



What is the preferred antibody test for screening; a combo IgG/IgM, or separate IgG and IgM and why?

Please refer to this website for the most up to date information regarding this question: <https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html>

What are methods and platforms available for antibody testing for COVID19 and any study yet suggesting most reliable method?

Please refer to this website for the most up to date information regarding this question: <https://www.cms.gov/files/document/admin-info-20-06-clia.pdf>

Is it possible for ASCP to put a stronger message about serology testing?

ASCP member experts are working closely with multiple agencies to address the challenges of serology now and in the future, including publications and continued discussions and dissemination of information through the Town Halls.

What would you say is the primary goal for antibody testing?

To determine the effective infected/carrier rate of the population (the denominator) by which we can then understand illness (hospitalizations) and deaths. To determine past exposure to identify donors for convalescent plasma. Potentially, to determine status for return to work (requires understanding protective nature of antibodies).

What are the guidelines for antibody detection for convalescent plasma? Is the clinical outcome more accurate when detects Total Immunoglobulins or IgG?

Please refer to this website for the most up to date information regarding this question: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

How much will Covid 19 antibody testing be available to all?

Unclear and depends on evolution of testing recommendations and guidelines as well as availability and cost. Each health system will decide how testing is integrated into their plans for triage and care.

How do we decide which epitope on the COVID 19 virus is important in deciding which antibody will actually protect individuals from getting a second infection with this virus.

Scientific investigation in the laboratory in experimental models and measurements in convalescent plasma (to be done).

What is the value of offering COVID-19 antibody testing in a hospital or Urgent setting?

Antibody testing for COVID 19 is to determine the effective infected/carrier rate of the population (the denominator) by which we can then understand illness (hospitalizations) and deaths. In a hospital or urgent care, it may be used for staff to determine prior exposure or past infection for return to work or safety measures, but that is not yet confirmed as the protective level of antibodies in current tests is not confirmed. There is likely no role for patients in the immediate care pathways as it would not change therapy (which depends on patients symptoms).

Questions for antibody testing: 1) How soon can the antibody be developed after one is Covid 19 infected? 2) How long can the antibody be presented in the body after infection? 3) Will there be a need to check the titer of the antibody? To identify the titer of antibody is a much more labor intensive test. 4) I heard the current antibody tests that are manufactured are from other countries and the accuracy is only 50-60%. Is this true? 5) Can someone have antibody but is still in the infection phase?

1. IgM is within 5 to 14 days and IgG is from 10 days to unknown. Because this is a new coronavirus, we can only assume IgG and IgM behave as in other similar infections. Final data will require scientific study. 2. Antibodies are typically permanent (IgG) after an infection but may change levels over time or with re-exposure. 3. Titers for antibody are not yet determined or clear how they are useful in COVID19. 4. The quality, accuracy, and reliability of any antibody test is dependent on the antibody affinity, avidity, and target. Typically, high quality antibody tests (which use high quality targets in the assay) take many months to years to develop in order to get a proper antigen as a target. Crude assays can be developed from lysates but, historically, do not perform as well as well-developed tests. Compare, for example, with 1st through 4th generation HIV antibody testing. 5. Yes, IgM is likely only present during active infection and then wanes while IgG can develop within a symptomatic phase.



This concerns the serology tests listed as submitted to the FDA under section IV.D. that do not, as yet have EUA status. Is there a mechanism to submit data to the FDA for a test that does not perform well in a specific lab, and is there any way that a test on that list but not yet granted EUA can be removed from the IV.D list so that it cannot be marketed and used?

Please refer to this website for the most up to date information regarding this question: <https://www.fda.gov/consumers/consumer-updates/how-report-product-problems-and-complaints-fda>

Is it possible to develop a testing protocol for COVID-19 similar to the group of tests for hepatitis B: HBsAg, HBeAg, HBcAb, HBeAb and HBsAb to determine level of infectivity and convalescence. Thank you!

Yes, that may be possible in the future when the entire protein repertoire of the virus is known along with which protein epitopes humans for natural responses to, which ones convey protection, and when they antibodies appear during infection. For now, much more research is needed.

What does a qualitative IgG positive test imply if we cannot determine titers at this point?

It would mean that the patient has made a response antibody to an antigen in the test sample which may be specific (to COVID19, true positive) or non-specific (false positive). Likewise, a negative result could mean the patient has not made a response to the antigen in the test sample but that does not mean they have not been exposed (false negative). True negative results will require much higher quality tests with higher affinity and avidity.

Has there been any discussion with the FDA regarding traceability of the serology assays? Standards for judging relative performance of the various assays?

Please refer to these websites for the most up to date information regarding this question:

- <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers>
- <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests>
- <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>

There is a kit available in Germany that can determine IgG titers. Any idea which kit that is and when it would be available in the US?

We are not aware of this kit, and only kits with FDA clearance should be used.

On the topic of antibody serology testing validation: What do you consider a good test 95% sensitivity and specificity? Where would suggest getting negative controls, including those potential cross reactive antibodies?

Sensitivity and Specificity of an assay have two forms: Analytical S&S and Clinical S&S. Analytical S&S is determined using high quality positive and negative controls and positive and negative cases which have been confirmed by another method. Once determined, it is inherent to the assay whenever performed. Clinical S&S is massively affected by the prevalence of disease and, therefore, Positive and Negative Predictive Value are better measures of the clinical performance of a test.

How is ASCP approaching the lack of specificity and sensitivity of the serology tests currently with or without EUAs?

ASCP does not regulate the use of tests in the United States, nor do we endorse specific commercial products or test types or platforms. We can only endorse best practice guidelines for testing which include validation and using tests which have a clinically useful sensitivity, specificity, Positive predictive value, and negative predictive value.

What is the significance of cross reactivity of other coronaviruses with antibody testing in interpreting results?

The antigens used to create a human antibody test (has a patient made an antibody response?) have various sources which could be lysates (crude mixture of all proteins) to purified antigens (from culture and purification). As the virus is relatively new, the current assays are likely using crude lysates or non-optimized purified antigens. If either of these contains protein signatures that are also found in other Coronavirus, cross-reactivity may occur (the patient has an antibody to an epitope that is shared by SARS-CoV-2 and other coronaviruses); however, the patient may still be positive for SARS-CoV-2. The best antibody test will be with a purified protein that is unique to SARS-CoV-2

Is it beneficial to have combined serology and urine testing done (similar to Zika Virus testing)?

We do not know of any data on the testing of urine for COVID19.



