school pupil came home with a raised temperature, a panicked call from the parents—and once again an entire class stayed home because of ›swine flu‹. In the USA, the authorities quadrupled the number of swine flu victims in this way. They introduced a new way of counting: From mid-November, every elderly person who ›appears to have died from the flu‹ was suddenly counted. In this way, every victim of pneumonia became a swine flu fatality. A prudent approach to a pathogen looks different«[32]

[32] Elke Bodderas: Der enorme Schaden der Pandemie, die keine war [*The enormous damage caused by the pandemic that was not*] (Welt 3.1.2020). Online: https://www.welt.de/gesundheit/article5710912/Der-enorme-Schaden-der-Pandemie-die-keine-war.html.

Drosten, who had meanwhile moved from Hamburg to Bonn, and Landt were already considerably faster with swine flu than with SARS, as Drosten reported:

> »I was at my desk at about 11am on Friday 24 April [2009] when the phone rang. It was Stephan Becker, head of virology at the University of Marburg in Germany. He had heard about swine flu from colleagues in America. […]
>
> On Saturday, Marcus Panning at the University of Freiburg identified which primers were needed (while I went to a wedding!). Olfert Landt of the Berlin company TIB Molbiol made the primers physically on Sunday. This part was critical—it is not so easy to get primers physically made to short order, especially over a weekend. I was lucky to have such a good contact in Olfert, again thanks to our work together in the SARS days.«[33]

This resulted in a joint article in *Eurosurveillance* entitled »Detection of influenza A(H1N1)v virus by real-time RT-PCR«[34] and the test kit:

> »Based on Roche's Real-Time PCR technology, Tib Molbiol has developed a new influenza virus A(H1N1) test.
>
> TIB MOLBIOL, a Roche Applied Science collaboration partner, has developed an influenza virus A(H1N1) detection test. […] ›We are proud to be able to contribute to the fight against the global threat of swine flu. The new test was able to identify the virus in samples from Mexico this week, proving its suitability,‹ said Olfert Landt of Tib Molbiol.
>
> ›Roche wants to support governments and institutions worldwide in the fight against this influenza outbreak, and we are providing scientists researching the flu virus with efficient tools for their work,‹ added Manfred Baier, Head of Roche Applied Science.«[35]

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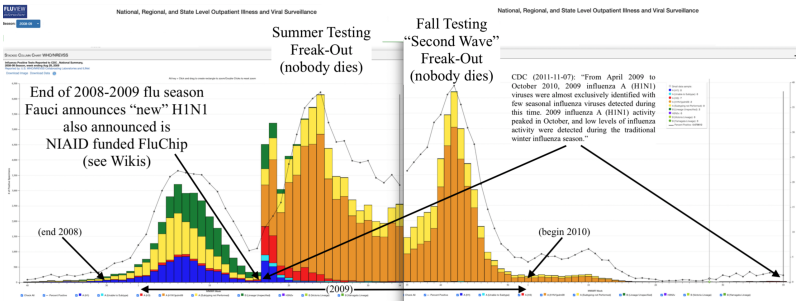
33 Alison Abbott: German virologist's race for swine flu test (Nature 30.4.2009). Online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095450/.

34 M. Panning et al.: Detection of influenza A(H1N1)v virus by real-time RT-PCR. Online: https://www.eurosurveillance.org/content/10.2807/ese.14.36.19329-en.

35 Olaf Spörkel: Real-Time-PCR-Nachweis des neuen Influenza-Virus A(H1N1) [*Real-Time PCR Detection of Novel Influenza Virus A(H1N1)*] (Laborpraxis 6.5.2009). Online: https://www.laborpraxis.vogel.de/real-time-pcr-nachweis-des-neuen-influenza-virus-ah1n1-a-186490/.

What such support using PCR could look like in this context can be illustrated by a graph showing the US figures. Coinciding with the end of the flu season in mid-April 2009, increased testing for H1N1 began when Anthony Fauci (head of the *National Institute for Allergies and Infectious Diseases* NIAID) had his institute's sponsored PCR called *FluChip* put to use. In the graph, the brown and yellow parts of the bars representing swine flu abruptly show a »first wave« in the summer and a »second wave« in the autumn, then the test epidemic was over with no fatalities.[36] This, too, has some similarities with our current situation—but for us it is not over yet.



This test epidemic has left behind enormous profits for a few, such as for the *FluChip* manufacturer *InDevR*, where Klaus Stöhr (ex-WHO, ex-*Novartis*) has been acting as »Strategic Advisor« since 2015.[37] Landt was also highly satisfied years later: »During the swine flu epidemic in 2009/2010, for example, we were able to double our annual turnover«.[38] While for *TIB Molbiol* millions were at stake, for *Roche's* and *Novartis'* businesses it was a matter of billions. After a weak start to 2009, the *Roche/TIB Molbiol* test was joined in the spring by the *Roche/Gilead* drug:

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[36] https://twitter.com/ragnar_lives/status/1287232146743029760. Data from FluView Intreractive / Centers for Disease Control and Prevention CDC. Online: https://www.cdc.gov/flu/weekly/fluviewinteractive.htm.

[37] InDevR Announces Creation of Strategic Advisory Board (30.9.2015). Online: https://www.indevr.com/2015/09/advisory-board-announcement/.

[38] Sigrid März: Biotechnologischer Ausnahmezustand [*Biotechnological state of emergency*] (Laborjournal 4/2020). Online: https://www.laborjournal.de/epaper/LJ_20_04.pdf.

> »The rapid spread of swine flu is now bringing a renewed boom in demand. Fear is on the rise again. After all, according to the WHO, 150,000 infections have been reported since April, including 700 deaths. As one of the few available virus-inhibiting flu drugs, Tamiflu is also coming back into play. In order to prevent an even greater spread of the new epidemic, Roche activated its Tamiflu emergency stockpile of 3 million packages at the beginning of May at the urging of the WHO.
>
> The new scare is now bringing the Basel-based company record sales, as it did three years ago. The company reported a 9 % increase in sales in the first half of the year to CHF 24 billion, with Tamiflu accounting for a large part of the increase. In fact, sales of the flu drug climbed by 203 % to CHF 1 billion in the first six months of the year. […] No wonder that the company's share price has risen significantly since the first mass spread of flu cases in Mexico became known. For example, in late April, Roche's share price went up about 10 % in a single day after cases were reported in the US. […]
>
> Other pharmaceutical companies are also among the winners. Several large companies are working feverishly on a vaccine against the new virus. Novartis began producing a vaccine at the beginning of June.«[28]

> »No sooner had the H1N1 virus been declared a pandemic than Novartis had already finished the first batch of swine flu vaccine. […] The pharmaceutical company expects the vaccine to be approved in autumn 2009, just in time for the winter flu season.
>
> ›Novartis is potentially able to produce vaccine for a third of the population in Western Europe,‹ says Karl-Heinz Koch, pharmaceutical analyst at Helvea. He estimates the sales potential of the Novartis vaccine at around 1 to 2 billion dollars. So this could become a blockbuster for Novartis.«[39]

What may be a »blockbuster« for some looks like this for the majority: »The damage is enormous: the cost of the vaccine sera ordered is estimated at at least 700 million euros, of which not even a tenth has been used yet—and a large part still has to be produced by March.«[32]

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[39] Natalie Gratwohl: H1N1-Impfstoff von Novartis weckt Fantasien [*H1N1 vaccine from Novartis triggers fantasies*]. Online: https://www.handelszeitung.ch/invest/h1n1-impfstoff-von-novartis-weckt-fantasien.

The vaccine promotion also came from the Virological Institute in Bonn, where Drosten was working at the time: »Drosten urgently called for people to be vaccinated against swine flu. ›The disease is a serious general viral infection, which has considerably stronger side effects than anyone can imagine from the worst vaccine.‹«[40] But between the squandering of public money and the injection in one's own arm there was something quite decisive: »In the end it was the common sense of the population not to surrender to this vaccination pull after all«.[32]

Epidemiologist Ulrich Keil concluded: »If pandemic level 6 had not been declared [by the WHO], we would not have noticed anything and would have said to ourselves: ›Oh, that was a mild course, that was nice this year.‹«[41] In the meantime, we have already survived several winters with the swine flu virus, as reported by the US *Centers for Disease Control and Prevention* CDC: »The H1N1 virus that caused the pandemic is now a normal human flu virus and continues to circulate seasonally around the world.«[42] We didn't notice anything about it because it wasn't tested for.

This was followed by a series of smaller events like MERS, which is a kind of SARS especially in Saudi Arabia. Most significant are quotes from Drosten like the following one: »Asymptomatic individuals should not be tested with PCR.«[43] The motto of *TIB Molbiol*, which was shown at a PowerPoint presentation of the US branch in 2016,[17] should not be forgotten either:

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[40] Schweinegrippe / Zweite Welle hat begonnen – Tote erwartet [*Swine flu / Second wave has begun - deaths expected*] (3.11.2009). Online: https://www.kma-online.de/aktuelles/panorama/detail/zweite-welle-hat-begonnen-tote-erwartet-a-18682.

[41] Milliardengrab Schweinegrippe: Wer steuerte die WHO? [*Swine flu—a billion-dollar grave. Who was controlling the WHO?*] (WDR Monitor 19.11.2009; from 1:30). Online: https://www.youtube.com/watch?v=DKQF-vWYmCU.

[42] Centers for Disease Control and Prevention. Online: https://www.cdc.gov/h1n1flu/reportingqa.htm.

[43] Kai Kupferschmidt: MERS: A Virologist's View From Saudi Arabia (Science 6.5.2014). Online: https://www.sciencemag.org/news/2014/05/mers-virologists-view-saudi-arabia.

Doing now what Roche will need next

Corona as grand finale

In 2020, Corona, or more precisely COVID-19, was the grand finale, and Drosten and Landt used their SARS test from 2003 as the basis for the PCR protocol for the new virus in record time. Thus, in January, they not only outperformed all the others worldwide, but at the same time were able to take care of mundane but important matters with astonishing foresight:

> »Drosten […] noted […] ›that our laboratories in Germany are technically very well equipped, that our regulations in Germany are very free in setting up new test procedures in laboratories—and that our National Association of Statutory Health Insurance Physicians already introduced a billing code [*for the diagnostic test*] in January and in this way ensured that the laboratories now also earn money with it.‹« [*Quote from the NDR-Podcast on the 5 March, 2020. See also p. 63 footnote 13.*]

> »And indeed, Germany is at the forefront of the diagnostics kit race. The small Berlin diagnostics company TIB-MOLBIOL, for example, which already played an important role in the SARS pandemic of 2002/2003, deserves special mention. […] In 2003, a good four months passed between the outbreak of the disease and the dispatch of the first kits. This time, everything went much more quickly. ›We already issued our kits from 14 January, so once again we were the very first,‹ says Olfert Landt in conversation with Laborjournal. His E-gene assay already left for Asia on 11 January, he immediately adds.«[38]

According to Drosten, the recipients were »colleagues in China […] whose names I cannot mention now«.[44] His colleague was more forthcoming: »On January 11, Landt sent his kit to Taiwan's Centers for Disease Control and diagnostic company Roche in Hong Kong. […] In the end, the test he sent over was perfect, he said.«[45]

Together with some other authors, Drosten and Landt published a first version of the test protocol on 13 January (with primers for E-, RdRp-, N-genes). In this protocol, the E gene was intended for the rough »first line screening assay«, the others as »confirmatory assays«.[46] A modified version was published on 17 January (E gene plus 2 regions of the RdRp gene for confirmation).[47] On 23 January, without reference to the WHO publications, their article appeared at *Eurosurveillance* (E-, RdRp-genes recommended, N-genes shown in diagram but neglected in text), having been submitted on the 21st and accepted on the 22nd.[48] Usually, months pass between submission and publication for articles—but with Drosten as co-editor of the journal[49], publication can be accelerated considerably. Besides the abnormally high number of cycles of 45^4, there are other significant flaws in the PCR protocol.[50]

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[44] Volkart Wildermuth: Diagnostischer Test aus Berlin weltweit gefragt (Deutschlandfunk 23.1.2020). Online: https://www.deutschlandfunk.de/neues-coronavirus-diagnostischer-test-aus-berlin-weltweit.676.de.html?dram:article_id=468640.

[45] Julia Hollingsworth: A coronavirus test can be developed in 24 hours. So why are some countries still struggling to diagnose? (CNN 25.3.2020). Online: https://edition.cnn.com/2020/03/24/asia/testing-coronavirus-science-intl-hnk/index.html.

[46] Victor Corman et al.: Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 13, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf.

[47] Victor Corman et al.: Diagnostic detection of 2019-nCoV by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 17, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

[48] Victor Corman et al.: Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Online: https://www.eurosurveillance.org/content/10.2807/ese.17.39.20285-en.

[49] https://www.eurosurveillance.org/board.

[50] Stiftung Corona Ausschuss: Live Sitzung 22 – Die Player: Drosten, Ferguson, die Charité und die Rolle von TIB Molbiol (Video ab ca. 3:55). Online: https://corona-ausschuss.de/sitzungen/. At the time of publishing, the YouTube video for this has been deleted.

The conflict of interest of Landt and Marco Kaiser was concealed during publication and corrected only on 29 July. The co-author Kaiser had been assigned to *TIB Molbiol* at the time of publication, but after the correction to *GenExpress GmbH* in Berlin, another of Landt's companies in the same building:[51] »Marco Kaiser is a senior researcher at GenExpress and serves as a scientific advisor to Tib-Molbiol.«[48] Drosten's conflict of interest has remained unmentioned until now. As head of virology at *Labor Berlin—Charité Vivantes GmbH* he has to achieve »sustainable growth«.[52] This year, this may have been achieved not least through the COVID-19 tests, which are inextricably linked with the terms Charité and Drosten, far more than with the terms *Roche* and *TIB Molbiol*.

> »Roche distributes Tib-Molbiol Wuhan Coronavirus Assays for RNAP, Envelope and Nucleocapid Genes
> Roche Diagnostics are now distributing Tib-Molbiol's 2019-nCoV Real-Time Reverse Transcription PCR Kit worldwide. The LightMix® modular novel coronavirus assay developed by Tib-Molbiol is compatible with the Roche Light Cyler 480 series and the Magna Pure24 instruments and is being marketed for research use only (RUO). In the early days of the novel coronavirus being discovered, Tib-Miolbiol responded quickly to the urgent need for a diagnostic kit and were responsible for synthesizing and suppling the original oligonucleotides that were used in WHO's first protocol for the »Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR«.«[53]

TIB Molbiol produces several tests, all of which are available through *Roche*. Only one, *LightMix® Modular Sarbecovirus E-gene*, was approved as an *in vitro* diagnostic for patients via the CE mark in

[51] Netzwerk Landt noch größer – Firmengründer beim RKI?. [*Landt's network even bigger—company founder at the RKI?*] Online: https://www.corodok.de/netzwerk-landt-rki/.

[52] Drostens Testlabor muß »nachhaltiges Wachstum« erzielen – Fragen an Charité / Vivantes. [*Drostens test lab must achieve »sustainable growth«—Questions for Charité/Vivantes*] Online: https://www.corodok.de/labor-berlin-drosten-charite/.

[53] Paul Carton: Roche Distribute Tib-Molbiol Wuhan Coronavirus Assays for RNAP, Envelope and Nucleocapid Genes (Rapid Microbiology 12.2.2020). Online: https://www.rapidmicrobiology.com/news/roche-distribute-tib-molbiol-wuhan-coronavirus-assays-for-rnap-envelope-and-nucleocapid-genes.

