10 Proofs that COVID-19 Testing Is Not Reliable

Proofs Supplied by Directly by the United States FDA, United States CDC, South Korean CDC, Seven FDA-Certified South Korean RT-PCR Test Kit Manufacturers, and Other Qualified Institutions and Researchers

In this article, we will present quotes and references from official sources that prove that the COVID-19 testing methods and test kits are not reliable.

The proofs provided in this article do not question whether the RNA used in the test kits is viral or endogenous. If the RNA is not viral, then clearly the tests kits are of no value. However, such a question shall be the subject of an upcoming article. For the sake of critiquing the test kits themselves, this article shall *assume* the RNA used in the tests is viral.

1. Test kits might not be detecting COVID-19

The United States Centers for Disease Control and Prevention (CDC) says the following about their official test kit "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel":

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

"This test cannot rule out diseases caused by other bacterial or viral pathogens." [1]

Comment:

A positive test doesn't guarantee that the COVID-19 virus is causing infection at all. In fact, COVID-19 might not be in the patient's body at all, since the diseases could be caused by other bacterial or viral pathogens. In other words, a positive result might mean someone has COVID-19, but it also might mean that they have some other type of infection. What use is a test if it cannot guarantee its results? Patients who test positive will most likely be treated for COVID-19, even though they might have some other infection altogether.

2. FDA-approved Korean test kit makers admit their tests may not be accurate and are not validated for asymptomatic detection

There are currently seven South Korean RT-PCR test kit manufacturers that have been FDA-approved. The manufacturers include LabGenomics Co.,Ltd., OSANG Healthcare Co., Ltd., SEASUN BIOMATERIALS Inc., Seegene Inc., SD BIOSENSOR, Inc., 1drop Inc., and GeneMatrix Inc.

They have this to say about their test kits:

"The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostics information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease." [2] [3] [4] [5] [6] [7] [8]

GeneMatrix says this about its "NeoPlex TM COVID-19 Detection Kit":

"The performance of this device has not been evaluated for patients without signs and symptoms of infection."

Comment:

The test kits makers claim that the test can "generally" detect the presence of SARS-CoV-2 (i.e., the virus causing COVID-19) in a patient. But they admit that "the agent detected" on the test (i.e., COVID-19) "may not be the definite cause of disease." They also indirectly admit that unless the patient has an acute infection (i.e., symptoms), they won't be able to find COVID-19. Therefore, the idea of "asymptomatic patients" confirmed by the test is nonsense. GeneMatrix says clearly that "the performance of this device has not been evaluated for patients without signs and symptoms of infection" [8]. The FDA itself admits this in its "Molecular Diagnostic Template for Manufacturers" when it suggest that EUA submissions include the sentence, "Performance is unknown in asymptomatic patients" [9].

3. Test kit makers admit that the test cannot be used for diagnosis

SD BIOSENSOR says the following about its "STANDARD M nCoV Real-Time Detection kit":

"The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone." [6]

Kogene Biotech was the first company in Korea to be approved by the Korean CDC and Korean FDA. The Korean news outlet KBS said the following about Kogene Biotech's COVID-19 Virus Diagnostic Kit:

"Kogene Biotech has commercialized Real-time PCR (Polymerase chain reaction), which had been solely used for research purposes." [10] [11]

Comment:

This is a plain statement that the results of the test cannot be used for diagnosis purposes. In other words, the results are not sufficient for diagnostic accuracy and can only be used for reference. This is similar to what Creative Diagnostics says about their test kit: "Regulatory status: For research use only, not for use in diagnostic procedures" [12].

One of the reasons the tests cannot be used for diagnostic purposes is that they only test for a very small amount of the SARS-CoV-2 (i.e., the virus said to cause COVID-19) genome (usually just several hundred genomes out of a total of 29,903)[13][14] and are susceptible to cross-reactivity with other viruses, especially other coronaviruses.

For example, Seegene says, “Based on the in silico analysis, SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV-2 may cross-react with the Allplex™ 2019-nCoV Assay” [5].

As another example of cross-reactivity, Creative Diagnostics says, “non-specific interference of Influenza A Virus (H1N1), Influenza B Virus (Yamagata), Respiratory Syncytial Virus (type B), Respiratory Adenovirus (type 3, type 7), Parainfluenza Virus (type 2), Mycoplasma Pneumoniae, Chlamydia Pneumoniae, etc.” [12]. In other words, the test claims to be for COVID-19, but it might also register false positives if the patient is actually suffering from any of the above illnesses.