Wouldn't there be value in screening blood donors by an ELISA based test serving 2 purposes, population studies and identify donors for convalescent plasma or potential COVID IVIG?

Yes, screening donors may have value for epidemiological purposes. However, criteria for donation and basic health are crucial as with all blood donation. Until we know exactly which antibodies confer protective status, mass screening of plasma may be prohibitively expensive. Currently, recently ill COVID19 patients who have recovered may donate plasma after a certain period of time which may benefit ill COVID-19 patients.

How can we get the message out to providers who are desperate to help in the public health effort that the serology tests aren't as good and useful as the manufacturers are claiming? And that they AREN'T WAIVED!!!

Spreading the most recent FDA information: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests>

Which antibody test is the most accurate for COVID-19? Serology, nasal swab, saliva, buccal swab? I understand certain tests can be false positives.

There is insufficient data to determine that at this time. Serology testing is typically done from plasma. With high quality, refined assays, other human samples can be tested.

How about serology testing (IgG)? If they say people are infected again, what's the relevance of IgG (testing) (protecting) ? Is the virus changing itself?

The mutation rate of the virus and, therefore, changes in protein epitopes to which humans make responses is not entirely clear at this time. Whether or not a past infection is protective against future infection is still being determined.

When will antibody testing be available in NC?

Test suppliers are working with shortages and trying to provide testing to the "hardest hit" areas. As serology tests become available and the clear use case by each state is determined, tests should be available. Contact your local state government if you have specific questions.

Why are quick serology test kits not being adopted in the US as a first line testing method to get ahead of the infection?

Serology is not the best first line test for COVID-19. RT-PCR-based tests to determine active infection should be first line. Serology is primarily an epidemiological tool to parse individuals in to risk groups.

I want to know if the blood samples are being collected for people who have tested positive to Covid-19 from the time of the initial test to the time of the final test when they tested negative again, so that we can be able to run serological tests on the blood specimens to have a profile of their antibody response over the course of the disease.

Many laboratories around the country are considering research questions such as this and we will likely see many publications in the near future once sufficient data is collected

What is your guidance to laboratories trying to validate serology testing in terms of accuracy and correlation?

Have a clear use case for the serology in your setting; validate using manufacturer's recommendations, relevant existing guidelines, and in house standards; Using samples from patients who have testing positive or negative for COVID-19 more than 2 weeks prior are ideal samples; archived samples (from before pandemic) are also valuable negative samples.

Can I test patients for antibody with a non-EUA kit and bill for them?

Your billing compliance department or billing compliance officer is the best person to answer that question.

How helpful is serology testing in selecting who can get elective surgery? Is having Ab to Coronavirus guarantee lifetime immunity and/or is there a slight possibility of them getting remission of the infection and shed virus particles again endangering healthcare workers?

The answer is unclear at this point and more data is needed from patients and the population to determine the best practices.

Why are we so focused on NAAT testing when we need use serology for national testing? The NAAT testing is only testing for a point in time. The serology is not good but we are going to have to wait for it to get better. Fix the supply chain issue first.

NAAT testing provides a diagnosis for a patient's current illness. Serology only provides a snapshot of the immune system at that point. An IgG positive test (negative IgM) in a patient with a history of illness or a never sick patient may be protective. IgG/IgM negative tests, at this point, may not be sufficiently specific to exclude exposure. As new tests are available, we expect the Sens and Spec to improve.



In the serology testing realm, what is the data to support that the antigens detected are specific to the COVID19 coronavirus versus one of the other human-infecting strains?

Currently the bulk of serology testing is to determine the presence of an antibody in human blood (not antigen). The material used ranges from crude lysates to purified proteins. The more purified and specific a protein to SARS-CoV-2, the better the assay, in theory.

Serology testing: Because of the probable low COVID-19 prevalence in the USA and the poor PPV, even of a highly sensitive test, will we really need to perform TWO serology tests in our hospital lab to confirm positives for many (most) of our patients (HCWs)? Logistics? Cost?

Prevalence of COVID-19 in the US is not currently known because we do not have enough testing of the population. For every confirmed case, there are likely 100 to 1000 infected individuals who may be asymptomatic. To screen completely asymptomatic people with no history of infection but history of exposure (HCW), a single serology with high sensitivity is likely sufficient. Only data from laboratories can confirm this approach is sound.

With so many serology tests with low specificity allowed to be on the marketplace, how can any statistics be trusted? I worry that the laboratory professions are getting a black eye in the quality department.

Recent serology tests have reported 99.8% specificity. Hopefully, these tests will continue to improve.

As an ASCP-certified medical technologist, as an organization how is ASCP planning to help certified individuals during this pandemic?

Couple things to mention. First, ASCP's National Testing Strategy called for Congress to provide financial support for laboratory professionals in various forms, such as hazard pay, student loan forgiveness, funding for workforce training and development, coverage for mental health services. The Paycheck Protection Program and Healthcare Enhancement Act, at our urging, provides funds to support the laboratory workforce and we anticipate that besides helping to increase COVID-19 testing capacity that these will be used to provide for the support listed above.

As the COO of 2 Medical Lab Tech programs, our accreditor (ABHES) is looking to ASCP to allow our program to use simulation in place of clinical time. Is this something the organization is prepared to allow education programs to do? Thanks.

ASCP BOC COVID-19 page (<https://www.ascp.org/content/docs/default-source/boc-pdfs/boc/ascp-boc-covid-19-information.pdf?sfvrsn=64>) This page on the BOC website has information on how this ongoing health crisis may impact your program, eligibility, application, or exam date. The ASCP BOC does not stipulate how clinical hours are to be accomplished. It is our expectation that the accredited program will prepare them to sit for the certification examination. You should speak to your accreditor to see if simulation is addressed in their accreditation manual/standards. During this pandemic, we hope that the accreditation agencies are working with their programs to be flexible in how clinical hours can be completed to bring the student to entry level competency and successful completion of the program so they may challenge the certification examination.

I am ASCP certified. Can I get specific training on Abbott equipment, i.e., ID Now COVID-19 and Architect i100-4000SR?

Through either online resources or possibly visiting a laboratory that is running these assays, you could receive training on these platforms.

Is ASCP offering retired laboratory MT's the chance to fast-track to re-certification?

Retired Medical Technologist's may still hold an active credential. Individuals ASCP certified prior to January 2004 or ASCPi certified prior to January 2012 possess credentials which are not time limited. They may participate in CMP on a voluntary basis. If you have a time limited credential and you have allowed it to expire, then you will need to seek reinstatement of your credentials. There is no "fast-track" process for reinstating your expired credentials.