February.[54] The E gene is not very variable, i. e. the least specific, and is therefore only used as a screening test in the Drosten and Landt protocol before tests for more specific genes follow. In the meantime, the practice looks like this:

> »Many laboratories use PCR procedures that detect only the E gene of the virus to detect SARS-CoV-2. These tests are inexpensive and have a high sensitivity. Since the **E gene**, which only encodes the viral envelope, but is not specific for SARS-CoV-2, but also recognises other coronaviruses (sarbecoviruses) […], used to test E-gene positive samples with a 2nd PCR to make sure that it really is SARS-CoV-2. The confirmatory PCR looked for specific genes, such as the **RdRP gene**, the **S gene** or the **ORF1 gene**. When confirmatory testing was discontinued for endemic areas on the recommendation of the WHO, PCR detection of SARS-CoV-2 was only carried out via the E gene in many smaller laboratories since April 2020.«[55]

The manual for the test kit[54] raises further questions. The intended use is described in several languages. While the English, French, Spanish and Portuguese texts are almost identical, the German text differs significantly in one crucial point by saying: »Dieses Produkt erlaubt einen […] Nachweis aus Total-NA Nukleinsäureextrakten gewonnen aus Proben der Atmungswege.« In the other languages, however, the sample source reads: »obtained from respiratory tract specimen from patients with significant respiratory symptoms«—»de patients présentant d'importants symptômes respiratoires«—»de los pacientes con síntomas respiratorios significativos«—»di pazienti con sintomi respiratori significativi« and »de pacientes com sintomas respiratórios graves«—why is the presence of »severe respiratory symptoms« omitted only in the German version?

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54 LightMix®ModularSarbecovirus E-gene 500 Cat.-No. 50–0776-96 Roche SAP n°09164952001 / V200204 Release version 2020-02-04. Online: https://www.roche-as.es/lm_pdf/MDx_50-0776-96_Sarbecovirus-E-gene_RV_V200204_09164952001_CE-IVD.pdf.

55 bio vis' DIAGNOSTIK: SARS-CoV-2 / COVID-19 Teil 3 SARS-CoV-2-Diagnostik: kritischer Rückblick und Update für die bevorstehende Grippesaison (Fachinformation 08/20). Online: http://www.biovis-diagnostik.eu/wp-content/uploads/Biovis_SARS-CoV-2_Teil3_DE.pdf.

Only for German-speaking customers it says the test is »intended to identify the viral pathogen causative of respiratory disease«. In contrast, the French version is more cautious about »the detection of viral genome« and the versions in other languages about »the detection of infection with viral genome« or the »diagnosis of infection by detection of viral genome«. Throughout the manual, neither SARS nor COVID are found as terms. The number of cycles is given as 45, with no limit on evaluation and—very importantly—it is stated: »For use with Roche '480' devices«.[54]

There are three tests for research purposes only with comparable manuals, for comparison the *LightMix® Modular SARS and Wuhan CoV E-gene*[56] will be used here. This is a kit »for the detection of WH-Human_1 genomic RNA«, which is also to be run on *Roche* equipment. A cycle number of 45 is also given for execution, but for scoring, only »Cp <39+« is considered »WH-CoV positive« and the purpose is: »This test will detect SARS and Wuhan 2019 CoV pneumonia virus as well as other bat-associated SARS-related viruses (sarbecovirus)«. Like the other test, it is also distributed by *Roche*. So one may wonder which E-gene test is being used: the approved one or the non-approved one? And which one do you think is exported all over the world?

Part of the export goes through the Ministry for Cooperation and Development (*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*–BMZ), more precisely the Rapid Expert Group on Health (*Schnell einsetzbare Expertengruppe Gesundheit*—SEEG). This group, which includes the RKI and the BNI, in the case of COVID-19 is reinforced by Charité staff from Drosten's Virological Institute, who distribute *TIB Molbiol* test kits in Africa, Latin America and probably also in Asia.[57] If this makes sense for the recipients may be debatable, but the benefits for a Berlin biotech company and the Swiss pharmaceutical giant are certain. Moreover, workshops were already organised by *Roche* and *TIB Molbiol* in Africa early on.

[56] LightMix®Modular SARSandWuhan CoV E-gene 530 Cat.-No. 53–0776-96 Roche SAP n°09155368001 / V200111 Release version 2020-01-11. Online: https://microbiologia-alicante.umh.es/files/2020/02/MDx_Wuhan-E-gene-PI.pdf.

[57] Entwicklungshilfe für Test-Hersteller. Online: https://www.corodok.de/entwicklungshilfe-test-hersteller/.

A tweet on February 22, 2020 about the *Roche* workshop in South Africa said: »Laboratory experts receive practice certificates and test kits at the end of the training«—from *TIB Molbiol*, as can be seen in one of the photos—and the co-organiser Africa CDC thanked, among others, the *Bill and Melinda Gates Foundation* (*Twitter* motto: »We are impatient optimists working to reduce injustice«).[58]

Here are some random findings without claiming to be complete: The kits reach Moldova[59] and Dubai[60] via the WHO[61], for example, and are also offered by a laboratory for »coronavirus testing« on Malta (cf. the following picture)[62], have arrived in Puerto Rico[63] and reach Iran via the United Arab Emirates.[64] One image is captioned: »On Thursday, 6 March 2020, bundles of coronavirus diagnostic test kits are ready for shipment to the World Health Organisation (WHO) at the TIB Molbiol Syntheselabor GmbH production facility in Berlin. TIB has switched its business to coronaviruses and runs its machines at nights and weekends to produce the kits, which sell for about 160 ($180) each.«[65]

This shows that all the test kits are exported by *TIB Molbiol*, both the one with the CE mark and the other, unapproved ones, all with unknown sensitivity and specificity (accuracy). That there are min-

[58] Southern Africa Regional Collaborating Centre (RCC) serves as a representative of the AfricaCDC in the Southern Africa region. Online: https://twitter.com/SouthernRCC/status/1231209016153518081.

[59] World Health Organization in Moldova: https://www.facebook.com/OMSMoldova/photos/a.1578876852403611/2416514588639829/?type=3&source=57&__tn__=EHH-R.

[60] Tawfiq Nasrallah: UAE announces 14 new coronavirus cases (Gulf News 9.3.2020). Online: https://gulfnews.com/uae/uae-announces-14-new-coronavirus-cases-1.1583753297673.

[61] Corinne Gretler, Naomi Kreske: Search for Virus Origin Heats Up With WHO Seeking China Mission (Bloomberg 6./8.5.2020). Online: https://www.bloombergquint.com/politics/who-considers-mission-to-seek-source-of-coronavirus-in-china.

[62] Medical Laboratory Services: https://www.facebook.com/152831228095436/photos/a.874005859311299/2906768609368337/?type=3&source=48&__tn__=EH-R.

[63] Laboratorio de Arecibo se prepara para hacer pruebas de COVID-19 (Telemundo Puerto Rico 11.3.2020). Online: https://www.telemundopr.com/noticias/puerto-rico/laboratorio-de-arecibo-se-prepara-para-hacer-pruebas-de-covid-19/2056807/.

[64] UAE Air Force flies medical supplies to Iran to help fight virus (Arabian Business

imum requirements for a test used for diagnosis—be it PCR or an antigen test—is not only known to Drosten:

> »These antigen tests must first be technically and qualitatively certified with a CE label. For this purpose, they will certainly also be scrutinised with regard to their analytical performance within the scope of the approval. This would then be an approval via the BfArM, the Federal Institute for Drugs and Medical Devices. These two approvals must first be obtained for such tests.«[66]

This interview with Drosten which contained this quote appeared in October 2020, three quarters of a year and millions of tests after his and Landt's PCR protocol. Fittingly, an ad by *TIB Molbiol* was placed

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2.3.2020). Online: https://www.arabianbusiness.com/healthcare/441727-uae-air-force-flies-medical-supplies-to-iran-to-help-fight-virus.

65 https://www.gettyimages.de/detail/nachrichtenfoto/bundles-of-coronavirus-diagnostic-test-kits-sit-ready-nachrichtenfoto/1206690132.

66 Ralf Neumann: IM CORONA-GESPRÄCH: CHRISTIAN DROSTEN, BERLIN »Wir werden das Virus nicht auslöschen« (Laborjournal 10/2020). Online: https://www.laborjournal.de/epaper/LJ_20_10.pdf.

alongside it, with a design that is a recycled product from 2003, just like the test[4].

Roche provides—even more than with the swine flu in 2009—an almost complete pandemic all-round supply. In terms of tests, it is not only PCR that is still dominated by the company, but also the antibody tests that have been marketed from spring 2020 and were followed some months later by antigen tests: »Roche plans to supply hundreds of millions of rapid antigen tests per month«.[67] Additionally, the drugs market is being worked on, by *Roche* as well as *Novartis*. The latter is currently focusing on pharmaceuticals, having sold its vaccine production to *BioNTech*[68] and is benefiting from the booming diagnostics business via *Roche*.

It all started in the last century, with an ingenious idea and a record sum for a patent. In order for this investment to pay off many

[67] Roche will pro Monat Hunderte Millionen Antigen-Schnelltests liefern (29.10.2020). Online: https://www.finanzen.net/nachricht/aktien/coronavirus-infektionen-roche-will-pro-monat-hunderte-millionen-antigen-schnelltests-liefern-9451193.

[68] Übernahme von Novartis-Standort BioNTech produziert Covid-19-Impfstoff in Marburg (Tagesspiegel 17.9.2020). Online: https://www.tagesspiegel.de/wissen/uebernahme-von-novartis-standort-biontech-produziert-covid-19-impfstoff-in-marburg/26195662.html.

times over, the problem to be solved was sought and found, among other areas, in clinical virology. The fact that PCR cannot distinguish between a complete genome and fragments, between the ability and inability to replicate and therefore inevitably produces false-positive results in the context of an infectious disease is of no interest to a pharmaceutical giant when billions upon billions are at stake. Maybe it doesn't matter at all, because it was already said in the swine flu business: »The driver is not only the pathogen, but also the fear.«[28] Even with a viral mound and a mountain of false positives, you can create fear and make money. This is also called *fear mongering*.[69]

This business model works terribly well, and has done so for decades, only we in most parts of the world haven't noticed it so far because the »measures« were imposed in China or Canada. Now it affects us all directly and it is an illusion to think it will pass on its own. As long as PCR is used as senselessly as it is now, there will be no end to this situation, be it with this or any other virus. The well-rehearsed team is making an excellent living from it and will continue to do so as long as they are allowed to. It also has an immense amount to lose if it becomes apparent what is being done to PCR and to us.

The abbreviation SARS still contained the symptoms, it was the ***S**evere **A**cute **R**espiratory **S**yndrome*. The abbreviation MERS—which stands for ***M**iddle **E**ast **R**espiratory **S**yndrome*—was a mixture of symptomatology and geography. The abbreviation COVID stands for ***Co**rona **Vi**rus **D**isease*, so it is symptom-open and only related to the causative virus. This, in turn, is to be proven by the test, by PCR, which is methodically incapable of doing so. The results are correspondingly erratic: on the one hand, sick people whose X-rays indicate a COVID disease are tested negatively, on the other hand, healthy people get a positive test result, as it happened before with SARS 2003.

Since, according to central dogma, the PCR results are correct, the negative patients are either not mentioned or announced as a sensa-

[69] Wolfgang Wodarg: »Falscher Alarm: Die Schweinegrippe-Pandemie« in: Big Pharma, ed. Mikkel Borch-Jacobsen (Piper 2015) [*»False Alarm: The Swine Flu Pandemic«*]. Online: https://www.wissenschaftsladen-dortmund.de/wp-content/uploads/2020/04/2020-03-25-Wodarg-Die-Schweinegrippe.pdf.

tion while positive healthy people are declared asymptomatic. At the same time, there is stonewalling when it comes to test specificity and false-positive results, because this is highly dangerous territory for all those who use PCR for their own purposes in one way or another. So more and more tests are being made and more and more symptoms are being gathered under the symptom-open acronym of COVID, because as soon as the test is positive for a disease, it might already have something to do with it. And so, through PCR, a lung disease in China became a global conglomeration of symptoms.

This disaster far eclipses that of swine flu. For *Roche*/*Novartis*, *TIB Molbiol*, Drosten and Landt, however, PCR has paid off, and over decades profit, career, honours have accrued. The path is very short between virology at the renowned Charité to a little-known Berlin biotech company and from there it is not far to the notorious pharmaceutical giants in Switzerland. The audience is presented with superficial information in the form of charming home stories about Landt as well as Drosten's podcasts and interviews with many statements that age badly. He used to know this, that and the other, which is well documented, but now it's all forgotten. Instead his ubiquitous presence feels like an infinite loop now.

The last word should go to Kary Mullis, who died in 2019. He would certainly have spoken out clearly, perhaps in the same way as in 1998:

> »Scientists are doing an awful lot of damage to the world in the name of helping it. I don't mind attacking my own fraternity because I am ashamed of it.«[70]

[70] Kary B. Mullis, 74, Dies; Found a Way to Analyze DNA and Won Nobel (New York Times 15.8.2019). Online: https://www.nytimes.com/2019/08/15/science/kary-b-mullis-dead.html.

The »Drosten Test«: How it began

The origin of the »corona crisis« is the use of the polymerase chain reaction PCR. By now, the problems of this method, which is meant to detect COVID-19, are quite well known. It is known that it cannot distinguish whole viral genomes from fragments and what is being sought-after from impurities that fit certain specifications, and that there is no way for PCR to detect the ability of viruses to replicate. Without an exact check—which, however, only takes place in the rarest of cases—the results are worthless and everything that follows from them is meaningless or even wrong.[1] To make matters worse, the PCR protocol presented as a standard by the *World Health Organization* (WHO) in January 2020 has several serious methodological flaws, such as the cycle number of 45[2], which make it »useless«.[3]

How could it happen that this inadequate protocol was accepted by the WHO and presented as a standard? How could it happen that the ECDC (*European Centre for Disease Prevention and Control*), the authority responsible for infectious diseases in Europe, published this protocol in its journal *Eurosurveillance*? Was there no peer review at all at WHO and *Eurosurveillance*? And why does Christian Drosten, the director of the Virological Institute of the Berlin Charité, appear everywhere?

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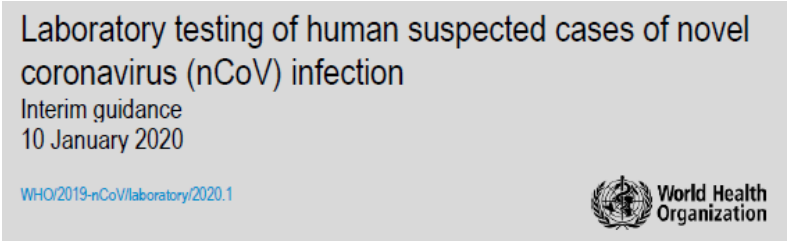
[1] Cf. the preceding chapter »PCR technology between the pharmaceutical industry and virology«. Also online in German: https://www.corodok.de/pcr-technologie-pharmaindustrie/.

[2] Cf. the first chapter »Cycling and Recycling of SARS-CoV-PCR«. Also online in German: https://www.corodok.de/cycling-recycling-sars/.

[3] Pieter Borger et al.: Review report Corman-Drosten et al. *Eurosurveillance* 2020 (27.11.2020). online: https://cormandrostenreview.com/report/.

Friday, 10 January:
Drosten as WHO advisor on laboratory testing

The WHO publication on »Laboratory testing of suspected human cases of infection with novel coronavirus (nCoV)« is published.[4]



As a source for the state of affairs in China, a report by the state television CCTV from 9 January is listed in the bibliography[5] (the following refers to the *deepL* translation from Chinese into English). It reports, citing an »expert group«, »that the causative agent of this unexplained case of viral pneumonia was originally classified as a new type of coronavirus« and that »methods such as genome sequencing, nucleic acid tests and virus isolation« were used. The Chinese group explained that »usually« several issues need to be clarified to determine whether a virus found in patients is the cause of their disease in the first place. A list based on Koch's postulates (the requirements of proof for bacterial diseases established in the 19th century) is described and elaborated:

> »The discovery of nucleic acid, genomic and antibody evidence of the pathogen from patients can be accomplished in a short period of time. Scientific studies such as the isolation and pathogenicity identification of the pathogen can take several weeks.«[5]

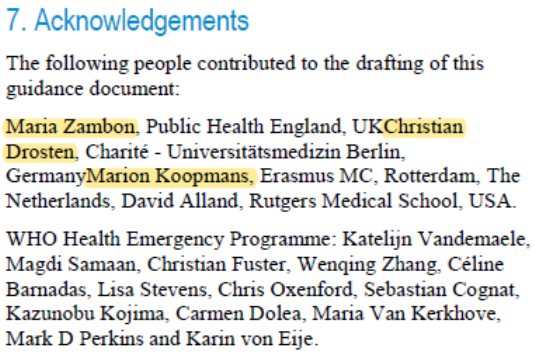
The WHO publication, on the other hand, refrains from calling for evidence, stating instead: »Once the genome sequences of the novel

[4] Laboratory testing of human suspected cases of novel coronavirus (nCoV) infection Interim guidance 10 January 2020. Online: https://apps.who.int/iris/rest/bitstreams/1264830/retrieve.