Of course, most FDA-approved test kits state that they have established a certain analytic specificity (usually 100%) that prevents cross-reactivity with other viruses, but as we will see in the Proof 4, there is a big difference between analytic specificity and clinical specificity. Simply saying that the test kit has an analytical specificity of 100% does not mean that it can protect against false positives in the real world.

4. Test kit accuracy not guaranteed in the real world

The FDA’s EUA templates require analytic sensitivity and specificity analyses. Analytic sensitivity represents an assay’s ability to detect a low concentration of a given substance in a specimen, where as analytic specificity represents an assay’s ability to exclusively identify a target substance or organism rather than similar but different substances [8].

Simply put, sensitivity is supposed to show how often the test is positive in patients who actually suffer from the disease being tested for. 100% sensitivity means that there are no false negatives. Specificity shows how often the test is negative in patients who actually do not suffer from the disease being tested for. 100% specificity means that there are no false positives.

For example, Labgenomics says, “The analytical sensitivity (limit of detection or LoD) experiments were performed to determine the lowest concentration of SARS-CoV-2 detected at which approximately 95% of all (true positive) replicates tested positive” [2].

OSANG Healthcare says, “The analytical specificity of GeneFinder COVID-19 Plus RealAmp Kit was evaluated both in silico and by wet testing of other organisms and viruses that may be present in respiratory specimens” [3].

Comment:

These FDA analytical sensitivity and specificity requirements may be useful in the context of a lab, but that doesn’t make them useful for clinical diagnosis. In other words, the analytical sensitivity and specificity percentages of 100% given by the test kit makers mean nothing in the real world of diagnostic testing.

A clinical microbiologist writing for the American Society of Microbiology (ASM) stated this clearly: “[Analytic sensitivity and specificity] differ in meaning from clinical sensitivity and specificity (the percentage of positive patients who test positive and negative patients who test negative, respectively) and a test with good analytical sensitivity and specificity does not necessarily have good clinical sensitivity and specificity. The overall performance of SARS-CoV-2 RT-PCR tests cannot be known until we understand who is truly infected and who isn’t” [15]. The ASM paper concludes by acknowledging that "as yet, there is no consensus on how accurate our testing is”.

For more information on this, refer to the paper “Sensitivity and Specificity Reconsidered: The Meaning of These Terms in Analytical and Diagnostic Settings” [16] for a more detailed explanation on the difference between analytical and clinical sensitivities and specificities.

5. Tests kits cannot detect the amount of virus in a patient

LabGenomics says the following in regard to its “LabGun™ COVID-19 RT-PCR Kit”:

“This kit is used for qualitative detection of SARS-CoV-2 RNA...The results do not reflect the viral load in the original specimens.” [2]

Likewise, 1drop says the following in regard to its “1copy™ COVID-19 qPCR Multi Kit”:

“Results do not reflect the viral load in the clinical specimens.” [7]

SEASUN BIOMATERIALS says the following in regard to its “U-TOP™ COVID-19 Detection Kit”:

“This test is a qualitative test and does not provide the quantitative value of viral load in the original specimens.” [4]

Comment:

These disclosures mean that the tests are not able to detect how much of the virus is in a person's body. However, in order to talk about illness in the real world (as opposed to in a lab), the patient would need to have a certain amount of the virus replicating in his or her body. Certainly there would be a difference between a person with just a few molecules of non-replicating SARS-CoV-2 RNA in his body and a person with millions of molecules of replicating RNA in his body. Yet the test will register them both equally positive.

There have already been many reports of people testing positive again after initially recovering (see Proof 9 for more information on this). In most of these cases, the patients are asymptomatic. As a result, experts such as Oh Myoung-don, head of South Korea’s Central Clinical Committee for Emerging Disease Control, have stated that “RNA fragments still can exist in a cell even if the virus is inactivated” [17]. Likewise, Genematrix clearly said this in its Instructions for Use: “Analyte targets (viral sequences) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious. or are the causative agents for clinical symptoms” [8]. In other words, the virus is no longer infectious and no longer replicating in the person’s body. However, these people still test positive. One of the reasons for this is because the test kits cannot reflect the viral load in the body. Therefore, these fragments are detected by the test, and this essentially creates a false positive.