- [Voluntary CMP Participation \(www.ascp.org/boc/cmp-voluntary\)](http://www.ascp.org/boc/cmp-voluntary)
- [Mandatory CMP Participation \(www.ascp.org/boc/cmp-mandatory\)](http://www.ascp.org/boc/cmp-mandatory)
- [Reinstatement for Expired BOC Credentials \(www.ascp.org/boc/cmp-reinstatement\)](http://www.ascp.org/boc/cmp-reinstatement)



What are some of the ways that laboratory professionals can speak to the role of our profession? Pam did speak wonderfully. She didn't need anyone to add anything on.

You should communicate the role of the laboratory whenever there is an opportunity to do so. Letters to the editors of the papers you read. There's a lot of incorrect information in local and national papers. Pathologists, laboratory personnel are among the best folks to raise concern about inaccurate info. Become a Career Ambassador and speak at career fairs, and at elementary and secondary schools.

- (<https://www.ascp.org/content/news-archive/news-detail/2019/04/02/be-engaging!-ascp-career-ambassador-advises-fellow-volunteers>)

The public does not make the jump from specimen collection to the laboratory. I'm a retired MT(ASCP) and worked straight through a 60-year career. It's sad the public does not know about laboratory professionals. We need to recruit, educate and retain many more professionals. This is a golden opportunity to do that. Do not blow this!

Excellent point. We have been raising concerns about this with the media, but it's challenging to get this point across. We have also been active in supporting the development of the Paycheck Protection and Healthcare Enhancement Act which provides \$25 billion for laboratory response to COVID-19. This law allows for funding to be allocated to workforce development and training and ASCP will work with the government to better support today's and tomorrow's laboratory personnel.

Who are we supposed to be relying on to educate the general public? Because frankly you guys have been nearly silent. Ortho has said more than you have.

ASCP has been very active working to address improve COVID-19 test capacity, ensure quality testing and support the laboratory workforce. Please see the latest ePolicy as well as our COVID-19 Resource Page.

There should be a live, dynamic survey dashboard designed by ASCP, which can be an opt-in by labs to provide information about logistical/supply issues. For instance, if several labs have the same issue with supply, then this ASCP as an organization can push on the federal level to highlight the issue because a certain significant proportion of labs are reporting this similar issues.

As you point out, the supply chain issues are serious and why we have called for the formation of a national testing task force. ASCP is willing to consider additional options where we inform and urge the federal government to take appropriate actions.

As a membership society, what has ASCP done in the last month to recognize the lab?

See the recent issue of ePolicy, ASCP News, and the ASCP COVID-19 Resource web page.

Why are we not getting hazard pay? I am personally doing testing in the micro lab. We are working extra shifts as well. Meanwhile, we were told a coworker nurse in the ccu was getting 100 dollars an hour.

ASCP has called for hazard pay and it is part of our national testing strategy. We will continue to support efforts to institute this policy.

Is there a chance of waving or reducing the ASCP membership fees for this year considering the massive work hours reductions for MLS working at small physicians office labs?!

ASCP is seeking creative and innovative ways to assist our members and future members in meeting their needs during this challenging time.

Is there a need for retired licensed medical technologists to help laboratories with the testing?

We are happy to work with government agencies and licensing bureaus to determine innovative ways to meet the current pandemic workforce shortages. Many states have created a webpage for retired medical workers to volunteer to help in your state. Unfortunately, many hospitals and clinics have suspended elective procedures during the pandemic. As a result, many laboratory professionals are being furloughed; work hours are reduced; and may also be required to use paid time-off.

- (<https://www.beckershospitalreview.com/finance/49-hospitals-furloughing-workers-in-response-to-covid-19.html>)



What exactly is ASCP doing for the Medical Laboratory Scientists to help them get proper testing kits, supplies and be acknowledged during this global crisis as the healthcare professionals running and resulting the SARS-coV-2 (Covid-19) test?

The supply chain issues are serious and why we have called for the formation of a national testing task force. ASCP is willing to consider additional options where we inform and urge the federal government to take appropriate actions. Please see the most recent copy of ASCP ePolicy for more on some of what ASCP has been doing that last month.

How can we approach advocacy for hazard pay for the laboratory professionals, especially the ones working directly with testing?

ASCP has called for hazard pay and it is part of our national testing strategy. We will continue to support efforts to institute this policy.

If I want to sign out remotely and digitally, do I need an FDA cleared system? Also, how about physical slides; can they be shipped if we don't have scanning infrastructure?

Please refer to the FDA's guidance on remote sign out and slide review: <https://www.fda.gov/media/137307/download>

Why would you need pathologists and others to run testing when we need to address this problem of understaff laboratories with medical laboratory scientists? They are under-appreciated and under paid. No other positions allow other medical professionals to do their job. Stop giving the OK to outsource laboratory positions and jobs to pathologists, RNs, pharmacists, etc.

High complexity testing should only be performed by qualified laboratory professionals. ASCP supports the field's professional recognition, scope of practice and clinical empowerment through workforce studies and advocacy activities.

- [Wage and Vacancy](#)
- [ASCP, ASCP BOC, Thousands Urge CMS to Abandon Nursing Policy \(https://www.ascp.org/content/news-archive/news-detail/2018/04/05/epolicy-news-april-2018#1\)](#)
- [CLIAC Supports Majority of ASCP Proposals on Personnel Standards-\(https://www.ascp.org/content/news-archive/news-detail/2019/04/25/cliac-supports-majority-of-ascp-proposals-on-personnel-standards\)](#)

- [ASCP Workforce Initiatives \(https://www.ascp.org/content/get-involved/institute-of-science-technology-policy/workforce-initiatives\)](#)
- [ASCP, ASCP BOC, Thousands Urge CMS to Abandon Nursing Policy \(https://www.ascp.org/content/news-archive/news-detail/2018/04/05/epolicy-news-april-2018#1\)](#)
- [CLIAC Supports Majority of ASCP Proposals on Personnel Standards-\(https://www.ascp.org/content/news-archive/news-detail/2019/04/25/cliac-supports-majority-of-ascp-proposals-on-personnel-standards\)](#)

Can ASCP provide guidelines for LDT for small labs?

ASCP's COVID-19 resource page might be of some assistance

What are the strategies on hand then from ASCP for all COVID-19 testing concerns? Are there any recommendations submitted to the CDC and WHO that can help federal states?

See the recent issue of ePolicy and ASCP News.

