THE RELIABILITY AND DIAGNOSTIC VALUE OF “COVID-19” RT-PCR TESTS

Print and keep a copy of this document with you in the event you are made a 2019-CoV statistic through the RT-PCR test, or in case someone in your family is tested and you are barred from seeing them for weeks, or if they are elderly, from ever seeing them again. Use it to educate others, including professionals who may not be aware.

These citations and frank admissions are taken directly from official documents of the FDA, WHO, test manufacturers and university institutions. A person may be severely ill in association with an influenza or non-influenza related virus but can and will be wrongly diagnosed as a “CoVID-19 case”. They and their families may then be subject to unwarranted detentions and quarantines, leading to anguish and anxiety which in turn can lead to disease states.

1. FDA DOCUMENT on the RT-PCR Test

https://www.fda.gov/media/134922/download

CDC 2019-Novel Coronavirus (2019-nCoV)
Real-Time RT-PCR Diagnostic Panel
For Emergency Use Only
Instructions for Use
For In-vitro Diagnostic (IVD) Use
Rx Only

> "Results are for the identification of 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in upper and lower respiratory specimens during infection. **Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease**. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities."

Meaning: This test is not evidence that the agent detected (the 2019-CoV) is the actual cause of disease. There could be other bacterial or virus infections that are causing the symptoms.

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

Meaning: If the test detects any viral RNA, it is no evidence that there is any 2019-CoV virus in the patients body, even though the test will indicate that there is. Given this, the test cannot therefore

show that 2019-CoV is the causative agent for the disease symptoms of the person tested.

> "Optimum specimen types and timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (types and time points) from the same patient may be necessary to detect the virus."

Meaning: We do not know what are the best specimens to take from a person for the test and nor the best time to take samples in order to minimize errors (false negatives, false positives). Given this, multiple specimens at multiple times would have to be taken to eventually detect any 2019-CoV virus.

Note, even if this is done for each suspected case, the other issues pointed out about the limitations of this test would still apply, namely a positive test is no evidence that the virus is causing anything. A man may be wearing Adidas running shoes while he got knocked over by a car. To say he was injured or died "with Adidas running shoes (ARS)" in explanation of the cause of injury or death would be the statement of a lunatic.

> "Positive and negative **predictive values**[1] are highly dependent on prevalence. False negative test results are more likely when prevalence of disease is high. False positive test results are more likely when prevalence is moderate to low."

[1] You may not understand why the word "**predictive**" is being used here, whereas the authors know full well what they say and mean. Without having a thorough, technical understanding of the RT-PCR test itself, what principles it is based upon and how it works, a person might be surprised at this word choice.

Meaning: That the positive and negative results are **predictive values**. Because coronaviruses are well distributed in populations and most people are asymptomatic [that's because the virus itself is not really the cause of disease][2], then when there is no disease outbreak in a place, this test will give false positives and make it potentially look like there is an outbreak when there is not. And where there is an outbreak, then this test will give false negatives and not provide an evaluation of the true number of people who have the virus. The effect this will have in this scenario is to inflate the death rate. This is because it will give false negative results for people who have the virus and are disease free. If they had tested positive as disease free people, this would then decrease the case fatality rate.

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

Meaning: Your disease symptoms (cold, flu, pneumonia) could be due to other than 2019-CoV and this test is not able to tell you that at all and rule out any other causes.

[2] This is another discussion that is for another place.

2. Another FDA DOCUMENT on the RT-PCR Test

https://www.fda.gov/media/136151/download

LabCorp COVID-19RT-PCR test
EUA Summary
ACCELERATED EMERGENCY USE AUTHORIZATION
(EUA) SUMMARY COVID-19 RT-PCR TEST
(LABORATORY CORPORATION OF AMERICA)

> "The SARS-CoV-2RNA [i.e. the virus] is **generally detectable** in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status…**the agent detected may not be the definite cause of disease**. **Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities**."

Meaning: The test is "generally" able to detect the 2019-CoV, but detection does not mean at all that it is the cause of the disease. Nevertheless, we still require laboratories **to report all positive results** to the public health authorities. This means that healthy people who carry many viruses (because most people have colds and flus through their lives) and are currently disease free can be counted as "cases". This gives the impression that the virus is spreading, when in reality, it is only the testing that is creating that impression. The reader should be able to see clearly how an epidemic can be an artefact (creation) of a roll out of testing across a nation. Further, making tests a priority only for those who are very sick can lead to inflated case fatality rates.

3. A Manufacturer of the RT-PRC Test

https://www.creative-diagnostics.com/sars-cov-2-coronavirus-multiplex-rt-qpcr-kit-277854-457.htm

SARS-CoV-2 Coronavirus Multiplex RT-qPCR Kit (CD019RT)

> "Regulatory status: For research use only, not for use in diagnostic procedures."

