



Any current data on mask efficacy—cloth masks versus surgical masks?

Please refer to this CDC article regarding masks: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html#:~:text=In%20light%20of%20this%20new,community%2Dbased%20transmission.>

Any opinion regarding how specific the serology platforms are for SARS-CoV-2? Can they represent non-SARS-CoV-2 immunity?

The FDA has approved more than 117 tests of various types including serology tests (<https://bit.ly/36ReEBR>). Check the FDA website for the most recent updates. Note that both FDA and CDC are involved with all of these companies to generate data on the performance of their tests and refine their list using this data. Specifically for serology, detailed testing to understand the titers, protective effect, and dynamics are underway by companies, the CDC, and academic centers.

Apologies for what may be a ignorant question, but why are clinicians asking for CT values for PCR? What clinical value would that serve?

CT values are the in-between step to calculating a viral load. Very clever clinicians understand the mathematical relationship between CT and viral load. Since we are not allowed to report viral load, CT values may give clinicians information about viral volume and changes in volume in a patient. But this is not yet discussed in guidelines. Proper viral load testing would be more valuable.

Are all positive tests from all labs being followed up by public health tracers who recommend quarantine to the positive cases and their contacts? If not, why not, and what can be done to solve this issue? Because of the massive unemployment caused by late response and anti-response (dissing of masks by Trump), wouldn't it be wise to hire and train many of the unemployed to trace and counsel quarantine? Wouldn't it be a good idea to supply health care to the unemployed and also to hire some of them in public health and train them? And to supply monetary compensation to businesses who have lost staff temporarily and to contacts who have to quarantine to cover the costs of lost income?

Excellent questions which are at the center of the current crisis. The CDC and FDA have SPECIFICALLY not recommended using serology testing for “return to work” practices because of the lack of knowledge about antibody protection, re-infection, and carrier rates. We still need tools to determine if/when it is safe for our workers to return to work or for people to interact with the public safely. Contact tracing, testing, and isolation/quarantine are the current three-pronged approach that Robert Redfield, Director of the CDC is recommending. With that as a guideline from the CDC, states and local organizations will need to build out contact tracing programs, and the unemployed are an excellent source of tracers.

Are there any guidelines for employee testing performed or facilitated by employers? Best methodologies, legal implications?

The CDC has reported the following for employers regarding COVID: <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>.

Are there any recommendations for testing university students as they return to campus?

The CDC and FDA have SPECIFICALLY not recommended using serology testing for “return to work” practices because of the lack of knowledge about antibody protection, re-infection, and carrier rates. Therefore, the only valid uses currently are for diagnostics of patients (RT-PCR) or college-based epidemiological studies (serology).



Did one of the speakers also infer that the amount of virus detected in an individual is much higher than for other respiratory illnesses? I assume that would be one of the reasons this virus is so infectious.

Yes, Dr. Greninger reported that CT values for RT-PCR suggest that there could be trillions of virus on a single swab, much more than is seen in typical respiratory viral swab samples.

Do any of you have experience with a saliva test for COVID?

The FDA has recently approved several EUAs for saliva-based tests (<https://bit.ly/2Xv9Gl1>), and the information within that EUA plus the manufacturer's instructions should be followed. Feedback directly to the FDA on these issues is requested via this email address: COVID19DX@FDA.HHS.GOV.

Do you foresee a higher reporting rate of other respiratory pathogens due to this pandemic as a result of increased testing as a means of ruling them out prior to COVID-19 testing, and what are the implications of this?

Great question! It is a delicate balance between additional testing and the impact of social distancing/masks/etc. Data on influenza will be helpful in understanding this.

Do you have any comments on the difference in the mortality rates between Asian countries (Korea, China, Japan, India, Thailand) and European countries, as well as the U.S.?

In these Asian countries, extraordinary, top-down, consistent, and diffuse measures were taken to identify patients (testing) and isolate, and monitor positive individuals, as well as provide massive protection for healthcare workers. These responses were immediate and early. Delayed response time is the most likely root cause.

Everyone is looking for the right mix of solution between contact tracing and expanding testing in order to safely reopen the economy. What are the challenges that we face in order to expand testing to meet the demands? From a lab perspective, would it be possible to mass test on South Korea's scale?