Why have ASCP and CAP not offered a combined solution to the testing issues? You both are losing credibility as true leaders of laboratory medicine without action now.

ASCP has been working directly with the federal government and the leaders of the organization to address this pandemic. Our advocacy efforts have generated more than 40,000 letters to policymakers. We also have provided direction to the highest levels of government.

A housekeeping question: Will I be able to obtain Florida CEUs for this call? Thanks!

Yes, the ASCP town halls are valid for CEUs in California and Florida.

I am on the FEMA COVID task force here in DC as a lab professional advisor and liaison to the medical supply chain. How can a person like myself continue to provide indirect or direct support on the issues that are discussed today?

Thank you, Ms. Flores, for all of your work with the federal government and in the lab. I hope the direct phone call you had with our Chief Officer for Science, Technology and Policy last week helped answer the question.



I've been working in research genomics for a few years in the Chicago area. In light of the COVID crisis, I have applied for ASCP SMB certification so I may assist with testing in the future. When do you think new certification testing will be rolled out nationwide?

ASCP BOC COVID-19 page - this page is updated frequently (<https://www.ascp.org/content/docs/default-source/boc-pdfs/boc/ascp-boc-covid-19-information.pdf?sfvrsn=64>)

“PEARSON VUE SITES Pearson VUE will re-open testing locations within the U.S., Canada, and many international locations, beginning May 1st, 2020 where there are no restrictions prohibiting operation. They have received recognition as offering an essential service by delivering examinations for essential services personnel. The ASCP BOC has worked with Pearson VUE to ensure that all ASCP BOC examinations are recognized as essential services. See the Pearson Vue FAQs around Testing for Essential Services for complete information. Make sure to view Country Specific testing information as well.

How will all of the issues we are currently facing impact the training of new MLS professionals entering the field for the first time?

President Trump recently signed into law a measure that provides funding to support the laboratory workforce and training activities. ASCP hopes to provide more details on this soon. New hires may have a delayed start date because many hospitals and clinics have suspended elective procedures during the pandemic. As a result, many laboratory professionals are being furloughed; work hours are reduced; and may also be required to use paid time-off. Other professionals are asked to job shift to help in other laboratory areas which are working on COVID-19 testing.

- (<https://www.beckershospitalreview.com/finance/49-hospitals-furloughing-workers-in-response-to-covid-19.html>)

What is the ASCP standing of staffing shortages?

ASCP's recommendation to Congress to provide funding for training activities to support the laboratory workforce was recently signed into law. ASCP hopes to provide more details on this soon. Please see the May e-Policy article titled, "Governors, State Health Directors Hear from ASCP BOC about COVID-19 Response," raising awareness about the important role that laboratory testing and laboratory professionals play in responding to the COVID-19 pandemic.

- [ASCP Workforce Initiatives \(https://www.ascp.org/content/get-involved/institute-of-science-technology-policy/workforce-initiatives\)](https://www.ascp.org/content/get-involved/institute-of-science-technology-policy/workforce-initiatives)

I am a senior in my final year of medical laboratory science. I am interested in getting my master's in health informatics. What are some other needs for improvement to improve supply information for different laboratories? And, is there an even bigger need for medical laboratory scientists to have a concentration in health informatics?

Medical laboratory professionals can continue to improve their value, impact, and development through life-long learning, adaptation to changing laboratory needs, and understanding integration of innovation. Medical informatics is an excellent example of an area where outstanding laboratory professionals can enhance their knowledge and improve systems of care for patients.

There are plenty of available lab techs out there where the stay home policy has actually resulted in the techs needing to take mandatory days off. Busy labs could tap the techs from these other sites.

You are correct. Many hospitals and clinics have suspended elective procedures during the pandemic. As a result, many laboratory professionals are being furloughed; work hours are reduced; and may also be required to use paid time-off. New hires may have a delayed start date. Other professionals are asked to job shift to help in other laboratory areas which are working on COVID-19 testing.

- (<https://www.beckershospitalreview.com/finance/49-hospitals-furloughing-workers-in-response-to-covid-19.html>)

As a clinical laboratory educator, we have to limit our student populations because laboratories will only take a limited number of students for their clinical experiences. We need labs to train students in order to be able to fill the MLS vacancies.

ASCP concurs. A new law signed by President Trump provides funding for workforce and training support. ASCP will be working with the federal government ways it could better help the laboratory workforce, clinical training programs and the laboratories serving as sites for clinical training. Please see ASCP BOC COVID-19 page (<https://www.ascp.org/content/docs/default-source/boc-pdfs/boc/ascp-boc-covid-19-information.pdf?sfvrsn=64>), for the most updated information on how this ongoing health crisis may impact your program, eligibility, application, or exam date.



Governor Cuomo needs to take back the regulation for state requirements for Medical Laboratory Scientist. I am an ASCP BOC-certified MLS that can't work in New York because of the state requirements.

May e-Policy - BOC Governors Letter - Governors, State Health Directors Hear from ASCP BOC about COVID-19 Response - The letter urged that as state governments take efforts to ensure the robustness of their healthcare workforces that these efforts, such as making adjustment to licensure requirements and other state benefits or requirements, also factor in laboratory professionals.

I am an ASCP-certified Histotechnologist. In what capacity can I help out? My specimens are processed within 12 hrs with a 24 hr TAT to slides to my pathologist. Do I need to adjust my fixation time in NBF for ininfectivit? Thank you.

Histology workforce: Many hospitals and clinics have suspended elective procedures during the pandemic. As a result, many laboratory professionals are being furloughed; work hours are reduced; and staff may also be required to use paid time-off. New hires may have a delayed start date. Other professionals are asked to job shift to help in other laboratory areas which are working on COVID-19 testing.

- (<https://www.fixationonhistology.com/post/covid-19-a-histology-recruiter-s-perspective>)
- **Histology Specimen Processing – Safety and Disinfection:** Please refer to the CDC guidelines for handling tissue: <https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>
- a. "Safety Considerations in the Laboratory Testing of Specimens Suspected or Known to Contain the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)," AJCP" (<https://academic.oup.com/ajcp/advance-article/doi/10.1093/ajcp/aqaa047/5810006?searchresult=1>)
- b. Coronavirus disinfection in histopathology, published in the Journal of Histotechnology [open access](<https://www.tandfonline.com/doi/full/10.1080/01478885.2020.1734718>)

Thank you to all who presented and added questions! How do we claim our CME points?