6. Test kits were validated using “contrived” samples

The FDA in its Molecular Diagnostic Template for Manufacturers says this in regard to determining the Limit of Detection (LOD) - Analytic Sensitivity of test kits:

“...Inactivated virus most closely reflects live virus in a clinical sample. If you are unable to acquire inactivated virus, FDA believes that viral genomic RNA is the next best material to use to [generate] contrived samples for testing” [9]

In this regard, SEASUN BIOMATERIALS says, “Performance of the U-TOP TM COVID-19 Detection Kit was evaluated using contrived clinical nasopharyngeal swab and sputum specimens. A total of 60 contrived positive specimens (30 contrived positive nasopharyngeal swab specimens and 30 contrived positive sputum specimens) and 60 negative specimens were tested (30 negative nasopharyngeal swab and 30 negative sputum specimens)” [4]

Similar statements can be found in the FDA’s Instruction for Use for OSANG Healthcare, LabGenomics, 1drop, SD BIOSENSOR, and GeneMatrix.

Comment:

The use of only 30 to 60 contrived samples instead of clinical trials using hundreds of samples of real patients should be sufficient to raise alarm.

Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, has this to say about the current situation: “This is the Wild West right now. Everybody is focused on how many tests will be out there. No one is really focusing on quality... We need to have the right data, not just more data.” [18]

The FDA itself has seemed to recognize this as problematic. Tim Stenzel, director of the FDA’s Office of In Vitro Diagnostics and Radiological Health, said, “the agency intends to shift away from the use of contrived samples to actual patient samples for demonstrations of clinical performance” [19]. If contrived samples were not problem, there would be no need for the FDA to shift away from them.

7. FDA not especially confident about the effectiveness of the test kits

The FDA in its authorization letters to test kits manufacturers says the following:

“Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product.” [20]

Comment:

The FDA doesn’t sound very confident about the test kits it is authorizing. “Reasonable to believe” is no guarantee. Even less reassuring is the phrase “may be effective.” Putting both of these phrases in the same sentence is definitely no confidence builder.

It is also reasonable to believe that an apple a day may be effective in keeping the doctor away.

It may also be reasonable to believe that flipping a coin may be effective in diagnosing COVID-19. Does this sound crazy? Maybe not when one considers the Chinese study that concluded that the potential false-positive rate among ‘asymptomatic infected individuals’ in close contact with COVID-19 patients was 80% [21] [22]. At least flipping a coin would only produce a false-positive rate of about 50%!

8. Test kits methods are not standardized

The RT-PCR test kits look for only a tiny fraction of the COVID-19 genome. Since testing methods are not standardized, different test kits often look for different tiny fractions of the genome. The tests work by amplifying trace amounts of genetic material to identify specific parts of DNA.

The Korean test kits makers provided the following information on the genes (including rules for detection) and amplification cycle:

Manufacturer	Amplification cycle count (ct.)	Genes for positive detection
LabGenomics	40	(1/2) RdRp+, E+
OSANG Healthcare	40	(1/3) RdRp+, N+, E+
SEASUN BIOMATERIALS	38	(1/2) Orf1ab+, N+
Seegene	40	(1/3) RdRp+, N+, E+
SD BIOSENSOR	36	(1/2) RdRp+, E+
1drop	40	(1/2) RdRp+, E+
GeneMatrix	40	(1/2) RdRp+, N+

Data sources: [2][3][4][5][6][7][8]
*Note 1: The numbers in parentheses refer to the number of genes that need to be found to give a positive result. For all tests, only one of the genes needs to be found to register positive. In the case of the E gene, the test kits might register presumptive positive, prompting the clinician to take further action for confirmation (see Note 2).
*Note 2: Some organizations are deeming the detection of the E gene as positive instead of presumptive positive. For example, the German organization Labor Augsburg MVZ GmbH had this to say: “Taking into account the epidemiological situation and the overall increase in the positive rate, we are now following the WHO recommendation and are already issuing a result as ‘positive’ if only the E gene has been amplified” [23]

Comment:

PCR technology was not created for diagnostic purposes. It is widely known that the inventor of PCR and Nobel Laureate, Kary Mullis, questioned the use of PCR in DNA analysis [24]. PCR is really a manufacturing technique. It starts with a small amount of DNA and on each cycle the amount doubles. After about 30 cycles, it produces about a billion times more material than it started with. This is very useful for research purposes, and the methods of its use can be adapted to the application. Therefore, there are no standardized specifications regarding how to use the technology.