[5] [Pathogen of Wuhan viral pneumonia outbreak tentatively determined to be a novel coronavirus, 9 January 2020 08:15 CCTV News Client]. Online: http://www.chinanews.com/m/sh/2020/01-09/9054817.shtml.

coronavirus have been published and specific NAAT assays [tests based on nucleic acid amplification such as PCR] have been developed, confirmation of cases of infection with the novel virus will be based on specific detection of unique sequences of the viral nucleic acid by reverse transcriptase-polymerase chain reaction (RT-PCR) with probe detection or sequencing.«[4] The first information on genome sequences of nCoV (now SARS-CoV-2) are also published on 10 January,[6] paving the way for a rapid nucleic acid-based test, without virus and without proof of pathogenicity.

The members of the body that wrote this WHO standard for laboratory evidence are mentioned in the paper under point 7. On the one hand, there are the staff of the *WHO Health Emergency Programme* including Maria van Kerkhove, who has become one of the better-known faces of WHO because of her media presence since 2020. But more interesting are the three external advisors marked of the total four—among them Drosten.



7. Acknowledgements

The following people contributed to the drafting of this guidance document:

Maria Zambon, Public Health England, UKChristian Drosten, Charité - Universitätsmedizin Berlin, GermanyMarion Koopmans, Erasmus MC, Rotterdam, The Netherlands, David Alland, Rutgers Medical School, USA.

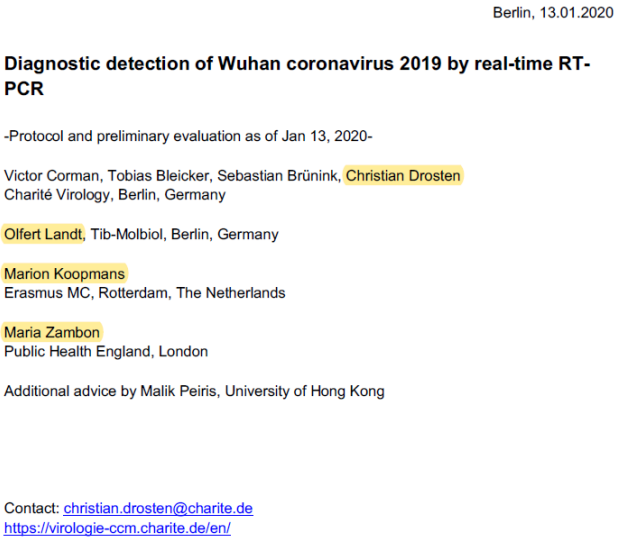
WHO Health Emergency Programme: Katelijn Vandemaele, Magdi Samaan, Christian Fuster, Wenqing Zhang, Céline Barnadas, Lisa Stevens, Chris Oxenford, Sebastian Cognat, Kazunobu Kojima, Carmen Dolea, Maria Van Kerkhove, Mark D Perkins and Karin von Eije.

Apart from Drosten, the Dutch Marion Koopmans (Head of the Department of Virology at Erasmus University Rotterdam) and the British Maria Zambon (Director of *Reference Microbiology* for *Public Health in England*) are of interest.

[6] https://virological.org/t/novel-2019-coronavirus-genome/319.

Monday, January 13:
Drosten as author of the first WHO protocol

This is the date of the first PCR protocol published by the WHO.[7] »Additional advice« had been given by Malik Peiris of the University of Hong Kong, who, like Drosten, had been one of the central investigators of *Severe Acute Respiratory Syndrome* SARS in 2003. The three WHO advisors marked above, Drosten, Koopmans and Zambon, were joined by several people from the Charité and Olfert Landt, owner of the Berlin biotechnology company *TIB Molbiol Syntheselabor GmbH*, or *TIB Molbiol* for short.



Berlin, 13.01.2020

Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR

-Protocol and preliminary evaluation as of Jan 13, 2020-

Victor Corman, Tobias Bleicker, Sebastian Brünink, Christian Drosten
Charité Virology, Berlin, Germany

Olfert Landt, Tib-Molbiol, Berlin, Germany

Marion Koopmans
Erasmus MC, Rotterdam, The Netherlands

Maria Zambon
Public Health England, London

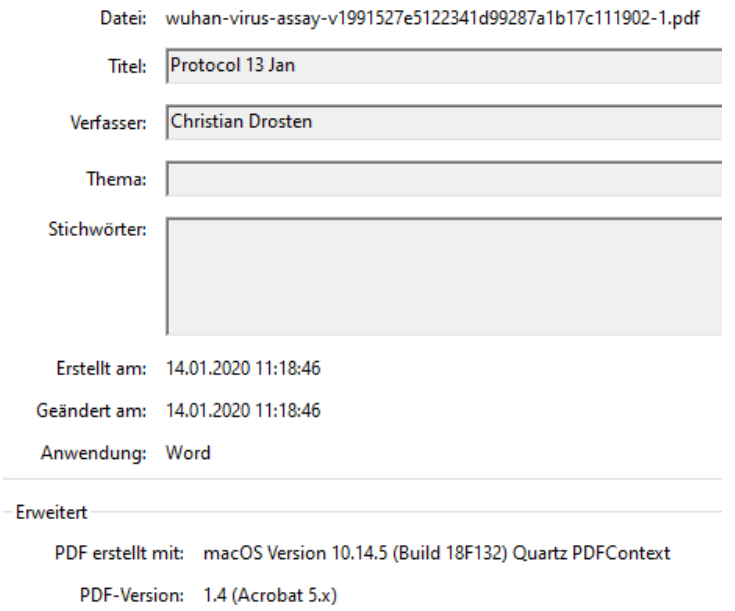
Additional advice by Malik Peiris, University of Hong Kong

Contact: christian.drosten@charite.de
https://virologie-ccm.charite.de/en/

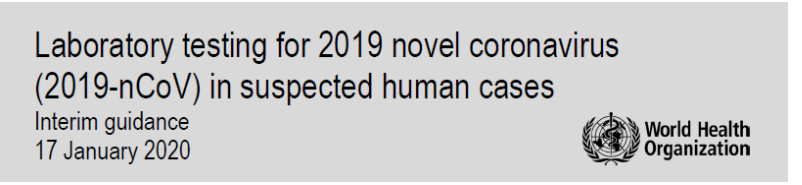
The cooperation between Drosten and Landt also dates back to SARS. The PCR test jointly developed for it marked the beginning of Drosten's popularity and led to his first Federal Cross of Merit. Since then, Drosten and Landt have been active with their jointly developed PCR tests on various viruses, with swine flu in 2009 being a climax for both: for one in popularity, for the other in profit.

[7] Victor Corman et al.: Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 13, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf.

The WHO protocol originates from Drosten, as the PDF document properties show:



Friday, 17 January:
Drosten as WHO advisor & Protocol author
The follow-up document on laboratory testing is published by WHO.[8]



It was again written by the *WHO Health Emergency Programme* and the same external advisors as a week earlier plus George Gao, who

[8] Laboratory testing of 2019 novel coronavirus (2019-nCoV) in suspected human cases: interim guidance, 17 January 2020. Online: https://apps.who.int/iris/rest/bitstreams/1266309/retrieve.

is, among others, Director General of the *Chinese Center for Disease Control and Prevention* (China CDC) and board member of the *Global Preparedness Monitoring Board* of the WHO, a kind of steering committee for the »Corona Crisis«. Further members include Anthony Fauci (US government advisor), Jeremy Farrar (Director of the UK *Wellcome Trust*) and Chris Elias of the *Bill and Melinda Gates Foundation.* The document states:

> »The etiologic agent responsible for the cluster of pneumonia cases in Wuhan has been identified as a novel betacoronavirus […]. Working directly from sequence information, the team developed a series of genetic amplification (PCR) assays used by laboratories associated with the China CDC to detect several dozen cases as of today.«[8]

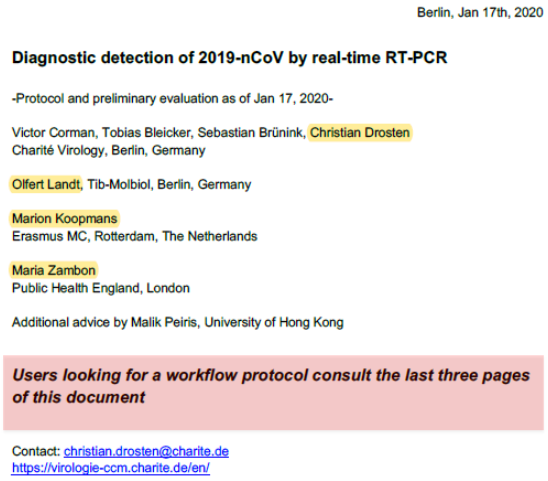
»Several weeks« of evidence, as described by the Chinese expert group about a week earlier,[5] were completed thus *par ordre du mufti* and this is what is said about the test:

> »As sequence information from the 2019-nCoV has recently been made available, PCR assays can be designed to detect these sequences. […] Laboratories may desire to use a pan-coronavirus assay for amplification followed by sequencing of amplicons from non-conserved regions for characterization and confirmation. The importance of the need for confirmation of results of testing with pan-coronavirus primers is underscored by the fact that four human coronaviruses (HcoVs) are endemic globally […]. Two other betacoronaviruses that cause zoonotic infection in humans are MERS-CoV […] and SARS […].
>
> Alternatively, amplification and detection of 2019-nCoV specific sequences can be diagnostic without the necessity for further sequencing. […] Once specific NAAT assays are developed and validated, confirmation of cases of the novel virus infection will be based on specific detection of unique sequences of viral nucleic acid by reverse-transcriptase polymerase chain reaction (RT-PCR).«[8]

In short, this was the starting signal for PCR as a diagnostic tool for »suspected human cases« either with specific gene sequences without verification or non-specific gene sequences with or without verification by sequencing. There was thus an explicit invitation

to carry out unspecific and unverified PCR tests, which virtually provokes false-positive results. However, these are not mentioned at all, while the concern is expressed that there could be false-negative results, i. e. those tested negatively could be positives in disguise.

Fittingly, the second version of the PCR protocol is released with the same personnel as on 13 January, but with slightly different content.[9] Again, according to the PDF document properties, it was written by Drosten. Everything is again directly under his control and responsibility from authorship to contact for feedback.



Berlin, Jan 17th, 2020

Diagnostic detection of 2019-nCoV by real-time RT-PCR

-Protocol and preliminary evaluation as of Jan 17, 2020-

Victor Corman, Tobias Bleicker, Sebastian Brünink, Christian Drosten
Charité Virology, Berlin, Germany

Olfert Landt, Tib-Molbiol, Berlin, Germany

Marion Koopmans
Erasmus MC, Rotterdam, The Netherlands

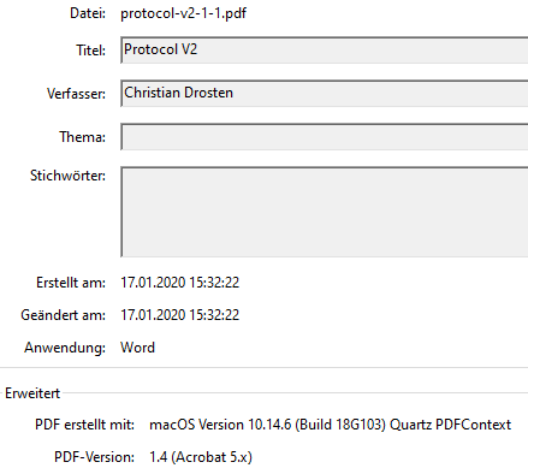
Maria Zambon
Public Health England, London

Additional advice by Malik Peiris, University of Hong Kong

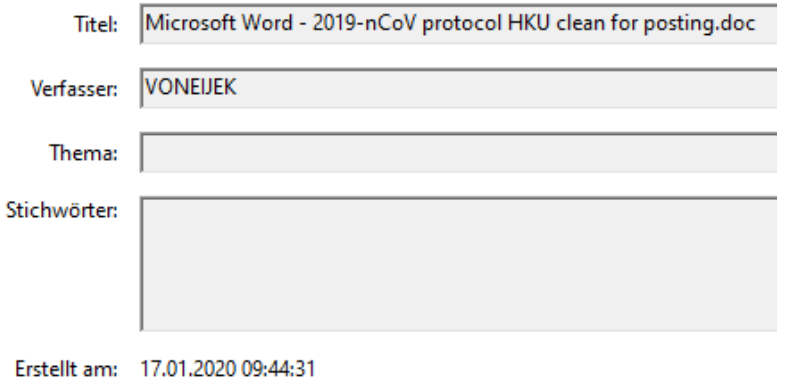
Users looking for a workflow protocol consult the last three pages of this document

Contact: christian.drosten@charite.de
https://virologie-ccm.charite.de/en/

[9] Victor Corman et al.: Diagnostic detection of 2019-nCoV by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 17, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.



On the same day, the WHO publishes the PCR protocol of Peiris from Hong Kong.[10] with a cycle number of 40. The PDF file was created by Karin von Eijek from the *WHO Health Emergency Programme*.



[10] Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR. Online: https://www.who.int/docs/default-source/coronaviruse/peiris-protocol-16-1-20.pdf?sfvrsn=af1aac73_4.

Tuesday, January 21:
Drosten as the main author of the *Eurosurveillance* article.
The two WHO protocols resulted in an article that is submitted to *Eurosurveillance*.

Thursday, January 23:
Drosten as co-editor of his article
The article, submitted two days earlier, appears in *Eurosurveillance* with the findings, »The work plan reliably detects 2019-nCoV and also distinguishes 2019-nCoV from SARS-CoV.«[11] This incredible pace of publication has been visualised by Wouter Aukema and is shown on the next page.[12]

Not even »Rapid Communications« (blue dots on the left side of the diagram) are published that fast, let alone regular articles (green dots in the middle), whose publication last around 100 days—except one: the green dot at the very bottom, at which the arrow points, stands for the Drosten paper published with unique speed.

This article is longer than the two WHO protocols that are not mentioned, with an authorship that had grown to 24:

- six from the Charité (the four from the WHO protocol including Drosten plus two others)—Drosten is listed as the last and thus most important author and is also named as the contact person;
- Landt of *TIB Molbiol* and Marco Kaiser of *GenExpress Gesellschaft für Proteindesign mbH* (another Landt company not named at the time of publication, instead Kaiser was also listed as *TIB Molbiol* in January, which was corrected in July);
- four from Erasmus University Rotterdam including Koopmans;
- six from the RIVM (Dutch National Institute for Public Health and the Environment) including Chantal Reusken;
- two from the University of Hong Kong including Peiris;
- one each from the Universities of Marseille and Antwerp;
- two from Public Health England including Zambon;

[11] Victor Corman et al.: Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR (*Eurosurveillance* 23.1.2020). Online: https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045.

[12] https://www.corodok.de/the-christian-drosten/.