The ASCP Town Halls are virtual events that all medical laboratory professionals can attend live or watch via on demand video at a later date. Viewers can claim 1 CME or 1 CMLE credit for attending/viewing an ASCP Town Hall. To claim CME/CMLE credits for participation in this activity, please "purchase" (it is free) the activity, add it to your learning plan, and complete the course evaluation. Detailed instructions can be found in the store under the product listing.

I think a key question as of the last few hours is: Is any state currently ready to reopen? Are there enough tests and testing supplies currently, especially if there is a spike in the next 2 weeks? This is in light of GA saying they are "opening" some businesses including gyms/some restaurants on Friday?!

State re-openings are at the discretion of the leadership of that state and these decisions are being made independently of a national strategy or approach. Each state's leadership should be informed by their local epidemiology, case load, and direct advice from their public health and other healthcare providers networks. Depending on the re-opening strategy, there may or may not be sufficient testing.

If you are a public health expert and economist, developing a strategy to re-open vicinities in the U.S. that incorporates testing, given the heterogeneity of testing, what minimal data set is necessary to be useful to provide to those experts? Would that be test type, performance characteristics, prevalence/stage of disease in the local population as we know currently? I am writing in regards to the possibility if a national data collection infrastructure comes to fruition (this is the position of the Association for Pathology Informatics), what type of data would that infrastructure contain to be useful for that strategy?

We have the precedent of influenza to guide us on how data is collected on highly prevalent and annual infections. Strains of influenza are collected, sequenced, and cataloged annually to inform and develop the next phase of vaccines for influenza. This system is efficient and existing. Piggy-backing onto this infrastructure would be an ideal way to gather national data on SARS-CoV-2. The data collected depends on the intended use. For epidemiology, test type and result by zip code are minimal. For vaccine development, sequence sampling will be required.

Has anyone demonstrated clinical improvement with convalescent plasma infusion, and looking at titers of serologic IgG level for improvement? Are any blood centers/testing centers leading this charge?

Please refer to these websites for the most up to date information regarding this question: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>



What level of sensitivity is needed to infer safety in a community; that is, to inform the decision to ‘reopen’?

Reopening will need to focus on a) detecting sick individuals (symptoms plus positive test) and quarantining them for recovery, b) identifying serological positive individuals (likely non-infections depending on time scale), and c) identifying serological negative individuals with risk factors (reiterate preventative measures). General public health measures (hand washing, avoiding sick contacts, avoiding work when ill) should be reiterated.

We’re hearing that a rebound could be much worse if restrictions are lifted.

Data to support rebound effect is difficult to find and interpret at this time.

Has the ASCP’s National Testing Strategy been well received by the federal government (President Trump, in particular)?

Many elements of the testing strategy were included in the President’s blueprint. We are hopeful much more will be accomplished in the days ahead.

There are so many manufacturers to offer Covid 19 testing currently. Has there been any parallel testing performed among all these different manufacturers? Is there a need to do parallel testing?

There are many problems associated with the EUA’s issued by the FDA in the early days of the pandemic. We need more data and we need to ensure that the right test is done at the right time on the right patient. There is much to do to ensure we are optimizing testing.

Much has been made about the supply chain for swabs and reagents. What about instrumentation? Are the companies making instrumentation ramping up production?

We understand that companies are ramping up production but believe a testing task force can help track production and needs better.

Surely there are already best practices in place on how to roll out laboratory testing in a pandemic, from the WHO or the equivalent? How is it that we’re months behind on even pulling together organizations to produce evidence-driven practices?

We agree with the premise of your question and a national testing task force can help address the current pandemic and prepare for future outbreaks.

What is ASCP’s position on the VITAL and VALID Acts?

We have not endorsed any legislation on LDTs.

What other National Testing Strategies exist today?

Other nations may have pandemic testing strategies in place.

We need a rapid “choosing wisely campaign for COVID” meant for clinicians and patients

ASCP’s Effective Test Utilization Steering Committee, which is responsible for Choosing Wisely, is discussing this issue.

What are the takeaways that we are already seeing, what are some ideas that we will be taking with us in the future?

The environment is changing rapidly, day by day in some instances. A panel of experts, assembled at the national level, should be prepared to provide expert advice on laboratory related issues. It should include experts from our profession.

Given that certain tests are more applicable in certain settings than others depending on their performance characteristics, can a start for ASCP be to provide guidelines of performance ranges that would apply to certain settings for those health care delivery centers trying to deploy and apply optimal strategies for testing?

There is a great need for guidelines for the right test, right time, right patient. We agree with the need for guidelines and there are many new tests. There needs to be rapid action in this area and we are suited to provide expertise to the process.

How do we partner with other specialty societies to decide best practices for Covid management and practice? And which societies would you target working with?

ASCP believes we are StrongerTogether and believes in the concept of partnership. There are many pathology, laboratory medicine and infectious disease organizations that can partner together in the coming days.



Can we invite experts outside of pathology and the lab to advise and integrate their perspective as we fine-tune our strategy and develop guidelines? For instance, Paul Romer at NYU (Nobel Laureate in Economics), Mark McClellan at Duke and Jennifer Nuzzo at Hopkins (economist, public health expert, epidemiology respectively) have thought about integrated strategies for reopening the country with testing results as the foundation.

These are great suggestions and we agree with the need for collaboration.

Can you give specific manufacturer or test characteristics?

See LOINC mapping: <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>

What is ASCP's stance on monitoring the public's temperature through Fitbits and Apple watches under the Detect app to follow the spread of COVID -19 ?

We have no position on this issue at this time.

I manage a college/student health laboratory. We will need a plan to help the university to be able to bring back students. Any advice on how to plan for testing and laboratory readiness for the testing we will need?

The widespread availability of testing will be helpful. A national task force could help establish standards.

At what point is testing asymptomatic individuals valuable?

Serological testing of asymptomatic patients may have epidemiological value. RT-PCR testing of asymptomatic individuals may be prohibitively expensive unless there is a clear follow up action.

Is there a need for retired licensed medical technologists to help laboratories with the testing?

We are happy to work with government agencies and licensing bureaus to determine innovative ways to meet the current pandemic workforce shortages.

Drs. Holladay, Finn and Procop & Ms. Sun: Thank you! 1) Now that we have very reliable diagnostic PCR-based tests, and a more reliable supply chain, why is there still such dramatic under-testing in most jurisdictions, despite a call for universal testing? 2) There is a gaping need for an algorithmic approach to using serology for pre-operative clearance, return to work, picking up gaps in clinical sensitivity (people who don't harbor virus in their nasopharynx) etc. Where is ASCP on weighing in on that? Jennifer Kasten, pediatric pathologist, Cincinnati, OH

Testing capacity in the United States is uneven. The establishment of a national testing task force will help address the the supply chain and ensure that no community is left behind. ASCP leadership has been urging the FDA to provide more guidance on serology tests and has been in constant communication with the FDA regarding our concerns in this area.