Meaning: This test on its own should not be used to make diagnosis of a disease or active "infection".

> "**Application** Qualitative"

Meaning: This test can only tell you if the virus was present, it cannot tell you how much of it was present.

This is important to grasp because people already have bacteria and viruses that are usually associated with disease states but they remain perfectly healthy and disease free. This means that detection of a virus is not proof that a person is sick, or is "infected" so to speak, or that that particular virus is even associated with the clinical symptoms, if any are manifested.

> **Specificity** 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.

Meaning: **This is astounding**. The test can detect 2019-CoV **BUT** **it can also give a positive result if any of these other viruses are present!** So this would not be any evidence that 2019-CoV is associated with the symptoms at all.[3]

> "The detection result of this product is only for clinical reference, and it should not be used as the only evidence for clinical diagnosis and treatment. **The clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses**. The detection results **should not be** directly used as the evidence for clinical diagnosis, and are only for the reference of clinicians."

Meaning: This test should not be used **as evidence** in clinical diagnosis and treatment.

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[3] This shows that a person could really have the flu or **flu like illness**, but if he or she is tested only for 2019-CoV, he or she will be declared a "coronavirus case" and added to the statistics. If they become severely ill or die from that flu, they will be treated as a "coronavirus victim". If you read news reports very carefully, caution is taken in their language when they say, "So and so person died **with** coronavirus", whereas others will not show this caution and technical accuracy and say that the person died "of the coronavirus". Either way, a grossly misleading picture is presented to people who do not know any better. They are then driven to fear by these inaccurate and misleading words, and this fear itself can sometimes generates the disease that one is fearful of.

4. World Health Organisation

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

Home / Emergencies / Diseases / Coronavirus disease 2019 / Technical guidance / National laboratories

Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans

3. Molecular assays to diagnose 2019-nCoV

Several assays that detect the 2019-nCoV have been and are currently under development, both *in-house* and commercially. Some assays may detect only the novel virus and some may also detect other strains (e.g. SARS-CoV) that are genetically similar.

Protocol use limitations: *Optional clinical specimens for testing has not yet been validated.*

Meaning: There is “cross-reactivity” between strains of the coronavirus (because they are genetically similar). This means there will be false positives for 2019-CoV.

Prior studies have shown that people can fall ill and die in association with other well known viruses, such as Coronavirus OC43 and Adenoviruses with the same disease outcomes (death

through complications with pneumonia in the background of other illnesses). However, in testing, the O4C3 strain can be identified as the SARS Coronavirus. In the study below, patients were tested for SARS-Coronavirus and showed positive, but they were false. This shows that you can test for what you are already looking for, and it can show positive, but you can be totally wrong because the test gives false positives due to “cross-reactivity”.

Here is the abstract of the paper for some basic details:

> **An Outbreak of Human Coronavirus OC43 Infection and Serological Cross-reactivity with SARS Coronavirus**
> Can J Infect Dis Med Microbiol. 2006 Nov-Dec; 17(6): 330–336.
> https://www.ncbi.nlm.nih.gov/pubmed/18382647
>
> **BACKGROUND:**
> In summer 2003, a respiratory outbreak was investigated in British Columbia, during which nucleic acid tests and serology unexpectedly indicated reactivity for severe acute respiratory syndrome coronavirus (SARS-CoV).
>
> **METHODS:**
> Cases at a care facility were epidemiologically characterized and sequentially investigated for conventional agents of respiratory infection, SARS-CoV and other human CoVs. Serological cross-reactivity between SARS-CoV and human CoV-OC43 (HCoV-OC43) was investigated by peptide spot assay.
>
> **RESULTS:**
> Ninety-five of 142 residents (67%) and 53 of 160 staff members

(33%) experienced symptoms of respiratory infection. Symptomatic residents experienced cough (66%), fever (21%) and pneumonia (12%). Eight residents died, six with pneumonia. No staff members developed pneumonia. Findings on reverse transcriptase-polymerase chain reaction assays for SARS-CoV at a national reference laboratory were suspected to represent false positives, but this was confounded by concurrent identification of antibody to N protein on serology. Subsequent testing by reverse transcriptase-polymerase chain reaction confirmed HCoV-OC43 infection. Convalescent serology ruled out SARS. Notably, sera demonstrated cross-reactivity against nucleocapsid peptide sequences common to HCoV-OC43 and SARS-CoV.

CONCLUSIONS:
These findings underscore the virulence of human CoV-OC43 in elderly populations and confirm that cross-reactivity to antibody against nucleocapsid proteins from these viruses must be considered when interpreting serological tests for SARS-CoV.