The cycle count (ct.) is a very important part of the test. If the cycle count is too low, the test will generate false negatives. If the cycle count is too high, the test will produce false positives. Stephen Bustin, perhaps the world’s leading expert on quality control of RT-PCR, told researcher David Crowe in an interview that the cycle count should probably be limited to 35 cycles [25]. In addition, the MIQE (Minimum Information for Publication of Quantitative RT-PCR Experiments) guidelines for operation and reporting of RT-PCR states that the use of 40 or more cycles is unwise [26].

Looking at the date for the seven Korean manufacturers, they all go above 35 cycles, thereby exceeding Stephen Bustin’s recommendation. Five of the manufacturers use a cycle count of 40, which exceeds the recommendation of MIQE.

In addition, the tests for the different manufacturers will perform very differently even when using the same sample of genetic material. For example, the tests of LabGenomics and SD BIOSENSOR both search for the same genes, but since their cycle count is different, it should be expected that LabGenomics will register more positives since it has the higher cycle count (on the condition that all other testing variables are equal). This lack of testing standards and high cycle count have repercussions in the real world, and it might be the reason why so many asymptomatic people are registering positive for the test.

The genes being looked for are also significant. Manufacturers whose tests look for different genes are essentially looking for different things. It is as if we went looking for leopards with one person using spots as the guide, another the claws, another the teeth and another the eyes.

Worse than differences in what they are looking for is the way of defining whether they have found it. The tests are basically only looking for one out of 2-3 genes that must be present for the test to be declared positive. This is worth thinking about. A test that looks for three portions of the genome is generally happy if only one is found. That means that we can have a leopard without spots or teeth as long as it has leopard-like claws. Or it could have spots, but different teeth and claws. In the case of a very simple creature like a virus, does it make sense to say that we have found what we are looking for if any part of its genome is missing? And if we only have 1% of an animal, is it possible we will decide it is a leopard when it is actually an ocelot?

9. Test results flip flop between positive and negative

Researchers in China have written a paper entitled "Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19" [27]. In this paper, they found that "RT-PCR results from several tests at different points were variable from the same patients during the course of diagnosis and treatment of these patients." In particular, there were 29 patients out of 600 whose test results kept flip flopping between negative (N), positive (P), and dubious (D): 1 DDPDD 2 NNPN 3 NNNPN 4 DNPN 5 NNDP 6 NDP 7 DNP 8 NDDPN 9 NNNDPN 10 NNPD 11 DNP 12 NNNP 13 PPNDPN 14 PNPPP 15 DPNPNN 16 PNNP 17 NPNPN 18 PNP 19 NPNP 20 PNPN 21 PNP 22 PNP 23 PNP 24 PNDDP 25 PNPNN 26 PNPP 27 PNP 28 PNPN 29 PNP.

A study from Singapore did tests almost daily on 18 patients, and the majority went from positive to negative back to positive at least once, and up to four times in one patient [28].

In China they have found that 5-14% of patients who have been cleared, with two consecutive negative tests, later tested positive again, usually without new symptoms [29].

Likewise in South Korea, they recently reported 277 such patients [17].

Comment:

Some of the reasons for this could be the following:

1) The patients were reinfected. But this seems unlikely in light of the rapid flip flopping experienced by the 29 Chinese patients. Also, most of those who test positive again have had no symptoms;

2) The tests kits are not reliable;

3) Different test kits were being used with different testing protocols, causing the test to yield different results. See Proof 8 above.

4) The same test kits were being used but the testing protocols were too difficult for clinicians to adhere to, and this caused the tests to yield different results. In such a case, the test results are basically useless;

5) SARS-CoV-2 RNA remnants (i.e., RNA that is basically dead or not functional) are still in the body of the person who had previously tested positive for COVID-19 (whether symptomatic or asymptomatic). This would indeed be equivalent to a false positive. Furthermore, in such a case, how would it be possible to distinguish between infected and recovered persons when they are asymptomatic? Or how would it be possible to distinguish between people infected with COVID-19 and people who recovered from COVID-19 but currently have the common cold or flu since the symptoms in most cases are exactly the same? I suspect that there will be no adequate answers to these questions.