Can ASCP get federal funding and provide grant/loan to clinical laboratories to help offer the test?

We are always seeking ways to assist our members with legislation and with funding and are actively following the funding available from the US government and other sources and how we can move that funding to our members.

What are your thoughts on pharmacists performing rapid testing for COVID-19?

High complexity testing should be performed by medical laboratory professionals.

What is ASCP's stand on whether a biosafety hood is needed or not needed for POC testing (Abbott ID Now)?

Each laboratory's biosafety officer or infection control officer should be consulted to determine the laboratory staff's comfort level with performing any test of an infectious nature when data is unclear or there is a conflicting question.



Does ASCP have a particular stance on the minimum requirements for FDA Emergency Use Authorization (EUA) approvals for various tests being developed/distributed?

ASCP has been in regular contact with the FDA on a number of issues. We believe we were the first laboratory organization to call on the FDA to allow commercial laboratories (hospitals, academic medical centers, and reference labs) to develop and offer their own laboratory tests, as none were then available. We have consistently raised concerns with the FDA that access without quality does not benefit patients. We have been in regular contact with the agency, not only about diagnostic RT-PCR testing but also on antigen and serology testing too.

What is the status of standardization and accuracy/precision validation by a national entity of all the various antibody tests that have flooded the market?

This is an issue that is evolving daily. FDA just revised its guidance on serology testing requiring the filing of EUAs before marketing these tests. See the FDA document: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>

What exactly is the paycheck protection act?

The Paycheck Protection Program is a loan designed to provide a direct incentive for small businesses to keep their workers on the payroll. SBA will forgive loans if all employees are kept on the payroll for eight weeks and the money is used for payroll, rent, mortgage interest, or utilities. After funding for the program ran out, legislation (known as the Paycheck Protection Program and Healthcare Enhancement Act) to refund the program AND to provide \$25 billion to help increase U.S. laboratory test capacity for COVID-19.

What are your thoughts about pharmacists performing COVID-19 rapid testing in NYS?

ASCP believes that laboratory testing should be performed by individuals who are properly trained to perform them, such as pathologists and certified laboratory professionals, especially for more complex testing. That said, under CLIA, waived tests supposedly can be safely performed by individuals who are not trained laboratory professionals.

Do public health experts and the economists understand the challenge of testing quality of Covid-19?

A great question and a complex one as there are many academic papers that have a wide range of opinions.

Are there plans to get research labs to help do some of the tests, since it's impossible for the clinical labs to meet the demand caused by COVID-19?

For your first question, where this has occurred in institutions, there has been some semblance of a CLIA license in that institution. Although there is a relaxation at this point, CLIA regulations have to be followed.

My 2nd question: Is there a way to better perform population testing as it relates to testing according to where the needs are to help aid with the testing needs?

For your first question, where this has occurred in institutions, there has been some semblance of a CLIA license in that institution. Although there is a relaxation at this point, CLIA regulations have to be followed.

Are the states reporting Covid-19 test results consistently?

Determining the rate of accuracy and consistency of reporting would be the work of the CDC and the public health epidemiologists.

What is ASCP's standing on mass testing before reopening the economy again versus opening and allowing a second wave?

ASCP agrees with many public health experts that to re-open the economy and get Americans back to work, we need to significantly increase testing capacity for COVID-19. Experts have offered different ranges as to how many tests we need to be able to perform, with that range being 5-35 million tests per day. However, as of May 7 we have only performed 7.5 million tests since the pandemic came to the U.S. We have a long way to go.

There have been a lot of pairing problems with the federal government distributing supplies to their public health and state laboratories. For instance, swabs and media not optimal for testing platforms. Will the National Testing Strategy help them with this problem?

A national strategy should include guidance on this question. ASCP recommends a national testing task force be assembled with experts from laboratory medicine, federal and state governments to address these important issues in a coherent fashion.

In the near future, will it be mandatory for everyone to be vaccinated, for example, like the flu shot?

This is a valid question that will need to be answered as vaccines are under development.



Do we have a source that we can submit the data to, or is there an agency that collects nationwide data in one place to analyze them?

As part of CDC's ongoing COVID-19 response, a new Patient Impact Module has been created in NHSN to help facilities track and monitor the number of cases reported in their facilities daily. To monitor the rapid emergence of COVID-19 and its impact, all hospitals are to report to the NHSN COVID-19 Patient Impact and Hospital Capacity Module. All hospitals that currently utilize the NHSN should have received an email from the Centers for Disease Control and Prevention (CDC) outlining this request. For questions on this module or submission requirements, contact NHSN@cdc.gov and put "COVID-19 Module" in the subject line.

What data do you need to get to public health experts?

As part of CDC's ongoing COVID-19 response, a new Patient Impact Module has been created in NHSN to help facilities track and monitor the number of cases reported in their facilities daily. To monitor the rapid emergence of COVID-19 and its impact, all hospitals are to report to the NHSN COVID-19 Patient Impact and Hospital Capacity Module. All hospitals that currently utilize the NHSN should have received an email from the Centers for Disease Control and Prevention (CDC) outlining this request. For questions on this module or submission requirements, contact NHSN@cdc.gov and put "COVID-19 Module" in the subject line.

Since we can only truly understand the operating characteristics of COVID lab tests in the context of good epidemiological data, how do we put lab and epi data in one place?

Good question, as public reporting is generally handled by the states, emansing 50+ different entities receive this data and their may not be much real time data available. That said. The White House just requested that hospital with in-house labs report COVID-19 testing data daily. It's not complete, as it doesn't include testing a reference laboratories, but its a step toward a single real-time data source.

Is ASCP partnering with experts within other professional organizations, such as AACC and AMP? There are a lot of excellent scientists (Clinical Chemists and Molecular Biologists) in those organizations that have been collecting data and information on a variety of tests.

ASCP actively collaborates with all of our sibling organizations and seeks more opportunities to work directly with as many partners as possible. Through the National Testing Strategy efforts, for example, we have work with AMA, CAP, ASM, ACLA, and many other groups in moving this forward.

Ivory Ativie (MLS) in Minnesota - In terms of Bioinformatics: Are we aware of Health Information Networks at the state level, i.e., the Michigan Health Information Network (MiHIN) and New York Health Information Network and New Jersey Health Information Network? Are we able to reach out those companies for assistance in building a HIN/HIEs?