5. [Potential False-Positive Rate Among the 'Asymptomatic Infected Individuals' in Close Contacts of COVID-19 Patients]

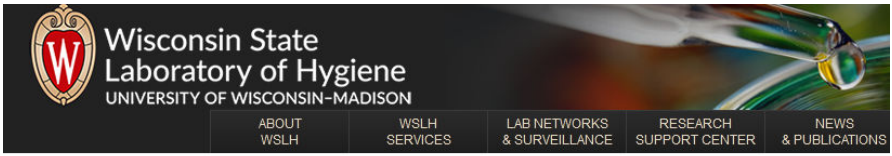
https://pubmed.ncbi.nlm.nih.gov/32133832[4]

Objective: As the prevention and control of COVID-19continues to advance, the active nucleic acid test screening in the close contacts of the patients has been carrying out in many parts of China. However, the false-positive rate of positive results in the screening has not been reported up to now. But to clearify the false-positive rate during screening is important in COVID-19 control and prevention. **Methods:** Point values and reasonable ranges of the indicators which impact the false-positive rate of positive results were estimated based on the information available to us at present. The false-positive rate of positive results in the active screening was deduced, and univariate and multivariate-probabilistic sensitivity analyses were performed to understand the robustness of the findings. **Results:** When the infection rate of the close contacts and the sensitivity and specificity of reported results were taken as the point estimates, **the positive predictive value of the active screening was only 19.67%, in contrast, the false-positive rate of positive results was 80.33%**. The multivariate-probabilistic sensitivity analysis results supported the base-case findings, **with a 75% probability for the false-positive rate of positive results over 47%**. **Conclusions:** In the close contacts of COVID-19 patients, **nearly half or even more of the 'asymptomatic infected individuals' reported in the active nucleic acid test screening might be false positives**.

[4] Note that this paper was withdrawn, despite the fact that their findings are in agreement with statements made by the FDA, WHO and test manufacturers about the test.

6. Wisconsin State University on the 2019-nCoV RT-PRC Test

http://www.slh.wisc.edu/wslhApps/RefMan/wslhSearch.php?searchTerm=covid&TEST_REFERENCE_ID=8105&submitIt=testDetail



COVID-19 virus (novel coronavirus 2019/SARS-CoV-2) RT-PCR

> **Limitations**: Negative results do not preclude 2019-nCoV infection. A false negative result may occur if a specimen is improperly collected, transported or handled. Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms.

Meaning: If a person tests negative, this does not mean that they do not have the 2019-nCoV in them. However, at the same time detection of the initial RNA in the first step of the test (RT) is no proof either of the presence of an “infectious virus”. Further, a positive test for 2019-nCoV after the second step (PCR) is no proof at all that 2019-nCoV is actually causing the clinical symptoms.

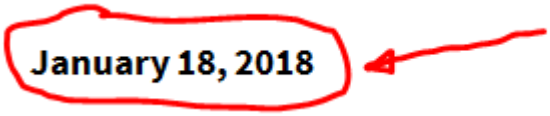
After all the above, I will leave you with a TIME news article from 2018 about the flu epidemic that broke out in the US and led to an overwhelming of the hospitals. Highlights are added.

Abu Iyaaḍ
8 Shaʿbān 1441 / 1 April 2020 v. 1.03

TIME

Hospitals Overwhelmed by Flu Patients Are Treating Them in Tents

https://time.com/5107984/hospitals-handling-burden-flu-patients/



The **2017-2018 influenza epidemic** is sending people to hospitals and urgent-care centers **in every state,** and medical centers are responding with extraordinary measures: **asking staff to work overtime, setting up triage tents, restricting friends and family visits and canceling elective surgeries**, to name a few.

“We are pretty much at capacity, and the volume is certainly different from previous flu seasons,” says Dr. Alfred Tallia, professor and chair of family medicine at

the Robert Wood Johnson Medical Center in New Brunswick, New Jersey. “I’ve been in practice for 30 years, and it’s been a good 15 or 20 years since I’ve seen a flu-related illness scenario like we’ve had this year.”

Tallia says his hospital is “managing, but just barely,” at keeping up with the increased number of sick patients in the last three weeks. **The hospital’s urgent-care centers have also been inundated, and its outpatient clinics have no appointments available**.

MORE: Here’s Why the Flu Is Especially Bad This Year

The story is similar in Alabama, **which declared a state of emergency last week** in response to the flu epidemic. Dr. Bernard Camins, associate professor of infectious diseases at the University of Alabama at Birmingham, says that UAB Hospital cancelled elective surgeries scheduled for Thursday and Friday of last week to make more beds available to flu patients.

“We had to treat patients in places where we normally wouldn’t, like in recovery rooms,” says Camins. “The emergency room was very crowded, both with sick patients who needed to be admitted and patients who just needed to be seen and given Tamiflu.”