Based on the most recent supply chain updates from the CDC, as of May (and projected for June), the testing goals that states currently have are being met through a combination of CDC-supported supply chains and privately-supported supply chains. Distribution of these tests at the state level remains challenging and labs are reporting lack of access to testing. The CDC and the FDA ask that individual laboratories that are in need of testing supplies can reach out to them directly at these addresses: deviceshortages@fda.hhs.gov and COVID19DX@FDA.HHS.GOV.

For viral shedding beyond 2-3 weeks, how strong is the evidence that these aren't viable virus?

Both Dr. Greninger and Dr. Baden indicated that WE DO NOT KNOW if these patients are infectious, and specific studies are needed to determine if this is the case.

Have you considered the impact of specimen quality between consumer self-sampling vs. trained technologist or nurse testing? Blood tests are less sensitive to this, but nasal swabs must be done correctly to get a quality sample.

The FDA has approved more than 117 tests of various types including at home sample collection (<https://bit.ly/3eNpVG5>). Check the FDA website for most recent updates. Note that both the FDA and the CDC are involved with all of these companies to generate data on the performance of their tests and refine their list using this data. For example, 15 tests have been removed from the list after data was received.

How can a lab get positive and negative patient samples to use for validation of assays?

The FDA has approved more than 117 tests of various types including serology tests (<https://bit.ly/36ReEBR>). Check the FDA website for most recent updates. Specific questions as well as help with validation can be found by contacting the CDC or the FDA. Another approach is sharing samples with nearby laboratories who have already validated.



How is the federal government or state government helping you? For the logistics of the preanalytics?

The CDC and FDA reported on their weekly call on June 1 that they are providing sampling supplies nationally to states who are then distributing them. If your lab is having a shortage of pre-analytic materials for sampling, please contact your state public health lab first and then follow up with the CDC/FDA at deviceshortages@fda.hhs.gov or COVID19DX@FDA.HHS.GOV. Please note that in the June 1 call, the CDC/FDA reported that they will be ramping up pre-analytic supplies to match testing kits for June.

I am a recent public health graduate, and I am wanting to know more about the public health aspect. In my state (Utah), we had 80 cases yesterday, with a jump to over 200 today. Do you have ideas as to why they would be jumping so high? My community is struggling to follow the guidelines. Do you have suggestions on how to promote continual COVID prevention methods?

Unless your state (or any population) has fully deployed testing (i.e., testing of a random sampling of the population to understand the true incidence and prevalence), random changes from one day to the next are VERY difficult to understand. For example, New York reported an additional 6,000 deaths in one day because those deaths (which had occurred over the last two months) were all categorized and released on one day. Turnaround time, etc. plays into daily totals.

I am curious if any of the speakers' facilities are testing saliva specimens. If so, are you adding anything to the specimen to make the viscosity more manageable?

The FDA has recently approved several EUAs for saliva-based tests (<https://bit.ly/2Xv9Gl1>), and the information within that EUA plus the manufacturer's instructions should be followed. Feedback directly to the FDA on these issues is requested via this email address: COVID19DX@FDA.HHS.GOV.

I don't understand the "pooling" thing ... for what ?

Suppose you have 1000 people who want to be tested from a single lab, but the prevalence of disease is only 0.1% (1 positive patient). You can pool the 1000 samples into 100 samples of 10 patients each, test, and then when you get a positive, retest those 10 individually. Now, you have only performed 20 tests and found the one patient, rather than 1000 tests....Thanks.

I have been sick/symptomatic for approximately 11 weeks now (fever went away about 3 weeks ago). I was tested about 5 weeks ago and was negative, but ID physician and pulmonologist believe it should have been positive. I'm fearful of being around my family members because of the unknown factor of transmissibility.

It is best to discuss with your doctor, but it is certainly possible for your testing to be negative now. With a negative PCR, it is unlikely that you are infectious, but there are no solid data to support that conclusion currently other than our knowledge of other viruses. Good hand washing is best to reduce your family's risk.

I would just like to clarify. Did you say that 50% of transmission is estimated to be from asymptomatic individuals?