These are great suggestions for connections to make on the bioinformatics front. Thank you.

How does the FDA SHIELDS Lab Codes fit into the national plan?

Those get you connections with some good groups. But, the ones that I mentioned (AACC and AMP) are the largest group of specialists (many at the PhD level) in the areas of testing that we're talking about. Are they also engaged? AACC and AMP are active partners of ASCP across many areas including the current pandemic.

Doesn't CAP have listings as to which labs have which platforms? Why can't we supply that to the federal gov't?

Great question for the CAP leadership.

Has Hc1 been useful in helping with disease and testing trends by zip code?

You can refer to this website to determine this directly: <https://www.hc1.com/blog/tag/covid-19-dashboard/>

What are your thoughts on comments that if the National Defense Act were implemened, the military could contribute their supply chain logistic capabilities to the effort?

ASCP has been in regular contact with with the Trump Admistration about improving the supply chain for scarce resources.



Do you recommend getting the COVID-19 antibody testing from a lab performing this test which has not been reviewed by the FDA?

ASCP believes that patients are best served by tests that have been appropriately reviewed for performance.

Working as a tech I have noticed that the lack that of a universal computerized test requisitioning and reporting system has been a big issue in our lab. Manually ordering lab tests ,from a manual requisition takes a long time. Our lab might be able to perform more testing if there were not the bottleneck at ordering and receiving specimens. Has this issue been mentioned?

Thank you for this important information regarding the operations. It is noted and a very important point.

Beyond supply chain, can our laboratory infrastructure handle the volume of tests needed to the country back on track?

ASCP hopes with more laboratories performing COVID-19 testing we will get to the point where we have the testing capacity needed to better respond to the pandemic.

Do you think there will be an employer requirement for antibody testing when environment is high risk?

Some employers are already discussing this as a goal, if they can secure the testing needed to support such a requirement.

In lieu of bringing on other healthcare professionals to do testing, do you think license states may relax and allow persons with an active ASCP certification to cross state lines to help?

Possibly. ASCP has been in touch with state governors and health department officials to ensure that as they consider efforts to ensure a robust healthcare workforce that they extend these efforts to laboratory professionals as well. This could allow laboratory professionals to cross state lines to assist with patient care.

In reference to my previous question: It would be impossible to test the entire population. So, would not a definitive algorithm followed over time to eventually incorporate medication and vaccine affects be critical to establish (such as w/Hep B)??

If an effective vaccine becomes available, that may well become the first line of defense against any near-term threat from COVID-19.

It oversimplifies the laboratory when we allow non-laboratorians to put out testing. Laboratories do not put out tests... they put out trust. Lose trust... you have no laboratory.

Thank you very much for your comment.

CV19 Lab Testing Dashboard Powered by hc1 is Fastest to Identify Emerging Local Spread and Control of COVID-19

Thank you for comment.

Most laboratories have a conflict of interest in their contracts if you work for another lab (pre covid-19). Since CLSs are in need right now would it be considered an exception to work for 2 competing labs?

That would require review of your contracts and a discussion with the HR staff of the involved institutions.

Please discuss FN and FP rates using NP swabs versus alveolar lavage. Also, are we aware assay materials are currently difficult to obtain?

- <https://www.jwatch.org/na51116/2020/03/17/pharyngeal-and-nasal-swabs-may-not-have-adequate>
- <https://jcm.asm.org/content/jcm/early/2020/02/20/JCM.00297-20.full.pdf>
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

I hear conflicting information on immunity after COVID-19 infection. How are they basing their information?

No context to answer this.

Do you think in the future the Sars-COV-2 testing will be required for all blood units/products? What is the consensus regarding transmission due to transfusion?

Unable to determine at this time.

You've spoken about PCR testing and antibody testing. I've done some work in dengue, where the ability to detect an antigen was about 1 day behind PCR detection. Do you see a place for an antigen test? Even a combination antigen-antibody test.

High quality antigen tests may be valuable if they can be developed but they require known antibody repertoires.



Has there been any conversation for testing for adverse side effects for potential treatments for SARS-Cov-2?

At this point, "point-of-care" testing (specifically meaning, CLIA-waived) is not available for SARS-CoV-2.

Please review the indications for testing you recommend and best method for obtaining most viral copies.

Science/medical community has not yet determined the risk of re-infection by SARS-CoV-2.

Dr. Procop: Can you cite the author or publication date of the JAMA specimen type paper?

There are currently no treatments for SARS-CoV-2 so we cannot yet study adverse affects of these treatments.

How do you move from a research use only platform to use for clinical diagnosis?

FDA approval

Is anyone able to speak to this being a Zoonotic, and what conversations have been had for a possible animal host?

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7086482/>

What is the risk for severe disease for people with only hypertension and no comorbidities?

<https://academic.oup.com/ajh/article/33/5/373/5816609>

What are the safety concerns for the labs that are trying to introduce the COVID testing and how would you address these concerns?

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

We have so many COVID tests out there. How do we ensure that the COVID test that we are using has over 90% sensitivity and over 90% specificity?

As tests are developed, each manufacturer will provide their validation data including sensitivity and specificity and the population used. Comparison of the testing groups to your population is key to making sure the test will fit your intended needs.

A colleague has shingles. Will she test positive on a serology test? She is COVID-19 free.

Unclear. The viruses are very different and the actual epitopes are key. It remains to be seen how each test demonstrates cross-reactivity or not.

Do those hosting this call have concerns about whether the number of tests that are being used to detect virus and/or antibodies have been properly vetted to feel comfortable that they are yielding valid results?

As tests are developed, each manufacturer will provide their validation data including sensitivity and specificity and the population used. Careful review of those results and comparison with actual clinical use is required to determine validity for each system.

What are some of the popular/effective rapid testing options available?

See LOINC mapping: <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>

Is there a suggested testing algorithm for SARS-CoV-2 for molecular and serological testing?

Multiple organizations are publishing testing guidelines (ASM, IDSA). Local algorithms in your facilities should reflect intended use, prevalence, and local supply chain.

If this idea scales through, what is the plan as per quality of the rapid test kits and intergrity of the test results?

Quality of laboratory testing reagents and supplies and results are always of greatest importance.

What is an appropriate time frame to retest a patient for COVID-19 that has an original negative test and the provider still believes the patient has it?

By RT-PCR, a single test properly collected should be sufficient. There are many other respiratory viruses in the population.