Review Process at eurosurveillance.org
Rapid Communications
Research Papers
Surveillance Reports
2015
2016
2017
2018
2019
2020
Num Days
1000
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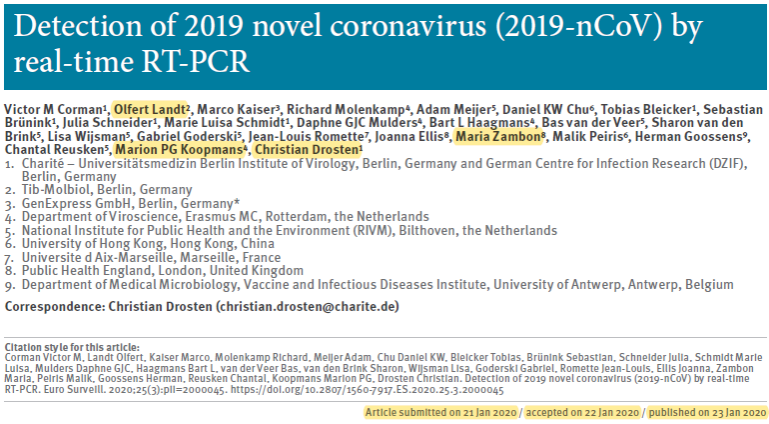
16
Doc Type : Research Papers
Html Doc: 2000045.htm
Nr of Days: 1
Received: 21-jan-2020
Accepted: 22-jan-2020
Meta-data: eurosurveillance.org (Collected 05-dec-2020)
Processing & Analysis by Wouter Aukema / @waukema

Two of the authors of the article are co-editors of *Eurosurveillance*: Drosten and Chantal Reusken, who was at RIVM at the time and has since moved to Erasmus University Rotterdam.



RESEARCH

Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR

Victor M Corman[1], Olfert Landt[2], Marco Kaiser[3], Richard Molenkamp[4], Adam Meijer[5], Daniel KW Chu[6], Tobias Bleicker[1], Sebastian Brünink[1], Julia Schneider[1], Marie Luisa Schmidt[1], Daphne GJC Mulders[4], Bart L Haagmans[4], Bas van der Veer[5], Sharon van den Brink[5], Lisa Wijsman[5], Gabriel Goderski[5], Jean-Louis Romette[7], Joanna Ellis[8], Maria Zambon[8], Malik Peiris[6], Herman Goossens[9], Chantal Reusken[5], Marion PG Koopmans[4], Christian Drosten[1]

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6. University of Hong Kong, Hong Kong, China
7. Universite d Aix-Marseille, Marseille, France
8. Public Health England, London, United Kingdom
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Citation style for this article:
Corman Victor M, Landt Olfert, Kaiser Marco, Molenkamp Richard, Meijer Adam, Chu Daniel KW, Bleicker Tobias, Brünink Sebastian, Schneider Julia, Schmidt Marie Luisa, Mulders Daphne GJC, Haagmans Bart L, van der Veer Bas, van den Brink Sharon, Wijsman Lisa, Goderski Gabriel, Romette Jean-Louis, Ellis Joanna, Zambon Maria, Peiris Malik, Goossens Herman, Reusken Chantal, Koopmans Marion PG, Drosten Christian. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020;25(3):pii=2000045. https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045

Article submitted on 21 Jan 2020 / accepted on 22 Jan 2020 / published on 23 Jan 2020

On 27 November, 22 PCR experts analysed a total of ten methodological flaws in the *Eurosurveillance* article and have since publicly demanded: »Given the scientific and methodological flaws presented here, we are confident that the publishers of *Eurosurveillance* have no choice but to withdraw the publication«[3]—which would also have consequences for the WHO protocols and everything that follows. The pace of a decision by *Eurosurveillance* and thus also by ECDC is inversely proportional to the pace of publication of the article. The decision was announced for the end of January 2021, the negative answer was given at the beginning of February and thus only after more than two months.[13]

Conflicts of interest of Drosten and Landt

The 22 PCR experts also criticised the dual role of Drosten and Reusken:

[13] https://cormandrostenreview.com/eurosurveillance-response/. Cf. for *Eurosurveillance*'s response on 4 February 2021 the transcript of Prof. Ulrike Kämmerer's report before the Corona Committee on 5 February, reproduced here on page 71.

> »It turns out that two authors of the Corman-Drosten paper, Christian Drosten and Chantal Reusken, are also members of the editorial board of this journal. […] Hence there is a severe conflict of interest which strengthens suspicions that the paper was not peer-reviewed. It has the appearance that the rapid publication was possible simply because the authors were also part of the editorial board at Eurosurveillance. This practice is categorized as compromising scientific integrity.«[3]

Another conflict of interest mentioned is the affiliation of Drosten and the first-mentioned author Victor Corman to the commercial *Labor Berlin*: »Both are responsible for viral diagnostics […] and the company works in the field of real-time PCR testing.«[3] *Labor Berlin—competence of Charité and Vivantes* explicitly has the task of making profit.[14]

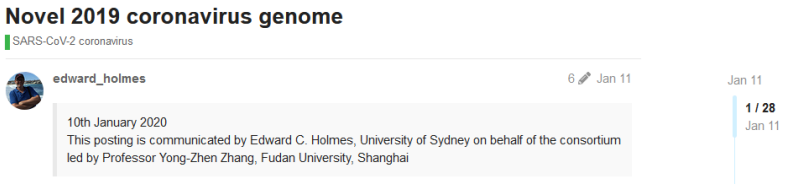
It had been noticed earlier that two other persons had declared their affiliation to *TIB Molbiol* but had not declared a conflict of interest: Landt and Marco Kaiser. The *Eurosurveillance* editors had been made aware of this on 10 June and replied on 30 July:

> »At the time of the publication, SARS-CoV-2 had been identified only 16 days earlier as the causing agent of coronavirus disease (COVID-19) and a viral genome sequence had been released on 10 January [1]. Sequences and laboratory protocols developed to detect this novel virus, had been shared by Corman et al. via the World Health Organization (WHO) website already from 13 January onwards and been updated on 17 January […]
>
> We also received a detailed statement from the corresponding author, Christian Drosten, and from Olfert Landt, who explained […] they do not consider that being Tib-Molbiol's CEO constituted a conflict of interest with respect to the article in question at the time of submission. They further confirmed that that [sic] reagent sets produced and marketed by Tib-Molbiol are different from those in the protocol published in the article and that they were validated independently from this work.
>
> Considering the above, and following consultation with experts on conflict of interest and research integrity and the journal's asso-

[14] Kommerzielle Interessen von Charité und Labor Berlin. Online: https://www.corodok.de/kommerzielle-interessen-charite/.

> ciate editors, the *Eurosurveillance* editor-in-chief decided to change the conflict of interest note by adding the following statement:
>
> *Olfert Landt is CEO of Tib-Molbiol; Marco Kaiser is senior researcher at GenExpress and serves as scientific advisor for Tib-Molbiol.*
>
> This change aims at further enhancing transparency and does not imply a judgment on whether or not a conflict of interest exists.«[15]

The text was written by the *Eurosurveillance* editorial team and is strongly reminiscent of Drosten's style. The first source mentioned in the quote under »[1]« informs about the publication of the genome sequencing, but in contradiction to the text with no word about an identification as a pathogen and dates from 10 January.[6] So a fortnight had passed from then until the publication of the *Eurosurveillance* article.



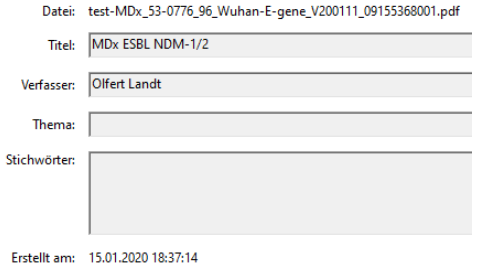
Moreover, Landt is not only the CEO of *TIB Molbiol*, but above all the owner of the company—which Drosten knows of course—and that is a big difference. Moreover, Landt had finished manuals for PCR on the E, N and RdRp genes in parallel with the WHO protocols, which, given the coincidence in time, raises the question of how far »the reagent sets manufactured and marketed by Tib-Molbiol are different from those in the protocol published in the article«. The version date of these manuals is 11 January, the day Landt sent a package of test samples to a branch of the Swiss pharmaceutical giant *Roche* in Hong Kong for verification.[16] According to the PDF file property, they were created on 15 and 16 January and already bore the *Roche*

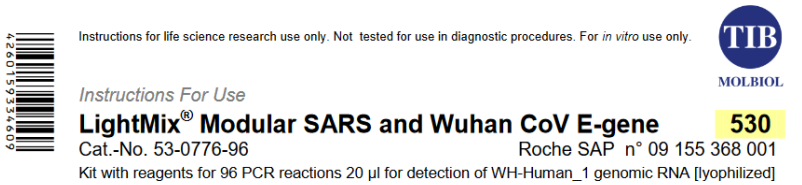
---

[15] *Eurosurveillance* editorial team: Editorial note: possible undisclosed conflict of interest. Online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7393849/.

[16] Julia Hollingsworth: A coronavirus test can be developed in 24 hours. So why are some countries still struggling to diagnose? (CNN 25.3.2020). Online: https://edition.cnn.com/2020/03/24/asia/testing-coronavirus-science-intl-hnk/index.html.

order numbers.[17] *TIB Molbiol*, together with *Roche*, thus had the First Mover Advantage, i. e. the advantage a company has when it is the first to appear on the market with a new product. Presumably, this was the culmination of their decades-long collaboration.[1]


Datei: test-MDx_53-0776_96_Wuhan-E-gene_V200111_09155368001.pdf
Titel: MDx ESBL NDM-1/2
Verfasser: Olfert Landt
Thema:
Stichwörter:
Erstellt am: 15.01.2020 18:37:14


Instructions for life science research use only. Not tested for use in diagnostic procedures. For *in vitro* use only.
TIB MOLBIOL
Instructions For Use
LightMix® Modular SARS and Wuhan CoV E-gene 530
Cat.-No. 53-0776-96 Roche SAP n° 09 155 368 001
Kit with reagents for 96 PCR reactions 20 µl for detection of WH-Human_1 genomic RNA [lyophilized]

And finally, the last sentence seems more petulant than concerned with transparency. One may wonder whether this »Editor's note: possible undisclosed conflict of interest« would not be better withdrawn, too. After all, the editor-in-chief's »special interests« include »publication ethics, i. e. quality and transparency of science reporting«.[18]

Submitting a »useless«[3] PCR protocol to *Eurosurveillance*, and thus to a European authority, while concealing conflicts of interest, is a serious lapse. It would have been even more serious if the process

[17] Vgl. Online: https://web.archive.org/web/20200327234500/https://www.roche-as.es/lm_pdf/MDx_53-0776_96_Wuhan-E-gene_V200111_09155368001.pdf, https://web.archive.org/web/20200327234514/https://www.roche-as.es/lm_pdf/mdx_53-0775_96_wuhan-n-gene_v200111_09155350001.pdf/ and https://web.archive.org/web/20200327234523/https://www.roche-as.es/lm_pdf/MDx_53-0777_96_Wuhan-R-gene_V200111_09155376001.pdf.

[18] Dr. Ines Steffens: Professional background and motivation for my application to become member of the EASE Council. Online: http://www.ease.org.uk/wp-content/uploads/ines_steffens.pdf.

at WHO, with its global reach, had been analogous. Considering the evidence presented here, this is reasonable speculation. Drosten was on the panel that set the conditions for laboratory testing »of suspected human cases« of infection with »the new coronavirus« and that was presumably the channel through which the PCR protocol could be published so quickly and also untested. Thus the standard was set, which until recently hardly anyone had dared to criticise publicly. And so the »Drosten test« came upon us, making the famous virologist ever more famous, the rich entrepreneur even richer, and leaving a trail of devastation in the world with its consequences.

The evolution of the »Drosten Test« towards a one-gene PCR

The author of the test for COVID-19 using polymerase chain reaction (PCR) is Christian Drosten, the director of the Virological Institute of the Berlin Charité. He personally wrote the first two test protocols published by the *World Health Organization* (WHO) in January and was probably also involved in their astonishingly rapid publication.[1] An article based on these protocols was published in *Eurosurveillance*, the official organ of publication of the ECDC, the agency responsible for infectious diseases in Europe. It appeared shortly after the WHO protocols at an equally rapid pace, presumably due to Drosten's intervention as co-editor of the journal. This article is so full of methodological errors that a group of scientists is calling for its complete withdrawal, because: »It is inevitable that this test will generate an enormous number of so-called ›false positives‹.«[2] Drosten, on the other hand, sees things completely differently, as expected:

> »The result of a laboratory test is always a diagnosis, never a raw test result. Especially positive test results are always confirmed by an additional test (additional gene site). This virtually eliminates the occurrence of false positive diagnoses.«[3]

As soon as people without symptoms (aka healthy people) were tested, the first claim of performing a diagnosis was obviously obsolete. Less obvious so far is that the second claim with the additional test is also untrue—and Drosten knows this because, after all, he himself helped to reduce the specification for the genes to be de-

[1] Cf. the preceding chapter »The ›Drosten Test‹: How it began«.

[2] Pieter Borger et al.: Review report Corman-Drosten et al. *Eurosurveillance* 2020 (27.11.2020). Online: https://cormandrostenreview.com/report/.

[3] Falsch positive Ergebnisse bei ausgeweiteten Corona-Tests? [*False positives due to expanded Corona tests?*] (Hamburger Abendblatt 2.9.2020). Online: https://www.abendblatt.de/ratgeber/wissen/article230318584/Falsch-positive-Ergebnisse-bei-ausgeweiteten-Corona-Tests.html.

tected from three to one. The third claim with the false-positive »diagnoses« was never true anyway.

The genome of SARS-CoV-2

The virus has a genome of about 30,000 nucleotides and thus the template for 10 proteins. Of relevance in this context are the following genes and the resulting proteins:

> ORF1 ⟶ large polyprotein of the replicase complex, including the enzyme RNA-dependent RNA polymerase RdRp
> S ⟶ spike protein = protruding part of the viral envelope which makes contact with the host cell
> E ⟶ envelope protein = protein of the viral envelope
> N ⟶ nucelocapsid protein = the envelope around the genome[4]

The common Real-Time PCR amplifies sites between two primers (size approx. 18-24 nucleotides each[5]) which bind to the nucleic acid of the sample to be examined if they match it exactly. The amplicon of approx. 50-150 nucleotides[5] that is formed between these primer pairs is a gene segment that can be amplified billions of times to make it detectable. Thus, only a very small part of the genome can be detected from each primer pair plus amplicon. A prerequisite for a useful test is a sensible primer design, which includes both the number and the location of the gene segments sought on the genome:

> »For a confirmative diagnosis of a specific virus, at least 3 specific primer pairs must be applied to detect 3 virus-specific genes. Preferably, these target genes should be located with the greatest distance possible in the viral genome (opposite ends included).«[2]

The more genes are recognised, the greater the probability that what is being searched for has also been found. If these recognised genes

4 https://de.wikipedia.org/wiki/SARS-CoV-2.

5 Real-time PCR handbook (life technologies / Thermo Fisher Scientific). Online: https://www.thermofisher.com/content/dam/LifeTech/global/Forms/PDF/real-time-pcr-handbook.pdf.

All assays can use SARS-CoV genomic RNA as positive control. Synthetic control RNA for Wuhan virus will be provided shortly.

First line screening assay: E gene assay
Confirmatory assay: RdRp gene assay
Additional confirmatory assay: N gene assay

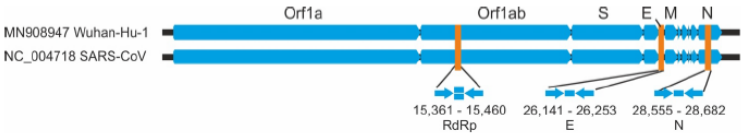


Figure 1 relative positions of amplicon targets on SARS-CoV ad Wuhan-CoV genome. N: nucleocapsid; ORF: open reading frame; RdRp: RNA-dependent RNA polymerase. Numbers below amplicon are genome positions according to SARS-CoV, NC_004718.

are distributed over the entire virus genome, it is assumed a complete virus was found, which is the prerequisite for activity.

January 13: Testing three genes

The WHO website published the first PCR protocol using three primer pairs for amplifying sections on three genes: RdRp, E and N.[6]

The scientists calling for the retraction of the *Eurosurveillance* article based on this and the following WHO protocol commented:

> »Although the Corman-Drosten paper describes 3 primers, these primers only cover roughly half of the virus' genome. This is another factor that decreases specificity for detection of intact COVID-19 virus RNA and increases the quote of false positive test results.
>
> Therefore, even if we obtain three positive signals (i. e. the three primer pairs give 3 different amplification products) in a sample, this does not prove the presence of a virus. A better primer design would have terminal primers on both ends of the viral genome. This is because the whole viral genome would be covered and three positive signals can better discriminate between a complete (and thus potentially infectious) virus and fragmented viral genomes (with-

[6] Victor Corman et al.: Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 13, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf.