In California, which has been particularly hard hit by this season’s flu, **several hospitals have set up large “surge**

tents" outside their emergency departments to accommodate and treat flu patients. Even then, the *LA Times* reported this week, emergency departments had standing-room only, and some patients had to be treated in hallways.

The Lehigh Valley Health System in Allentown, Pennsylvania, **set up a similar surge tent in its parking lot** on Monday, in response to an increase in patients presenting with various viral illnesses, **including norovirus, respiratory syncytial virus (RSV)**[5] and the flu. "We've put it into operation a couples times now over the last few days," said a hospital spokesperson. "I think Tuesday we saw upwards of about 40 people in the tent itself."

Many hospitals are also encouraging visitors to stay away. Kaiser Permanente Los Angeles Medical Center announced last week that it was temporarily restricting visits from children 14 and under and anyone with flu symptoms. "This measure is to prevent unnecessary spread of influenza and to protect you, our patients, and our staff," the health system posted on Facebook.

Loyola University Health System in Chicago—which set a hospital flu-activity record of 190 confirmed cases

[5] Comment: These are families of viruses, besides the known Influenza viruses. The illnesses associated with them are referred to as "influenza like illnesses". Coronavirus is one such family.

between January 7 and 13—has also instituted similar visitor restrictions, although a spokesperson for the hospital says it's a standard precaution for flu season. Loyola also requires all employees to receive a mandatory flu shot, a policy it started in 2009.

MORE: ‘It’s Actually a Nightmare.’ Mother Warns Others After 10-Year-Old Suddenly Dies From Flu

In Fenton, Missouri, SSM Health St. Clare Hospital has opened its emergency overflow wing, as well as all outpatient centers and surgical holding centers, to make more beds available to patients who need them. Nurses are being “pulled from all floors to care for them,” says registered nurse Jennifer Braciszewski, and are being offered an increased hourly rate to work above and beyond their normal schedules. Many nurses have also become sick, however, so the staff is also short-handed.

The flu has especially affected hospital patients with other health issues, says Braciszewski, who works with cardiac patients. “Almost every patient in the hospital has the flu, and it’s making their pre-existing conditions worse,” she says. “**More and more patients are needing mechanical ventilation due to respiratory failure from the flu and other rampant upper respiratory infections**.”

Braciszewski says she's picked up a few extra shifts so far this month, and that while the work is difficult and overwhelming, it's also rewarding. "They haven't gone into mandatory overtime on my floor yet, but nurses are helping out by staying an extra four hours here and there or coming in early," she says. "The thing about nursing is it's a sister/brotherhood; we can't leave each other in distress."

CDC director Brenda Fitzgerald said last week that the flu appeared to be peaking, but that "it will take many more weeks for flu activity to truly slow down." Camins says flu activity at UAB Hospital was slightly lower this week than last week, but that it's too early to know if the worst has come and gone.

"It's slowing down, thank God, but there have been some seasons that have actually had two peaks—so we really don't know what the next few months will be like," he says. "We've already had three times the volume of the peak from last year in Jefferson County, and I think we're going to end up quadrupling it by the time we finally get all the data in."

Doctors say it's not too late to get a flu shot this season—even if you've already been sick—and many hospitals are asking patients about the flu vaccine and offering it to those who haven't yet received it. They're also encouraging otherwise healthy people who think they

have the flu to call their primary care doctors rather than visit the emergency room, especially while hospital volume is so high.

If you're otherwise healthy, "you can ask your doctor to prescribe an anti-viral medicine over the phone," says Camins. That way, he adds, emergency departments can be freed up to care for patients who are the most vulnerable to serious complications from the flu—like children, the elderly and people with pre-existing conditions.

End of news report.

Note: The amount of cases and fatalities from the annual flu season across nations can vary drastically. Every now and then the cases are multiple times more than in other years and this causes a strain on the nation's resources. For example in 2015/2016 winter season there were just under 12,000 flu-related deaths in the UK. But two years later in 2017/2018 it was just under 26,500 deaths. In the US, in 2011/2012 there were an estimated 12,000 deaths from flu. But in 2017/2018 there were an estimated 61,000 deaths. So this is the first point.

Secondly, what the above news item reveals—along with everything else regarding testing—is that in all previous years, deaths which are currently being tied to 2019-CoV would have simply come under the heading of "**influenza like illnesses**" which are caused by viruses other than the well-known influenza viruses. These include adenoviruses, coronaviruses, respiratory

syncytial viruses among many others. These viruses have been shown to be associated with fatality in the elderly, chronically sick and those with impaired immune function, and this is nothing unusual and out of the ordinary.

You could easily manufacture a “rhinovirus” epidemic one year just by developing a rhinovirus test and testing the population, the sick admitted to hospital and those who go on to die. This could then give the illusion that something has happened this year that has not happened in past years, just by isolating one statistic, which previously would have been subsumed by the broader statistic of influenza like illnesses.