10. Test kits are being used on asymptomatic people despite not being validated for such use

In South Korea, Jeong Eun-kyeong, director of South Korea's CDC, said that "Korea currently has a significantly higher rate of asymptomatic cases than other countries, perhaps due to our extensive testing" and that "some 20 percent of them remained asymptomatic until they are discharged." She also said that "It's not clear yet whether asymptomatic patients are contagious. So far, there has been no objective evidence regarding asymptomatic transmission." [30]

Comment:

This is evidence that the test kits are inaccurate. Since 20% of hospitalized people showed no symptoms at all until discharge, shouldn't the possibility of false positives at least be considered? Why isn't the accuracy of the test kits ever questioned? How could such a large percentage of people infected with an alleged deadly disease that has turned society upside down show no symptoms at all from start to finish?

As mentioned in Proof 9 above, could it be that the people had already recovered from COVID-19 without even knowing they had it, and then tested positive due to remnants of the RNA? In such a case, they would indeed be false positives. Again if the tests were accurate, how could such a large number of people remain asymptomatic? This question needs to be answered.

In addition, by saying that there is no objective evidence of asymptomatic transmission, the Korean CDC is basically admitting that the government's actions of forcing people without symptoms in hospitals are not justified. In many cases, the people put in the hospitals are not only isolated from even their loved ones, but are also humiliated by being surrounded by doctors and nurses in PPE equipment, potentially subjected to dangerous medical treatments, and terrified by the thought of being sick with a deadly disease. Those conditions alone are enough to create a psychological state where real sickness can manifest.

All six FDA-approved Korean test kit manufacturers acknowledge that their test kits can generally detect SARS-CoV-2 RNA in respiratory specimens during the acute phase of infection (i.e., people who have symptoms) [2][3][4][5][6][7][8]. Also, referring to these FDA "Instructions for Use", OSANG Healthcare, Seegene, SD BIOSENSOR, and GeneMatrix state clearly that the performance of their test kits was evaluated in specimens of people with symptoms [3][5][6][8]. Furthermore, GeneMatrix in its Instructions for Use states clearly that "The performance of this device has not been evaluated for patients without signs and symptoms of infection" [8]. In other words, they are saying that their test kits can only "generally" detect SARS-CoV-2 RNA in people with symptoms. The tests cannot, or at least have not been validated, for people with alleged asymptomatic symptoms. The test kit makers do not acknowledge the use of their products in detecting viral RNA in asymptomatic people.

The FDA itself admits this in its "Molecular Diagnostic Template for Manufacturers" when they suggest that EUA submissions include the sentence, "Performance is unknown in asymptomatic patients" [9].

To sum up, there is no evidence of asymptomatic transmission and the test kits were not even designed to detect specimens from asymptomatic people. In spite of this, the test kits are being used on people with no symptoms, and in many cases drastic measures are being taken to wreck havoc on people's lives who aren't in any way sick.

Conclusion

In this article, we have presented quotes and references from official sources that prove that the COVID-19 testing methods and test kits are not reliable.

We have seen that neither the government nor the test kit manufacturers will guarantee the performance of the test. In many ways, the test kits seem to be designed to produce as many positive results as possible. The evidence for this is that they (1) provide no information on clinical specificity; (2) are incapable of detecting viral load; (3) exceed reasonable limits on the cycle count; (4) test positive when detecting only one gene despite being negative for one or two others; (5) sometimes give inconsistent results; and (6) often produce positive results for asymptomatic people.

It seems that the fear of missing a true positive is so great that test kit manufactures are designing their tests in a way that basically ignores the risk of false positives. However, false positives make the epidemic appear larger, and justify the complete shutdown of the economy, locking people in their own homes, forcing people to wear facial masks, violating the privacy of people through contact tracing, and potentially forcing a vaccine on people that surely will not be safe or effective [31].

By the time this is over, the destruction caused by the response of the government and medical industry has the potential to greatly exceed whatever damage might have been caused by the virus. This is especially true in light of recent studies that show that COVID-19 might be no more serious than the seasonal flu with a mortality rate between 0.1 and 0.3% [32] [33] [34] [35], and for which the majority of infected persons suffer no symptoms or only mild symptoms at most [36][37].

It is our hope that the evidence provided in this short article will motivate citizens to investigate the current situation for themselves and not rely on sensationalized television news solely for their source of information. This is a situation that has the potential to impact our lives for ever. Therefore, we must be diligent and demand a reasonable debate on this issue.

Acknowledgement

Some of the content of this article was taken from the works of biologist and researcher David Crowe [38] and investigative reporter Jon Rappoport [39].

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