> out infectious potency). In order to infer anything of significance about the infectivity of the virus, the Orf1 gene, which encodes the essential replicase enzyme of SARS-CoV viruses, should have been included as a target […] The positioning of the targets in the region of the viral genome that is most heavily and variably transcribed is another weakness of the protocol.«[2]

The designation »Corman-Drosten paper« was chosen because Victor Corman is the first-named author of both WHO protocols and the *Eurosurveillance* article. Corman is head of the virus diagnostics working group at the Virological Institute of the Charité, of which Drosten is director.[7] Both also belong to the commercial *Labor Berlin—Charité Vivantes GmbH*: Drosten in his function as Institute's Director and Corman as Head of Special Virus Diagnostics.[8] This conflict of interest has not been declared to *Eurosurveillance*.[2]

While the first named author of an article is usually the one who has done most of the work—in this case Corman—the person responsible is named last, which in the *Eurosurveillance* article is Drosten, who is also the contact person. In the two WHO protocols, the order of authorship is somewhat different with regard to Drosten, but he is also the contact person there and also wrote this protocol as well as the following one himself.[1] Every comma and every error are his: This is the »Drosten Test«.

January 17: Testing two genes

Four days after the first protocol, a new version is published[9] in which the detection of the N gene is missing without justification. The PCR workflow still includes the E gene as well as two sites of the RdRp gene, further reducing the distance between the primer pairs of both ends. Again, the rough »screening test« is put in front and if the result is positive, the »confirmation test« follows. In the workflow protocol, another »discrimination test« is attached, which is supposed to be specific for 2019-CoV (now SARS-CoV-2).

7 https://virologie-ccm.charite.de/ueber_das_institut/team/.

8 https://www.laborberlin.com/fachbereiche/virologie/.

9 Victor Corman et al.: Diagnostic detection of 2019-nCoV by real-time RT-PCR-Protocol and preliminary evaluation as of Jan 17, 2020-. Online: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf.

All assays can use SARS-CoV genomic RNA as positive control. Synthetic control RNA for 2019-nCoV E gene assay is available via EVAg. Synthetic control for 2019-nCoV RdRp is expected to be available via EVAg from Jan 21st onward.

First line screening assay: E gene assay
Confirmatory assay: RdRp gene assay

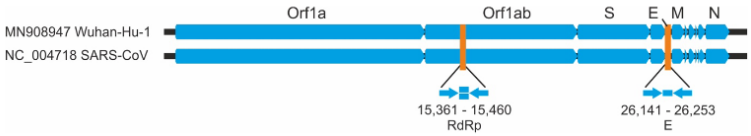


Figure 1 relative positions of amplicon targets on SARS-CoV an 2019-nCoV genome. ORF: open reading frame; RdRp: RNA-dependent RNA polymerase. Numbers below amplicon are genome positions according to SARS-CoV, NC_004718.

Workflow Protocol

1. First line screening assay

E assay:

If assay No 1 is positive, continue to assay No 2.

2. Confirmatory assay

RdRp assay:

If assay No 2 is positive, continue to assay No 3.

3. Discrimatory assay

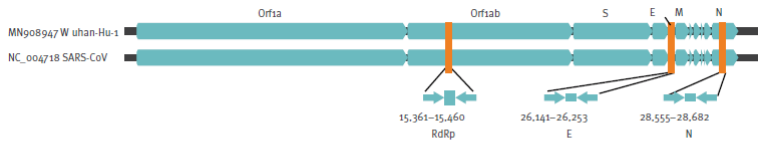
RdRp assay:

Assay No 3 is specific for 2019-nCoV

Januar 23: Testing two genes

A melange of both WHO protocols resulted in an article published at record speed in *Eurosurveillance*.[10] Although most of the graphs and tables are those from the first WHO protocol with instructions for testing for three genes including the N gene, this has been deleted in the new protocol: »For a routine workflow, we recommend the E gene test as the first screening test, followed by a confirmatory test for the RdRp gene.« And this reason was given: »It should be noted that the test for the N gene also gave good results but was not subjected to intensive further validation as it was somewhat less sensitive.« The twofold RdRp test was also modified:

> »For a routine workflow, we recommend the E gene assay as the first-line screening tool, followed by confirmatory testing with the RdRp gene assay. Application of the RdRp gene assay with dual colour technology can discriminate 2019-nCoV (both probes positive) from SARS-CoV RNA if the latter is used as positive control. Alternatively, laboratories may choose to run the RdRp assay with only the 2019-nCoV-specific probe.«[10]



E: envelope protein gene; M: membrane protein gene; N: nucleocapsid protein gene; ORF: open reading frame; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

Numbers below amplicons are genome positions according to SARS-CoV, GenBank NC_004718.

The scientists who demand the retraction of this article write about this selection:

> »This was an unfortunate omission as it would be best to use all three gene PCRs as confirmatory assays, and this would have resulted in an almost sufficient virus RNA detection diagnostic tool protocol. […] (Nonetheless, the protocol would still fall short

[10] Victor Corman et al.: Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR (*Eurosurveillance* 23.1.2020). Online: https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.3.2000045.

of any ›good laboratory practice‹, when factoring in all the other design-errors).

As it stands, the N gene assay is regrettably neither proposed in the WHO-recommendation (Figure 1) as a mandatory and crucial third confirmatory step, nor is it emphasized in the Corman-Drosten paper as important optional reassurance ›for a routine workflow‹ […].

Consequently, in nearly all test procedures worldwide, merely 2 primer matches were used instead of all three. This oversight renders the entire test-protocol useless with regards to delivering accurate test-results of real significance in an ongoing pandemic.«[2]

March 2: Testing one gene

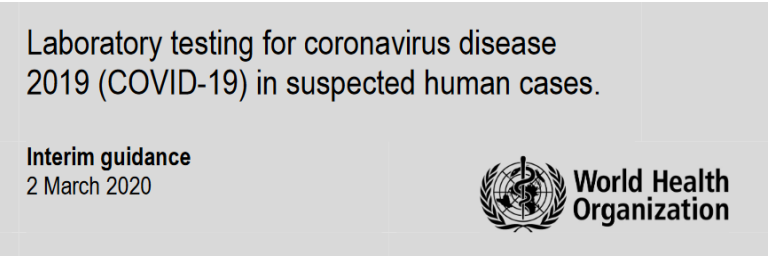
The beginning of the year 2020 was busy for those who earn money from products and services around PCR. Olfert Landt is the owner of the Berlin-based company *TIB Molbiol* and has been developing PCR tests for various viruses together with Drosten for almost two decades. He is co-author of both the WHO protocols and the *Eurosurveillance* article (named right after Corman), was involved in the development of the test »from the beginning«, according to Charité, and: »The cooperation is on both sides exclusively for humanitarian reasons«.[11] He distributes the resulting test kits together with the Swiss pharmaceutical giant *Roche*, with whom he has been associated even longer than with Drosten. In February, the two companies held promotional events in West Africa (Dakar) and South Africa to get the Berlin test kits to Africans.[12] And Drosten was pleased about the rosy prospects for *Labor Berlin*, because »our National Association of Statutory Health Insurance Physicians already introduced a billing code for this test in January and thus ensured that the laboratories earn money with it.«[13] The WHO also took action again.

At the beginning of March, a new guidance for laboratories is

[11] Charité räumt Begünstigung von TIB Molbiol von Olfert Landt ein. [*Charité admits benefitting TIB Molbiol from Olfert Landt*] Online: https://www.corodok.de/charite-beguenstigung-tib/.

[12] Entwicklungshilfe für Test-Hersteller. [*Development aid for test manufacturers*] Online: https://www.corodok.de/entwicklungshilfe-test-hersteller/.

[13] Podcast 5.3.2020: https://www.ndr.de/nachrichten/info/coronaskript174.pdf.



published, regulating the use of NAAT—meaning tests based on nucleic acid amplification, in this case specifically PCR.[14] Firstly, there is the unambitious »laboratory confirmation of cases by NAAT in areas where there is no known COVID-19 virus circulation«:

> »A positive NAAT result for at least two different targets on the COVID-19 virus genome, of which at least one target is preferably specific for COVID-19 virus using a validated assay (as at present no other SARS-like coronaviruses are circulating in the human population it can be debated whether it has to be COVID-19 or SARS-like coronavirus specific); one positive NAAT result for the presence of betacoronavirus, and COVID-19 virus further identified by sequencing partial or whole genome of the virus as long as the sequence target is larger or different from the amplicon probed in the NAAT assay used.«[14]

Even easier to fulfil is the »laboratory-confirmed case by NAAT in areas with established COVID-19 virus circulation«:

> »In areas where COVID-19 virus is widely spread a simpler algorithm might be adopted in which for example screening by rRT-PCR of a single discriminatory target is considered sufficient.«[14]

This *carte blanche* for testing only one gene was developed with the help of several external consultants, including Drosten. Also involved were Marion Koopmans from the Netherlands and Maria

[14] Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases. Interim guidance 2 March 2020. Online: https://apps.who.int/iris/bitstream/handle/10665/331329/WHO-COVID-19-laboratory-2020.4-eng.pdf?sequence=1&isAllowed=y.

Zambon from the UK, both co-authors of the two WHO protocols and the *Eurosurveillance* article. In addition, Leo Poon from Hong Kong, a collaborator of Malik Peiris, who was also involved in the WHO protocols and is co-author of the *Eurosurveillance* article, as well as Katrin Leitmeyer from ECDC, the editor of *Eurosurveillance*, and finally George Gao from the authority responsible for infectious diseases in China (China CDC) and board member of the *Global Preparedness Monitoring Board* of WHO, also participated. This board is a kind of steering committee for the »Corona crisis«, which also includes US government advisor Anthony Fauci as well as high-ranking representatives of the British *Wellcome Trust* and the US *Bill and Melinda Gates Foundation*.[15]

Acknowledgements

The following people contributed to the drafting of the evolving versions of this guidance document: Katrin Leitmeyer, European Center for Disease Control, Maria Zambon, Public Health England, UK; Christian Drosten, Charité - Universitätsmedizin Berlin, Germany; Marion Koopmans, Erasmus MC, Rotterdam, The Netherlands; Leo Poon, Hong Kong University, China, Hong Kong SAR; George Gao, Chinese CDC, China.

WHO: Karen Nahapetyan, Francis Inbanathan, Dmitriy Pereyaslov, Christine Uhlenhaut, Varja Grabovac, Katelijn Vandemaele, Magdi Samaan, Christian Fuster, Wenqing Zhang, Lisa Stevens, Chris Oxenford, Sebastian Cognat, Kazunobu Kojima, Carmen Dolea, Caroline Brown, Céline Barnadas, Maria Van Kerkhove, Lisa Carter, Mark D Perkins and Karin von Eije

One gene testing in practice

That testing for only one gene is not an academic consideration without concrete consequences is shown by examples from practice. Apparently, this simplification was quickly and persistently implemented, at least in Germany:

> Augsburg Laboratory MVZ GmbH in April 2020: » Altered reporting layout of SARS-CoV-2 PCR results […]
>
> During analysis of the sample with the Roche method, we have indicated the measurement results for both target sequences of the PCR (ORF1 and E gene) separately. The ORF1 gene is specific for

[15] https://apps.who.int/gpmb/board.html.

SARS-CoV-2, while the E gene also occurs in other coronaviruses. The cases in which only the ORF gene was amplified have also been positive so far. Few cases with isolated positive E gene were considered questionable […]. Taking into account the epidemiological situation and the overall increase in the positive rate, from now on we follow the WHO recommendation and already give a result as »positive« if only the E gene was amplified. […] A result is positive if at least one of the two target sequences of SARS-CoV-2 was detected in the swab material.

If the sample was analysed using procedures from rBiopharm or TibMolbiol, we previously performed separate screening and confirmatory tests. In analogy to the procedure described above, we restrict ourselves to the previous screening test targeting the E gene due to the high positive predictive value with increasing COVID-19 prevalence.«[16]

Bioscientia Healthcare GmbH in July 2020: »In our experience, we therefore also assess isolated detection of a single gene as positive for SARS-CoV-2, depending on specificity, but recommend checking in unclear cases.«[17]

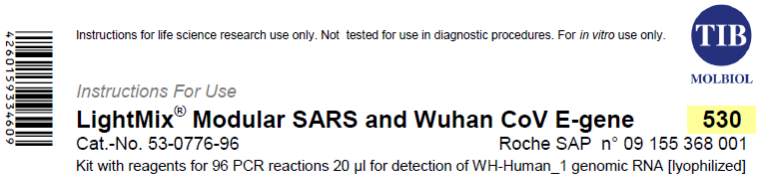
Various in August 2020: »Many laboratories use PCR methods that detect only the E gene of the virus to detect SARS-CoV-2. These tests are inexpensive and are characterised by high sensitivity. However, since the **E gene**, which only encodes the viral envelope, is not specific for SARS-CoV-2 but also recognises other coronaviruses (sarbecoviruses) […], E gene-positive samples used to be tested with a 2nd PCR to ensure that it really was SARS-CoV-2. The confirmatory PCR looked for specific genes, such as the RdRP gene, the S gene or the ORF1 gene. When confirmatory testing was discontinued for endemic areas at the recommendation of the

[16] Geändertes Befundlayout der SARS-CoV2 PCR-Ergebnisse [*Changed reporting layout of SARS-CoV2 PCR results*] (Labor Augsburg MVZ GmbH 3.4.2020). Online: https://web.archive.org/web/20200509151946/https://labor-augsburg-mvz.de/de/aktuelles/geaendertes-befundlayout-der-sars-cov2-pcr-ergebnisse.

[17] Was bedeuten die Begriffe Dual-Target-PCR und Ct-Wert? [*What do the terms dual-target PCR and Ct value mean?*] (Bioscientia Healthcare GmbH 15.7.2020). Online: https://www.bioscientia.de/home/aktuelles/2020/07/was-bedeuten-die-begriffe-dual-target-pcr-und-ct-wert.

> WHO, PCR detection of SARS-CoV-2 was only done via the E gene in many smaller laboratories from April 2020.«[18]
>
> SYNLAB Medizinisches Versorgungszentrum Hamburg GmbH in September 2020: »Do laboratories really always test twice for positive results? […] Synlab, a provider that currently carries out up to 80,000 tests per week, answered this question. Synlab writes that it does not test for multiple gene sites by default. Also, not every positive test result is confirmed with an additional test.«[3]

In a generous interpretation of the already generous WHO guidelines, it seems that the E gene has been chosen in many cases—of all things, the gene that was originally only to be used in the rough screening test, to be checked later. Since *TIB Molbiol* is mentioned by name in this context, their test kits should serve as an example—the company even offers two of them. One is the test kit for the »SARS and Wuhan-CoV E gene« from January 2020, which also reacts to »other bat-associated SARS-related viruses (sarbecoviruses)«. However, this test is not approved for patient diagnosis, but may be used »for research use only« (RUO).[19]



Then there is a test kit for the »sarbecovirus E gene« with CE marking from February, which allows it to be used for diagnosis for patients.[20]

Since the diagnostic specificity of both test kits is unclear, the proportion of false-positive results when using them is unknown.

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[18] SARS-CoV-2 / COVID-19 Teil 3 (biovis Diagnostik 08/2020). Online: https://www.biovis-diagnostik.eu/wp-content/uploads/Biovis_SARS-CoV-2_Teil3_DE.pdf.

[19] https://web.archive.org/web/20200327234500/https://www.roche-as.es/lm_pdf/MDx_53-0776_96_Wuhan-E-gene_V200111_09155368001.pdf.

[20] https://www.roche-as.es/lm_pdf/MDx_50-0776-96_Sarbecovirus-E-gene_RV_V200204_09164952001_CE-IVD.pdf.