It is estimated that 50% of transmission is due to asymptomatic individuals.

I've heard of increasing high school/college students with clinical disease?

Important studies are being conducted to understand this, such as this one: <https://www.nih.gov/news-events/news-releases/study-determine-incidence-novel-coronavirus-infection-us-children-begins>. More data is needed to determine this.

If this virus becomes a seasonal virus, which can provide a better protective and long lasting immunity, our own adaptive immunity against the virus (getting exposed and recovered) or a vaccine?

In modern medicine, the concept of "herd immunity" is based on vaccination. Natural acquisition of herd immunity by "culling" (allowing those that are susceptible to die) is not an ethically allowable practice and can take dozens of years and millions of deaths. It is not clear if this will be come seasonal, as its predecessor (SARS) has never reappeared after it ended. If a vaccine becomes available, the virus may be essentially eradicated by a combination of vaccine coverage and infection penetration.



In everyone's opinion at this session, until there is a development of a COVID vaccine, this pandemic will continue or increase even with testing and other precautions?

A vaccine will be helpful long-term for the dampening of recrudescence; however, it has been demonstrated that with appropriate control measures, countries can stop the disease in their local context. Delays in response to the virus in the U.S. are likely the cause of the current situation. How to change that situation will be a combination of tools (a vaccine may be one) that are overseen and controlled at a national level.

Is there a good resource that explains how a serology test can have nearly 100% sensitivity and specificity but still have false positives in low prevalence areas?

There are many websites that explain this if you search using terms, "sensitivity," "specificity," and "positive predictive value." However, in brief, here is an explanation. When analytical sensitivity and specificity is generated in the laboratory, typically 40 known positives and 40 known negatives are used to calculate (prevalence is 50%). However, as the prevalence drops (to say 5%) we begin to encounter problems. Please see this informative illustrative example: <https://bit.ly/2Xp9IX2>.

It is said that there's a significant number of infections that never progress to a symptomatic stage, based on results of serologic testing. How do we know that these are not false positive cases due to cross reactivity to antibodies against other coronaviruses such as those causing common colds? Have there been any validation studies done to make sure that such cross reactivity is not a significant factor in these serologic tests?

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My mom was really sick but never got tested the last week of March. She got tested a week ago, and she is positive, but now she has no symptoms and is well. Is this possible?

Yes, Dr. Greninger and Dr. Baden both noted that patients can be positive by PCR testing for 3 to 5 weeks after they are no longer sick. It is not clear if these patients are still infectious to others, and more data and studies are needed.

My organization serves youth in congregate settings. If their PCR testing is positive but they are asymptomatic, is it concerning to house them with other asymptomatic (positive-testing) youth and staff? If this is outside the purview of this group, please direct me accordingly.

Please consider this reference: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30236-X/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30236-X/fulltext). Children are transmitting, so considerations in this population need to be developed and understood.

Please explain why one lab would have multiple platforms, and how you decide what sample goes on what platform.

Thank you for your question! Our Town Hall earlier this month addressed this in detail. Because of the volume of testing coming into laboratories and the limited access to sample test kits for a given platform, many laboratories had to open up and bring online multiple platforms to cover JUST their volume. Panelists reported that they use different approaches to choosing which samples are tested how. Please see the recorded town hall for a detailed discussion!

Question for the speakers or anyone else. With social distancing, wouldn't the incidence of flu and colds go down this fall/winter?

Great question! Epidemiology for flu (which is constantly monitored) will reveal whether this effect has occurred!

We are advised to use surgical masks rather than N95 masks. What do you recommend for public users?

Individuals who are actively coughing with any infection should wear a mask to reduce their respiratory droplet production. Non-symptomatic individuals should comply with their local laws and recommendations.



What kind of testing should we have in a student health center in a large residential college?

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What special means are applied to managing potentially infectious specimens?

The CDC has provided guidelines which can be found here: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>. There are some specific suggestions from manufacturers about handling specific preparations under hoods which should be referred to the lab director to determine.

When validating how did you go about comparing against alternate methods? How did you come about specimens? As for prevalence and to prevent false positives in your region, how many manufacturers are you using for antibody testing?

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