In-vitro diagnostics reagent. For *in-vitro* use only.

Technical Information and Certificate of Analysis
Informations techniques et certificat d'analyse
Información técnica y certificado de análisis
Informazioni tecniche e certificato di analisi
Informação técnica e certificado de análise
Informacja techniczna oraz Certyfikat analizy
Informații tehnice și certificat de analiză
Specifikacije in Certifikat analize
Τεχνικές πληροφορίες και πιστοποιητικό ανάλυσης
Technische Informationen und Analysezertifikat
Techniache informatie en Certificate of Analysis
Teknisk information og Certificate of Analysis
Tekniak informasjon og analysesertifikat
Teknisk information och analyscertifikat
Technické informace a Certifikát analýzy
Tekniset tiedot ja Certificate of Analysis
A dokumentáció és Analitikai tanusítvány

TIB MOLBIOL

LightMix® Modular Sarbecovirus E-gene 500
Cat.-No. 50-0776-96 Roche SAP n° 09 164 952 001

The following table shows how high this proportion can be and how much the results can diverge not only between manufacturers but also between individual batches from the same manufacturer. Negative samples from either human throat swabs, swabs from the nose or mouth of cattle, and water or buffer solution were tested at the Friedrich-Löffler-Institut (Federal Research Institute for Animal Health). The results vary between 0 % and 100 % false positives (my markings in the table for specificity values below 100 %, i. e. more than 0 % false positives). In this case, contaminated primers were identified as the cause, which is only one possibility for false positives and »it seems imperative to test each batch of reagents extensively before using them in routine diagnostics.«[21] And this is only one of many causes of contamination in PCR resulting in false-positive results.

Table 1: RNA preparations from SARS-CoV-2 negative human throat swabs, bovine nasal or oral swabs and further negative controls (phosphate buffered saline (PBS) or nuclease-free water) were tested by different batches of the identical in-house primers and probe (Corman et al., 2020). The primers/probe sets are named according to the company at which they were synthetized, the delivery dates are given in brackets. When several sets were ordered at the same supplier, they are consecutively numbered. The mean quantification cycle values (Cq) including standard deviations for the false positive results are given in brackets.

sample material	supplier A-1 (March 25) nCoV_IP4 no. tested/ pos. (Cq†)	supplier A-1 (March 25) E-Sarbeco no. tested/ pos. (Cq)	supplier A-2 (April 07) E-Sarbeco no. tested/ pos. (Cq)	supplier A-3 (May 07) E-Sarbeco no. tested/ pos. (Cq)	supplier B (April 02) E-Sarbeco no. tested/ pos. (Cq)	supplier C-1 (April 15) E-Sarbeco no. tested/ pos. (Cq)	supplier C-2 (April 24) E-Sarbeco no. tested/ pos. (Cq)	supplier D (March 27) E-Sarbeco no. tested/ pos. (Cq)
throat swab, human	41/0	41/0	41/3 (38.5±0.4)	41/1 (38.5)	41/1 (40.9)	n.d.§	n.d.	n.d.
nasal or oral swab, cattle	47/0	47/0	47/8 (38.6±0.4)	47/3 (39.4±0.9)	47/3 (37.6±0.3)	n.d.	n.d.	n.d.
PBS‡ or water	10/0	10/0	27/2 (38.4±0.3)	27/1 (41.2)	29/3 (39.3±0.9)	6/6 (17.5±0.1)	7/7 (22.4±0.2)	4/4 (30.8±0.1)

Table footnotes: ‡ PBS - phosphate buffered saline, † Cq - quantification cycle value, § n.d. - not done.

[21] Kerstin Wernicke et al.: Pitfalls in SARS-CoV-2 PCR diagnostic (Transboundary and Emerging Diseases Juni 2020). Online: https://www.researchgate.net/publication/342174242_Pitfalls_in_SARS-CoV-2_PCR_diagnostics.

Something similar might have happened at the Bavarian large-scale laboratory MVZ, which had already announced the reduction to one target gene in April 2020 (which has since been removed from the website): »There, 58 out of 60 positive tests would have turned out to be wrong. The managing director of the Augsburg MVZ laboratory explained the errors with the shortage of reagents. The laboratory had had to resort to another detection agent due to the failure of a manufacturer to deliver, which had apparently not been compatible.«[22] Oh, dear!

The »standard diagnostic case« is not an »important finding«

What does the person who developed, published and modified the test have to say to this? In his podcast in May by the NDR (*Norddeutscher Rundfunk*—the public broadcaster in northern Germany), the subject was a scientific article stating that the virus had been on the move in France earlier than previously assumed. Drosten criticised the lack of verification of the positive PCR result:

> »**Christian Drosten:** ›[…] A PCR test, this must be made clear, must first be regarded as doubtful as long as it is not confirmed by other PCR tests that detect the virus in other target regions of the genome. Especially in such an important finding, when it is not a normal routine operation in the laboratory, where you simply want to know, this is a standard diagnostic case: Is it positive or negative? You can say: PCR is positive. We consider the patient to be infected.‹
> **Korinna Hennig:** ›In normal everyday life.‹
> **Christian Drosten:** ›Right. But in a case like this, where we say we are rewriting the infection history of this disease and say: In reality, this already existed in France and then probably everywhere else in the world a month earlier or even longer. And something may have been concealed or not noticed. If you want to publish such a weighty finding, you also have to back it up. This would include, in addition to a second or third confirmatory PCR, also

[22] Zeitung – Probleme in Labor bringen falsche Corona-Testergebnisse [*Newspaper—Problems in laboratory produce false Corona test results*] (Reuters 28.10.2020). Online: https://www.reuters.com/article/virus-deutschland-tests-idDEKBN27D0MY.

> sequencing the virus, i. e. determining the entire genome sequence of the virus. This can be done if the PCRs become positive. That is technically very easy nowadays.‹«[23]

For Drosten, there exists the »important finding«, and if you want to »publish such a weighty finding« as an ambitious scientist, then »you also have to back it up«, which is done by »in addition to a second or third confirmatory PCR, also sequencing the virus«: three times PCR plus sequencing, because a PCR test »is first to be considered doubtful as long as it is not confirmed by further PCR tests that detect the virus in other target regions of the genome«. At least.

And then, on the other hand, there is the »routine operation«, namely the examination of people, »where you simply want to know, this is a standard diagnostic case: is it positive or negative? Then you can say: PCR is positive.« For real people, a single PCR is apparently sufficient, as he has agreed with the WHO—even if this must »be regarded as doubtful«, as he knows very well.

Simply, real people are of no interest to him, our government advisor. Advice is given accordingly. And the consequences follow.

[23] Podcast 12.5.2020: https://www.ndr.de/nachrichten/info/coronaskript174.pdf.

»Truth is like water: it will find its way«

> What if I told you that the PCR test isn't even that reliable if you don't use it properly—and that the WHO's rationale for using it to track the pandemic is based on a single paper that came about under highly dubious circumstances—and that a group of international scientists proved it in November—and that the media hasn't given it much coverage yet? A criminal story. To be continued …[1]
>
> *Gunnar Kaiser, philosopher and writer*

The Corona Committee founded by the four lawyers Viviane Fischer, Antonia Fischer, Dr Reiner Füllmich and Dr Justus Hoffmann met on 5 February 2021 in its 38th session on the topic »Attack on People and Society«.[2] The biologist Prof. Ulrike Kämmerer, who belongs to the group of scientists demanding that the medical journal *Eurosurveillance* withdraw the PCR protocol for the »Drosten Test«, was invited. At the meeting, she reported on the journal's decision the previous day. This is the edited version of her report.

Re: The *Eurosurveillance* reaction of 4 February 2021

Ulrike Kämmerer: It was about this work[3] which was issued by the working group around Mr. Drosten, a larger international group, in January, the »Original Sin of PCR«—so to speak; this is a bad word, though—and thus the starting point of the pandemic. Then, over a long period of time, many people who said »no, none of this really fits« got together and wrote a report with a letter to *Eurosurveillance*[4] in which we have identified

[1] https://www.instagram.com/p/CK-9e3uB6TB/

[2] https://corona-ausschuss.de/.

[3] Victor Corman et al: Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR (*Eurosurveillance* 23.1.2020). Online: https://www.eurosurveillance.org/content/10.2807/1560–7917.ES.2020.25.3.2000045.

[4] Pieter Borger et al.: External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level:

many points that are bad tools of the trade and said: »The work cannot be sustained in this way and it must be withdrawn.«

Perhaps we should say right away that the authors always said that we were not active virologists dealing with SARS-CoV-2. However, PCR is a totally ordinary, banal routine method in every laboratory. I don't have to be a top virologist or anything else but on the contrary: it is those people who use it in their day-to-day work who see much better where these technical errors are than someone hovering somewhere on top.

I don't have to be a bricklayer either to see that a wall is built at an angle. […]

We have summarised this in that report. We submitted it quite regularly to *Eurosurveillance* with an accompanying letter and then put it on various so-called preprint servers so that the academic community could also look at it and assess it before publication.

One of our colleagues also put it on Researchgate, where a lot of researchers also had a look at it. Funnily enough, a week ago we actually received a kind of certificate that the document had already been accessed over 100,000 times there. I would like to see that happen to a normal main research article. That is the absolute top record on this Researchgate. So that shows how interesting this topic is.

Because it was clear to us that we might have some problems with the normal scientific way, we decided to make a homepage relatively quickly. Because one thing has to be clear: In the current situation, I also had to learn that first, nothing works the way it did a year ago. We are no longer in a regular science business, but we are—that must be said unfortunately—in an information war, and this is about information sovereignty.

And by setting up this homepage, we very quickly gained a kind of information sovereignty for our comments as well; we have had many, very helpful discussions about it. The page has (as of today) been called up and accessed 23 million times from all over the world—only those who have looked at it for more than four minutes count. You can see, and we also notice this in the feedback, that this really does affect people in the scientific community.

That's why we also received a lot of questions along the lines of »What's up with that now?« *Eurosurveillance* had written to us: They have received this and they will process it. And a lot of people actually wrote to *Eurosurveillance* from this—let's say it, informal scientific community, some of whom we don't even know—of their own accord and sent us some of the feedback they had received: this is one example. They [*Eurosurveillance*]

consequences for false positive results. https://cormandrostenreview.com/report/.

said: Yes, we are working on it and the report will come at the end of January. […]

And then in between there was such nice feedback, because some asked even more intensively. That was the best thing here: that this was the first time that *Eurosurveillance* was pelted with critical comments. One then wrote back, very crassly, »I don't give a shit if you've had this before, now it's the case.« And last week another one was informed that this will appear in one of the regular *volumes*,—so again delaying tactics.

But then we had the advantage of a little »accident«—let's put it that way,—in a radio interview from another part of the world someone got terribly upset about our report[5] and was asked how he knew about it. He said that he was one of the reviewers of our report and that the results were now available from *Eurosurveillance*. Then we said: OK, they obviously already have the basis for the decision, why don't they make it?

Obviously, they realised that, too, so they quickly put the decision on their homepage yesterday, and it suddenly appeared there. Later, they sent us the official letter. The conclusion (about this letter) is actually: this is an absolute impertinence—that has to be said quite clearly. They did nothing of what is normally done in the expert opinion process: They did not respond to our individual technical comments, but just let off a general speech bubble. What they put on the homepage is perhaps scientifically transferred, if you all remember that ugly old lady in Berlin, who was showing the finger[6] to the audience,—this letter from *Eurosurveillance* is quasi writing down what this picture expresses. […]

The interesting thing is that they only addressed the conflict of the two authors (Drosten and *Reusken*[7]), who are on the editorial board; you can actually argue about that. What they have not done, however, is to address the massive financial interests which are actually much more important. As I said, this is general blah-blah, I won't read it out in detail now, you can find it on the site of *Eurosurveillance*,[8], anyone can read through it. We will of course also announce it accordingly on our homepage and then also

[5] https://cormandrostenreview.com/eurosurveillance-response/. This reviewer is Stephen Bustin, who wrote the MIQE guidelines for PCR. On the one hand, he is a high-profile expert, but on the other hand he is working on a commercial rapid PCR for COVID-19 and therefore has a conflict of interest. Cf. also page 9.

[6] A media campaign conducted by officials in Berlin depicted an elderly lady showing the finger to everyone not wearing a mask. Cf. online: https://www.tagesspiegel.de/berlin/erhobener-zeigefinger-fuer-alle-ohne-maske-berliner-senat-stoppt-umstrittene-mittelfinger-kampagne/26274924.html.

[7] Subsequent correction: in the original Marion Koopmans was mentioned by mistake

[8] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.5.2102

elaborate. It came yesterday evening … we are also an international group, which means that some are still sleeping or were already awake last night and have done a lot.

They said that there are no criteria, that this article is somehow objectionable and that they would have to react there. […] Again, it's amazing: this international scientific community reacted extremely quickly; even before I saw this, for example, the first person already wrote me an email: »Did you see that?« That's the beauty of it: it's actually the case that a lot of people join forces and also observe such things well. And then there were also very nice reports.

What I like is: *»This is the proof that science is dead now«.* And it really is like that, i. e. it no longer has anything to do with what you used to learn: you write a scientific publication or a letter to the editor or a critique, and then reviewers come and tell you: yes, you're right about that and you're wrong about that, that point is also stupid and now take a stand on it again. So, none of that works any more, but in fact, and that is also our conviction, that is why we all continue. The research community that works against it or with us is getting bigger and bigger. *»But truth is like water, it will find its way.«*

And that's it, I think, and that's how we have to work. As I said, there are also a lot of good letters that say: »That's exactly it«. So this energy that's coming out, that you just say, »Guys, we need to unite globally and sort of put more weight behind the *evidence* behind things again, because so far it's all just *eminence*«, i. e. people are put in the foreground and they proclaim the truth from above. That can't really be the case in science. That's why we have a kind of »movement« here that you can't really call »movement«, but we have already put an idea into the world: *unbiased science*, where such people can also report.

From the official answer: They practically copy-pasted our ten points and added two or three sentences—that is also a no-go. But they also agreed that the *potential conflict of interest* should actually be shown, but again just claimed: Corman and Drosten wouldn't sell anything. We didn't say that either, but they earn the money through diagnostics and Landt and the others sell *de facto*. We can bullshit ourselves on our own. What is quite interesting is that they are still saying: Yes, this was the only test to get a grip on the situation in an emergency and this was the only way to put a test system in the way of the pandemic that threatened us and collapsed on us. *»This paper successfully enabled many of those laboratories to respond to the COVID-19 pandemic.«* But there was no pandemic at that time.

041. Cf. also »Eurosurveillance checks itself: All is well at Corman/Drosten«. online: https://www.corodok.de/eurosurveillance-alles-corman/.

Reiner Füllmich: That is decisive from my point of view. That was on 23 January, when Drosten was still walking around telling everyone that most of us wouldn't even notice, and only when the command came did he refer to this paper that had obviously been prepared in preparation for the command. To argue at that point with this time pressure and all about »huhuihui, we had to act fast«: That is obvious bullshit, and I would agree with that.

Viviane Fischer: The nice thing here is that they actually open up the causality of this paper again, that this was the only one with which all these tests were carried out, so to speak; actually, we also have a confirmation of the journal here, if one wants to take action against the journal.

Reiner Füllmich: They are practically admitting here that they helped the world in an emergency, so to speak, with the help of their buddy Tedros from the WHO. At the same time, they are admitting what we know anyway, what is in the complaints, namely that this was the basis for all the fake figures worldwide.

Ulrike Kämmerer: Sure, you can argue well with hindsight, but the point was to show this paper, which was published at the time, with its flaws. That's the review process. As I mentioned earlier, what is also pleasing about the whole thing is the extreme response and the international network that has emerged with many really helpful comments. Of course, there are always—sorry—the assholes and the trolls who get involved and weren't too ashamed to think that they had to attack the authors personally. But well, you always get that, that much I have learned.

For example, we came to [Wouter Aukema] via the network; I think almost everyone knows the graphic (see page 51) by now. He is someone who knows a lot about big data collections and simply analysed all the accessible publications and review times of *Eurosurveillance* in a large database. And here you can see the years and then he divided it into *Rapid Communication*, *Research Papers* and *Surveillance Reports*. Here you can see the days and here you can see the average review time for these research papers: one stands out. You can also look this up on Wouter's official homepage and simply click on it.[9] If you then click on this dot, you will see Corman, Drosten et al. This dot is this 27-hour review paper.

Then they also wrote to us in the reply that there was a second case, because it was such a pandemic emergency, with a very quick assessment.

[9] http://www.aukema.org/2020/12/meta-data-analysis-at.html.

This is actually this publication.[10] This is also directly declared as *Rapid Communication*, which is what the one by Corman, Drosten et al. should have been at least.

This is a second work by the WHO, where the first cases were summarised in order to say how the pandemic is rolling.

They have nothing to do with the Chinese CDC, which at the same time submitted their much more substantial and proper publications to both the *Chinese Medical Journal* and the *New England Journal*. In other words, these two extremely fast papers both triggered the WHO, and the other papers came out later. We wouldn't have noticed that otherwise, but they kindly pointed out to us that a special arrangement was made here. Yes, and the interesting thing for the scientists is that we were told that the reviewers were on standby, got the work, worked around the clock, the authors were also on standby and the editors, because the emergency was so extreme, and managed to take this work to the market within this extremely short time with review, comments and improvements.

Reiner Füllmich: If the emergency was so extreme, why was it not communicated at the time? Why was it told in public all this time, especially by Drosten, that most people would not notice, etc.? Basically, this is just the last piece of evidence needed—there will be more to come, but for the time being the last piece of evidence needed—to show that a completely coordinated, planned behaviour was carried out here. One only has to find out who was behind it in the end, but that Drosten acted on command here will be clear from these very circumstances. If he had really been in a panic about »oh my God, this is all going to end badly«, then this should have been communicated to the outside world. That's what happened afterwards, when they wanted to officially announce the panic instead of always calming down and saying »it's all cool, most of us won't notice anything«. That is decisive for me. And of course the causality that Viviane just mentioned.

Viviane Fischer: And what is the average time of the assessment process at *Eurosurveillance* again?

[10] Peng Wu et al: Real-time tentative assessment of the epidemiological characteristics of novel coronavirus infections in Wuhan, China, as at 22 January 2020 »Article submitted on 21 Jan 2020 / accepted on 23 Jan 2020 / published on 23 Jan 2020«. Online: https://www.eurosurveillance.org/docserver/fulltext/eurosurveillance/25/3/eurosurv-25-3-2.pdf.

Ulrike Kämmerer: The fastest work here in this category was then about 12 days, and the average, you can see here, are about a hundred in the year—we have to look at 2019/2020. Wouter has not continued: 172 days in this category. This is also what you know so from normal practice, how long such work is reviewed. *Rapid Communications*—it's already in the name—these are mostly the urgent things with new issues, they have about 20 to 30 days review process, that is already extremely fast, one must say. There seem to be a few exceptions here, we'll have to look again to see what that was, but that's just this second quick paper that was also published at this time in January very early on the topic of the pandemic and nCoV-19. One is, sort of, the PCR. That it's transmitted from human to human and goes out from Wuhan to the world, that's the other work. Those are the two in combination that then show to the whole world: Oh, now we're about to go own and that plague and cholera and SARS and Ebola are coming together.

Viviane Fischer: Whereby it is also fascinating that this question regarding the error-prone nature of the paper was not considered worthy of *Rapid Communication.* If you say that this is what all these tests are based on, it would be extremely important to find out very quickly whether there is really something to it or not. And the fact that it took them two months to do this and they are then only able to give the finger and not really comment on the content is also astonishing in this matter.

Justus Hoffmann: Yes, that surprises me too. In order to produce that, they really only would have had to read it once and say: »Unfortunately no, unfortunately not at all, we don't need that, unfortunately it's all very bad.« I'm surprised that it took so long, a relatively long time, and then in the end they don't say anything at all.

Reiner Füllmich: I think we're all surprised about that. You are all angry about it, aren't you?

Ulrike Kämmerer: Well, let's put it this way: it was to be expected. But we would at least have expected them to try to keep up appearances a bit. That they simply, in their hubris, in their superiority, don't even bother to pretend to be scientific any more! That is the frightening thing; it is actually an admission of failure, because it also says: The Editorial Board had already met on December 4th and concluded that it was nothing. That means—it's also in writing—they got it, so to speak, then zoomed or called everyone together and said, »Guys, what are we going to do with this?«

And then it came out, »they can't do anything to us, so now we'll prolong it a bit and pretend we're giving it to external experts«.

They must have given it to the external experts—one of whom accidentally blabbed. Normally it would be: reviewer 1 has the following points, reviewer 2 has the following points, reviewer 3 has the following points and, as I said, this official, supposedly scientific reply letter to the corresponding author is really an absolute cheek, you simply have to say that the whole publication and scientific documentation system is simply dead. We have already suspected this, because it is also like this in other areas, and it is not only to do with SARS-CoV-2, the whole system is really only built up of networks and the like. But well, this is now a structural problem, we will have to look at it in the medium term.

We were told: »You didn't cook all this in the wet laboratory.« Then we also said: »We don't need that. We don't need to cook it in the lab.« When I examine a paper as a reviewer, I don't have to stand in the lab and reproduce all the experiments, but I just look: Is the work OK? Is it stringent? Is the correct literature cited? Are the methods adequately described and also able to get the results obtained? Are the results credible?—That's what a normal reviewer does with any scientific paper.

But what we did then, we spent all the Christmas and New Year's holidays on it—to say: Not only *Eurosurveillance* works around the clock—at that time we summarised all the publications here in which something was actually validated with this PCR.

I have framed a paper here that is particularly interesting: Poljak et al.[11] from Slovenia.

6-carboxyfluorescein (FAM)-labeled hydrolysis probes (11). LightMix Modular SARS and Wuhan CoV E-gene kit (Tib-Molbol, Berlin, Germany) amplifying a 76-bp-long fragment from a conserved region in the E gene (pan-sarbecovirus target) and LightMix Modular Wuhan CoV RdRp gene kit (Tib-Molbol) amplifying a 100-bp-long fragment from a conserved region of the RNA-dependent RNA polymerase (RdRp) gene (a SARS-CoV-2 specific target) was used in combination with TaqMan Fast Virus 1-Step

Additional data supporting the informed decision for a diagnostic approach switch. After extensive evaluation, our laboratory implemented LightMix-based SARS-CoV-2 testing on 17 January 2020. Routine SARS-CoV-2 testing started on 27 January 2020, and the first positive sample was detected on 4 March 2020 after testing 353

[11] Mario Poljak et al.: Clinical Evaluation of the cobas SARS-CoV-2 Test and a Diagnostic Platform Switch during 48 Hours in the Midst of the COVID-19 Pandemic. Online: https://www.researchgate.net/publication/340593669_Clinical_Evaluation_of_the_cobas_SARS-CoV-2_Test_and_a_Diagnostic_Platform_Switch_during_48_Hours_in_the_Midst_of_the_COVID-19_Pandemic.

They have in fact described in their paper that they have already implemented the *TIB Molbiol/Roche* test for nCoV-19 PCR in their laboratory routine on January 17th 2020 after extensive review. There was a commercial routine test described in this paper that was routinely implemented on 17 January after extensive review.

Of course, that's another thing where you have to say, »Guys, why?« And these instruction leaflets that come with it, they already have an SAP number, and it's all from *Roche*. That means that the thing must have been prepared at least as early as December. It is not possible for such a company to launch such a commercial kit within—let's say—five days. In this respect, it's quite good when you get critics, then you have to deal with the things more closely. And it's written in two little sentences at the back, but it's clearly written. That was another nice piece of information that we might otherwise have missed; and it also shows how important this scientific exchange really is, because you learn an incredible lot.

We have now created this Addendum[12] with all this peer-reviewed literature. It can also be viewed on this Zenodo preprint server. We had also sent this to *Eurosurveillance* to make their work easier, according to the motto: »You don't need to check everything individually, we have done this for you«. They don't even go into that, for example. […]

Reiner Füllmich: The question is, who is our tax money serving in the meantime? It seems increasingly clear to me that this is not only a scientific problem, but also a political one. I believe that Mrs Merkel recently said, when Mr Reitschuster[13] asked specific questions and she was at a loss, that this was essentially a political decision. That, in turn, is the concession that science is actually only being used, that Mr Drosten, for example, is only being used here with this stuff to give the impression that political decisions are based on science, we see that everywhere. She has now also conceded that this is the opportunity for a social reset, I don't remember exactly how she put it, whether she used the word *Great Reset*, I don't know, but it could be. That in turn raises the question: How long are we going to dwell on this?

So, your work is absolutely important, we are continuing it in the courts, that's what will matter when you are heard as expert witnesses and the others have no answers, just like in the reaction to your paper. There is

[12] https://zenodo.org/record/4433503

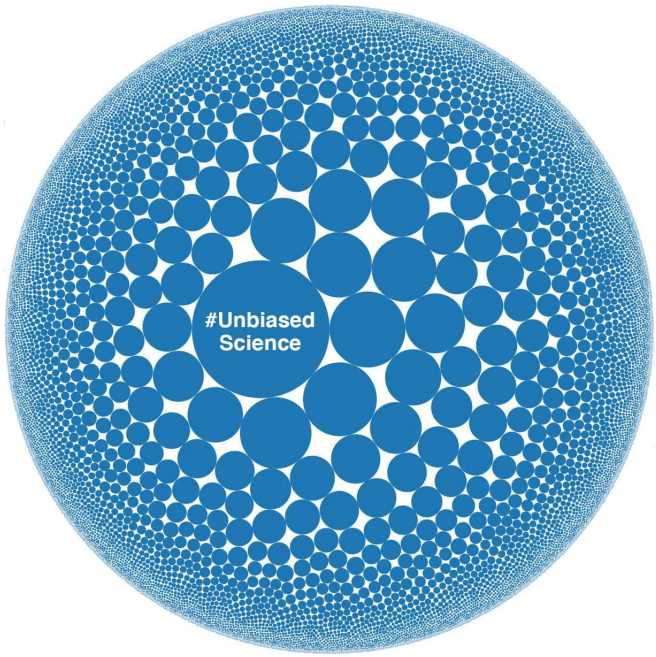
[13] Boris Reitschuster is a German journalist who has attracted some attention to PCR testing by repeteadly asking questions in the National Press conference. Online: https://reitschuster.de/post/schweigespirale-bei-pcr-tests-regierung-verweigert-zum-7-mal-antwort/.

no answer other than »oh, something had to be done very, very urgently«. We will continue this in the courts, but in truth the question is, what is this all about anyway, when it's all fake and it's all just so-and-so, just pushing through a socio-political agenda. I think that's clear to most of the scientists by now, isn't it?

Ulrike Kämmerer: I think that it is clear to many people, even if they don't want to admit it. We always assume that there is good in people. One question is: Why do so many still go along with it? The other is: What is behind it, what can be done? But of course we're not sure about that. Now it's up to the crowd again. All kinds of people have to get involved in the discussion, and they have to do so in a well-founded way, collect sound information and not expose themselves to this »there are the good guys, there are the bad guys«—that's becoming more and more prevalent—but look: Guys, at the end of the day we all have a problem and then everyone should contribute something to it.

Reiner Füllmich: I did not mean to say that this work is not important—on the contrary. It is crucial. Only if the first question, »Is this about health, is this about the dangerousness of the virus, is this about PCR tests?« is answered, can you even ask the question on the next level: »Yes, if that is the case, as we have established here in the meantime—then what is it about?« Your scientific work is crucial for this: to be able to answer the first question and ask the second.

Ulrike Kämmerer: But that's what it's all about, that everyone—just as it is the case with us with, this *Unbiased Science* logo with the many circles—everyone contributes his part. And even those who now simply make some press releases do their bit, which would also be extremely interesting, for example. At the beginning, we didn't really follow what was happening, maybe there are people who still know: Did this wave gradually emerge in the media landscape? So, that means: everyone can compile such a huge collection of data, so that at some point you simply get an overall picture. Our particle now is this unbiased science, and we're staying with the topic to work it out further. And others have to contribute other particles.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Annex: Questions to the Ministry of Health and the Robert Koch Institute

Questions to the Ministry of Health on testing for SARS-CoV-2

Via the portal www.fragdenstaat.de, the author prepared a lengthy list of questions for the Ministry of Health on 8 April 2020 (cf. the footnote on page 14). In Germany, it is possible to obtain specific information by government agencies via freedom of information legislation (*Informationsfreiheitsgesetz*—IFG).

A. General questions about the SARS-CoV-2 PCR test

1. Which tests from which manufacturers are used in Germany for the medical diagnosis of SARS-COV-2?
2. When and by which body was the approval of these tests for diagnostic use on patients granted?
3. What are the respective data for the sensitivity and specificity of these tests?

B. Specific questions on *TIB Molbiol*/Roche Diagnostics LightMix Modular SARS-CoV-2 (COVID19) for N-genes / RdRP-genes / E-genes:

1. The test most frequently mentioned in the media in this country is the one produced and distributed by the Berlin company *TIB Molbiol* or *TIB Molbiol* / Roche. What is the share of these tests in the total volume of tests used for medical diagnosis in Germany?
2. An online search revealed the following picture:

    - In the listing of https://www.finddx.org/covid-19/pipeline/ (accessed 6 April, 2020), all three parts of this test are listed under RUO (research use only).
    - The package insert for the test kits states at the top »Instructions for life science research use only. Not tested for use in diagnostic procedures. For in vitro use only.«
    - In March, Roche (press release of 13 March, 2020) received

an Emergency Use Authorisation (EUA) for another test (Cobas SARS-CoV-2 test) from the US FDA, which also allows diagnostic use in EU countries that recognise the CE marking. For *TIB Molbiol*/Roche Diagnostics LightMix Modular SARS-CoV-2 (COVID19), on the other hand, there is no EUA and no CE marking.

- In India, three tests were approved by the ICMR after review. The *TIB Molbiol*/Roche Diagnostics LightMix Modular SARS-CoV-2 (COVID19) test system was tested in this procedure but was not approved due to low concordance. https://www.expresshealthcare.in/covid19-updates/icmr-approves-three-covid19-test-kits-for-commercial-use/417799/ (accessed 6 April, 2020)

Is it correct that *TIB Molbiol*/Roche Diagnostics LightMix Modular SARS-CoV-2 (COVID19) does not have approval for medical diagnostics in Germany, but is nevertheless used for this purpose? On what scientific and legal basis is this use taking place, which body has decided this?

3. Prof. Dr. Drosten, who plays a central advisory role for the Federal Government with regard to the COVID19 test, among other things, was significantly involved in the development of the test. Is it possible that there is a conflict of interest here?

C. Questions about the use of the data generated by these tests

1. How is the specificity and sensitivity known for the respective tests taken into account when calculating the number of cases? Where is this documented or published?
2. What is the value for patients and statistics of data generated by tests with unknown specificity and sensitivity?
3. In the official case definition, a »case to be transmitted to the RKI via the responsible state authority« is dependent on or defined by a positive test in points C to E; it is sufficient in each case: »C. […] non-specific clinical picture of COVID-19 and laboratory diagnostic evidence. D. Laboratory evidence of a known clinical picture that does not meet the criteria for either the specific or

non-specific clinical picture of COVID-19. This includes asymptomatic infections. E. Laboratory diagnostic evidence in the absence of clinical picture information (not ascertainable or not collected).« How high is the proportion of these asymptomatic or clinically unknown or non-matching test-positive persons in the recorded case numbers? Are these cases documented separately, and where is the data published? Is the therapy for patients with a positive test different from that for those with a negative test? How can it be excluded that these groups are false positives?

Answer from Olfert Landt

Olfert Landt intervened on 13 May, 2020:

Good day,

Comments from the manufacturer regarding (B) in particular

The E gene-based detection test was registered as a CE-IVD diagnostic product on 4 February. The research-use classified products have EUA approval for diagnostic use in various countries.

There is a study on sensitivity and specificity, the results of which are available to the competent authority. The information at FIND is incomplete.

Our medical device advisors will be happy to answer other questions.

Olfert Landt

Author's Response:

The author responded to Landt's answer:

Thank you for responding despite what I am sure is your heavy workload—but this does not answer my questions. Therefore, I will present my point of view again and ask for correction if facts or conclusions should be wrong.

Also, further search only revealed that the test kit »Sarbecovirus E-gene« has a CE-IVD approval since 02/2020, nothing could be found on the EUA. All other kits may still be used for research purposes only, but not for diagnosis (RUO): »SARS-CoV (COVID19) N-gene« (removed from the protocol in January), »SARS-CoV (COVID19) E-gene«, »SARS-CoV (COVID19) RdRP«.

The test for SARS-CoV-2 was originally done for the E gene and the RdRP gene, with the test with E used as screening and the one with RdRP used as confirmation. The requirement for detection of RdRP was removed in March/April, since then detection of E has been sufficient.

So currently either the unapproved »SARS-CoV (COVID19) E-gene« test or the approved »Sarbecovirus E-gene« test is used. In addition, the non-approved »SARS-CoV (COVID19) RdRP« test was used until recently. With this, diagnoses were (are?) made with tests that are not approved for this—on what basis?

Now that only the E gene needs to be detected, this is a test for SARS-CoV-1 and SARS-CoV-2 (as well as other sarbecoviruses not yet known) and thus not specific for SARS-CoV-2.

In summary, it is about the data for *sensitivity* and *specificity*, which are presumably unknown for the non-approved tests, but should at least be known for the approved test.

The *sensitivity* is of general interest, since one wants to detect all infected persons. With 3,000,000 tests carried out in the meantime and a good sensitivity of 99 %, 30,000 (1 %) tests would be false-negative. Over the period of testing to date, a small medium-sized city would be on the way as an undetected source of infection; with a sensitivity of 95 %, it would be a large city of 150,000.

Little or no consideration is given to *specificity*, as there seems to be a general need for high numbers. With 3,000,000 tests carried out in the meantime and a good specificity of 99 %, 30,000 (1 %) tests would be false-positive, which would currently be one sixth of the RKI case numbers and would result in corresponding changes in the doubling times, R-values, etc. With a specificity of 95%, the majority of the current RKI case numbers would be eliminated.

Sensitivity and *specificity* are not trade secrets. This is especially true in this situation where, for 83 million people in this country, everything from diagnosis to statistics to relaxation or tightening of the lockdown ultimately depends on this test.

Nothing more followed from Olfert Landt.

Responses from the Ministry of Health

The Ministry of Health initially responded promptly one day later on 9 April, 2020 and asked for a postponement:

> [I] would like to inform you of the following regarding your request below:
>
> The legal provisions you mentioned (§ 1 IFG, § 3 UIG, § 1 VIG) are not relevant: The areas of application of the Environmental Information Act and the Consumer Information Act are not open. The Freedom of Information Act is not affected because your request is not for access to official records but for answers to specific questions. Your request has therefore been forwarded to the competent specialist unit.
>
> The Federal Ministry of Health (BMG) has a special responsibility to play a central role in dealing with the crisis caused by the effects of the coronavirus (COVID-19). These effects affect our entire society and the staff of the BMG in particular. I therefore ask for your understanding that due to these special circumstances it will probably not be possible to answer your enquiry immediately and would like to ask you for a little patience.

The author then waited in each case and sent the following letter on 1 May, 2020, 18 May, 2020, 20 July, 2020, 5 August, 2020 and 8 September, 2020 respectively requesting a response to the request:

> [M]y freedom of information request »Request to answer questions about testing for SARS-CoV-2« dated 8 April, 2020 (#184240) has not been answered by you within the time required by law. You have now exceeded the deadline by 1/7/40/86/120 days. Please inform me immediately about the status of my request.

The authority initially replied thus on 19 May, 2020:

> [A]s you have already been informed by email of 9 April 2020, your request has been forwarded to the responsible department for a response. As explained therein, your request was not an IFG request but a request for information that was only formally based on the Freedom of Information Act. The response to your request will take some time due to the high number of requests on this and similar topics.

The next response followed on 6 August, 2020:

> [I]n response to your enquiry that your IFG request of 8 April, 2020 is still unanswered, I would like to inform you of the following:

> Since all staff members who are primarily entrusted with the management of the COVID-19 pandemic still have to be called upon to answer your IFG request, there is still a delay in processing your request. Moreover, the volume of IFG requests on the pandemic received to date is very high and almost all of them are very extensive. I must therefore once again ask for your understanding for the long processing time and for your patience.
>
> Your extension below (#194590) of your request of 8 April, 2020 (#184240) is kept as one request.

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After that: nothing. We think it is important to document this Kafkaesque communication with the authorities so meticulously. Because: A detailed answer to these questions would also have been suitable to prudently counter all critics of the testing procedures and the resulting restrictions of fundamental rights and to refute the criticism. The questions raised are quite central. At best, the authorities do not know the answer; at worst, they withhold it. Both would be significant.

Questions to the Robert Koch Institute on case numbers, R-value & Second wave by false-positive PCR

Via the portal www.fragdenstaat.de, the author prepared a longer questionnaire to the Robert Koch Institute on July 5, 2020 (cf. the footnote on page 14).

1. What is the specificity of the COVID-19 PCR used in Germany?

Until your answer, I calculate 1 %, which also results from the results of the extra ring test of INSTAND Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V..[1]

For some weeks now, you have been stating in the Epidemiological Bulletin a value of approx. 1 % positive tests measured against the total number of tests carried out.

From the concordance of these values I conclude that we are currently in a COVID-19-free phase (which also corresponds to the seasonality of coronaviruses), in which you publish case numbers consisting of false-positive results.

From these results, you regularly calculate the R-value, which accordingly has nothing to do with COVID-19.

With an approximately constant number of tests performed, the number of cases—i. e. false-positive results—remains the same and the R-value remains permanently at about 1.

From this I conclude: the R-value is no longer significant, the epidemic is over.

Answer given by RKI: *In Germany, both commercial SARS-CoV-2 tests and in-house tests for direct pathogen detection of SARS-CoV-2 are used. These are RT-PCR systems that detect the presence of SARS-CoV-2 RNA.*

The analytical specificity of a test is the ability to correctly detect either a group of pathogens (e. g. screening tests for beta-coronaviruses, Pan-Sarbeco) or a specific agent (e. g. confirmatory test for SARS-CoV-2). To exclude cross-reactivity with other pathogens, the respective assay is also tested with other pathogens. This is done in silico by

[1] https://www.instand-ev.de/no_cache/ringversuche-online/ringversuche-service/#rvp//340/-2020/.

primer alignment with existing nucleic acid sequences but also by direct testing of reference materials.

The analytical performance data of the test systems are collected within the framework of assay validation and can be retrieved or requested for the commercial tests on the manufacturer's website, among others. The performance data of the in-house tests must be determined by the performing laboratory itself. The requirements for validation are described in national and international guidelines (e. g. RiliBäK, DIN EN ISO 15189).

RT-PCR assays allow a very high specificity due to their test principle (direct and specific binding to target sequences via at least three oligonucleotides), so that an almost 100 % specificity can be assumed if the test is carried out and evaluated correctly. However, due to the infinite variety of pathogens and the ever-present risk of errors in the laboratory procedure/interpretation, it is not possible to test for/exclude all eventualities in purely practical terms. For this reason, laboratory results may only be prepared by laboratory physicians who ensure a quality-assured evaluation of the tests. All laboratories are required or obliged to participate in regular interlaboratory tests for quality assurance.

The clinical specificity of a test procedure is the ability to detect the correct pathogen in a patient. If COVID-19 is suspected, a screening test (e. g. beta coronavirus yes/no) and then a confirmation test (SARS-CoV-2 yes/on) are usually carried out first (dual target). The epidemiological environment and the patient's individual medical history must always be taken into account here (see also: https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html#doc13490982bodyText7).

Therefore, an average specificity for PCR tests used in Germany cannot be given.

2. Can you confirm or refute this line of argument?

Local outbreaks may be due to cross-reactions, e. g. with other coronaviruses (this is a possibility for animal pathogens at the slaughterhouses) or laboratory artefacts (this is a possibility at the housing blocks).

I believe clarification is urgently needed on whether outbreaks are true-positive or false-positive, given the consequences for those affected and the general public.

Answer given by RKI: *Questions 2 and 5 do not constitute a request for official information within the meaning of the IFG.*

3. How do you investigate the possible sources of false positives, with what result?

In the INSTAND ring test, a virus-free cell lysate and cell lysates with two of the four known human coronaviruses were used as specificity controls. Lysate without virus and HCoV OC43 were positive to approx. 1 %, with HCoV 229E even to almost 7 %.

It is to be expected that in the coming autumn, as in every year, illnesses caused by the well-known coronaviruses that trigger colds will increase.

If the tests used so far to detect COVID-19 continue to be used, these coronaviruses will also be included.

Two of the four known coronaviruses therefore clearly cross-react, the other two have not yet been tested, and there may be others about which nothing has been known so far.

The tests of the interlaboratory study were carried out with laboratory samples; with patient samples, the proportion of false-positive results could increase even more (analytical vs. diagnostic specificity).

After all, more testing is to be done and the more tests are done, the more the absolute number of false-positive results increases.

Therefore, I fear that a »second wave« may be caused by false-positive results alone.

Answer given by RKI: *The high analytical specificity of PCR tests that have been carried out properly and confirmed by a specialist does not suggest the necessity of correcting the reporting data due to false-positive findings. It should also be pointed out that a (potentially small) number of false-positive findings is offset by an under-reporting of cases in the reporting system, the extent of which can only be clarified more precisely in the context of sero-epidemiological studies.*

The need to correct the reporting data is also not obvious for reasons of clinical specificity, as testing is not completely untargeted, but according to the testing strategy tested persons have a contact history or a relation to a high-risk setting (e. g. in old people's homes). In addition, after the detection of SARS-CoV-2 is reported to the public health department, each report is validated at the public health department, contact is usually made with the affected person to ascertain further information and initiate infection control measures. In this process, retesting could also be initiated if there is doubt about the test result available.

4. How do you detect the proportion of false positives, how do you correct the reporting data?

The fact that another swine flu is already in the headlines shows the urgency of validating tests and correcting statistics.

Above all, it shows how urgent real numbers and real information are.

Answer given by RKI: *See 3.*

5. What have you done so far and what will you do in the future to protect the population from pseudo-epidemics caused by faulty test results?

Answer given by RKI: *Questions 2 and 5 do not constitute a request for official information within the meaning of the IFG.*

Glossary

amplicon The amplification product of the →PCR formed between the →primers.
CDC Abbreviation for *Centers for Disease Control and Prevention*, the US agency for infectious diseases.
CoV Abbreviation for coronavirus; the genome of coronaviruses consists of RNA; →SARS-CoV and →SARS-CoV-2 belong to the coronaviruses.
COVID-19 Abbreviation for *Coronavirus Disease* (Coronavirus-disease) 2019
deoxyribonucleic acid →DNA
DNA Abbreviation for *deoxyribonucleic acid*, forms the genome of eukaryotes (living organisms with a true cell nucleus, i. e. animals, plants, fungi), where it is present in the cell nucleus as a →double helix and is distributed on chromosomes; its components are the sugar deoxyribose and the →nucleotides adenine, thymine, guanine, cytosine, abbreviated as A, T, G and C; the →nucleotides of one strand combine with those of the parallel strand, whereby only the pairings A-T, G-C are possible.
double helix The →DNA is present in the cell in the form of a spirally twisted double strand; the double helix model originates from Watson and Crick (Nobel Prize 1962).
ECDC Abbreviation for *European Center for Disease Control and Prevention*, the European authority for infectious diseases.
enzyme A variety of proteins that are formed in living cells and control the organism's metabolism, each enzyme having its particular function; enzymes have the name ending -ase (e. g. →transcriptase, →polymerase).
Eurosurveillance Official organ of publication issued by the →ECDC.
NAAT Abbreviation for *Nucleic Acid Amplification Technology*; group of procedures in which nucleic acids are amplified, making small amounts detectable; e. g. →PCR.
PCR Abbreviation for *Polymerase Chain Reaction*; this method

allows short sections of →DNA to be amplified by means of the →enzyme →Polymerase; it is a chain reaction, since the products of previous cycles serve as starting materials for the next cycle and thus enable exponential amplification; the cycles are initiated by changes in temperature: by increasing, both strands of the →double helix divide and by decreasing, it is possible to obtain new double strands from the two free single strands by adding the →nucleotides; therefore, each cycle leads to a duplication in the presence of the →target; Nobel Prize 1993 for Kary Mullis.

polymerase An endogenous enzyme that amplifies (multiplies) →DNA; during cell division, two double strands are formed from one DNA double strand with the help of the polymerase, which are distributed to the two newly forming cells; in →PCR, this →enzyme is used to amplify the →DNA in the →sample.

polymerase chain reaction → PCR

primer A single strand of →DNA consisting of a few →nucleotides (approx. 20), which serves as the starting point for DNA synthesis by the →enzyme →polymerase; for →PCR, two →primers are needed to define the length of the →amplicon formed between them.

probe A short piece of →DNA that is specific for the →target being searched for, can bind to it in its presence and makes this binding visible through fluorescence, which is recognisable in the curve progression of the →Real-Time PCR.

Real-Time PCR A method of →PCR in which it is possible to follow the curve progression of amplification (increase in the amount of amplified →DNA) in *real time*; the higher the amount of →target in the initial sample, the earlier a significant increase is observed; visibility is made possible by the release of a fluorescent dye coupled to the →probe. Not to be confused with →RT-PCR

reverse transcriptase An →enzyme that carries out the reverse process of transcription, i. e. it transcribes →RNA into →DNA.

ribonucleic acid →RNA

RKI Abbreviation for Robert Koch Institute, the German authority for infectious diseases. Among other things, it defines case definitions, compiles case statistics and makes recommendations; it is directly subordinate to the Federal Ministry of Health.

RNA Abbreviation for *ribonucleic acid*; components are the sugar

ribose and the →nucleotides adenine, uracil, guanine, cytosine, which are abbreviated as A, U, G and C; the genome of coronaviruses consists of →RNA; during protein biosynthesis, e. g. in the human body, →DNA is transcribed into RNA by →transcriptase.

RT-PCR Abbreviation for *ribonucleic acid*; components are the sugar ribose and the →nucleotides adenine, uracil, guanine, cytosine, which are abbreviated as A, U, G and C; the genome of coronaviruses consists of →RNA; during protein biosynthesis, e. g. in the human body, →DNA is overwritten into RNA by →transcriptase.

SARS Abbreviation for *Severe Acute Respiratory Syndrome*, which was discovered in 2003.

SARS-CoV causative coronavirus for →SARS.

SARS-CoV-2 causative coronavirus for →COVID-19.

sequencing The precise determination of the sequence of →nucleotides on a nucleic acid molecule.

Severe Acute Respiratory Syndrome →SARS.

target A gene region whose presence is searched for in a sample, in the case of →SARS-CoV-2 e. g. a specific section on the E gene, the extent of which is defined by the →primers.

transcriptase The →enzyme of transcription, i. e. the transcription of →DNA into →RNA as part of the biosynthesis of proteins.

WHO Abbreviation for *World Health Organisation*, the United Nations coordinating agency for international public health.

World Health Organisation →WHO.

It all started in the last century, with an ingenious idea and a record sum for a patent. In order for this investment to pay off many times over, the problem to solve was sought and found, among other areas, in clinical virology.

The fact that PCR cannot distinguish between complete genome and fragments, between the ability and inability to replicate, and therefore inevitably produces false-positive results in the context of an infectious disease is of no interest to a pharmaceutical giant when billions upon billions are at stake.

As long as PCR is used so senselessly as it is now, there will be no end to this situation, be it with this or any other virus. The well-rehearsed team is making an excellent living from it and will continue to do so as long as they are allowed to. It also has an immense amount to lose if it becomes apparent what is being done to PCR and to us.

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