How reliable are the tests that Walgreen's and Kroger recently started doing?

You would need to check to see the exact test kits they are using and running as well as the qualifications of the individuals performing the tests.



Does ASCP have any guidance for providers on labs to order for suspected COVID patients? What about follow-up labs?

Clinical management of COVID-19 patients and additional laboratory testing has been discussed in the recent IDSA guidelines that are forthcoming.

What are your thoughts about the Abbott ID NOW test being rolled out to “hot spots” and being performed at CVS and Walgreen’s? Our experience has been that there are large numbers of false negatives and we have decided not to implement.

You would need to check to the qualifications of the individuals performing the tests.

Does LabCorp report positives from its home kit?

Not known.

What is the role of saliva testing, considering its ease of specimen collection?

Please see recent FDA approval for first saliva test and look for additional data to follow.

What about saliva testing being more sensitive than NP swab testing? Will this testing be available in labs any time soon?

Please see recent FDA approval for first saliva test and look for additional data to follow.

Is it true that the ID Now is changing their package insert to only use dry swab because they are getting false negative on specimens delivered in viral transport media?

Not known.

Should patients who tested negative be retested if symptoms continue in the absence of any other possible diagnosis? Is there guidance on use of a different testing method than the initial method (ie, 1st NP, 2nd saliva, etc.)?

By RT-PCR, a single test properly collected should be sufficient. There are many other respiratory viruses in the population.

Governors are opening the states and people are going back to work. How will we ensure the vulnerable populations, especially in the nursing homes, and the staff that work there have access to appropriate testing with timely results?

Appropriate precautions and isolation.

What do you believe is the reason for an increase in positives since things have reopened last weekend? Is this not only selective of increased testing or the more accurate testing methods available now? I see posts all over social media surrounding fear of positive, numbers going up in area--a few by HUGE numbers. Your thoughts, please. Thank you!

Positive tests do not mean “more virus.” They simply mean we are detecting virus that is already there. It is important not to assume prevalence = incidence. Until we have sufficient testing to monitor the population, we will not be able to determine incidence. We expect prevalence to be high because for every symptomatic patient there are 100 to 1000 asymptomatic people who have been exposed/infected.

Re AP—are your institutions performing autopsy/tissue banking on deceased with COVID?

Many facilities are performing autopsies on COVID-19 patients using CDC guidelines.

How far along are we on quantitative or antibody titer testing for Covid-19?

Quantitative RT-PCR may be available (within) certain existing platforms but will not be useful until there is clinical utility. Antibody tests are coming along with a recent approval during the week of May 1.

Given our concern for the patients, I am also concerned about the safety of the laboratory personnel handling, processing and testing the samples that come through the laboratory. The PPE’s should include the N95 masks, but we are not considered essential personnel and are truly putting our lives at risk working in this environment. Would it be possible to recommend the proper mask to use when working with these specimens so that all of us do not inadvertently get the Covid-19 virus and subsequently have to go out on sick leave for at least 14 days? Thank you for your diligence!

Laboratory professionals are considered essential personnel and PPE sufficient to protect from the exposure level in your facility should be available.



How are we identifying, on an informatics level, what results are coming from which analyzers types? Results standards like LOINC don't always address the different platforms. They may address the method, but method by itself won't catch all the nuances between how different results would be on the variety of available platforms.

Each healthcare system that brings a test online to their testing battery should be charged with the correct integration of the testing to their LIS including controls and testing of results reporting. The challenge of multiple testing platforms due to testing supply shortage does not forgo standard laboratory safety and quality measures.

Ideally, would it not be best to suggest testing algorithms for different types of patients: 1) Those with symptoms 2) those with documented exposure and no symptoms, 3) those without symptoms or exposure.? And, with those algorithms in mind, then develop minimal testing strategy for these types of patients where there are limited supplies or testing labs available. Dr Ng's lab is so typical of many of us.

Yes, a national testing strategy would address this.

Dr. Ng mentioned BSL3. My laboratory director told me that we only need BSL2 to work with SARS-CoV-2. What safety standards should be followed?

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

What is the difference between PCR testing and the rapid antibody testing for Covid-19?

PCR testing is RT-PCR testing which detects the presence of RNA from the virus in a sample which indicates active virus is present. Rapid antibody testing (or any antibody testing) detects the presence of antibodies (the body response to the virus) in blood. It is a marker of current or past infection.

I am curious if the intent of the questions for mandatory vaccine like the flu applies to healthcare workers.

Unclear.

What has made South Korea so successful in solving supply chain issues? Can we model and implement a similar chain in the US?

Pandemic planning.

Herd immunity? I thought we didn't know if we developed immunity against re-infection.

Reinfection is possible if the antibody responses mounted in a natural infection are not protective (such as in HIV and HepC). However, there is no biological indication at this time to suggest that an infection with SARS-CoV-2 is not protective against a future infection.

In this day and age, how are we not prepared for Covid-19 when the coronavirus is a common cold?

<https://labmedicineblog.com/2020/05/04/covid19-and-the-lessons-we-learned-from-prior-pandemics/>

Do you think the vaccine research getting started up and ongoing now will be rushed through before obtaining sufficient information to identify its efficacy?

Vaccine development should proceed according to FDA guidelines and would be available to the public when it is safe with demonstrate efficacy.

How likely is a "second wave" to occur? Are these projections taking that into account, if it is likely?

Data to support rebound effect is difficult to find and interpret at this time.

Is viral load related to severity of the symptom? I read in a paper that viral load is highest when a patient is asymptomatic or just started to have symptoms.

Viral load correlation with infectivity remains to be study effectively.

In Puerto Rico, this is the first case of a patient, in critical condition, that receive plasma from a recovered patient of COVID-19. The hospital said the patient in critical condition, has tested negative for COVID after the treatment, but still in critical condition. Would you say it is due to a problem in the sample taken after treatment with plasma, or an interference in during sample testing?

It is difficult to determine without a complete chart and laboratory data testing review.

How is ASCP involved in the study of convalescent plasma? I would think that assessing the efficacy of the serology.

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>



How will we be able to access or find the probability of reinfection? Could you please share thoughts on the concerns we have on reinfection the population?

Reinfection is possible if the antibody responses mounted in a natural infection are not protective (such as in HIV and HepC). However, there is no biological indication at this time to suggest that an infection with SARS-CoV-2 is not protective against a future infection.

In our hematology lab, we have seen reactive, atypical looking lymphocytes. Has any other lab experienced these cells? Does anyone know if these cells correlate with disease status?

Unclear. You should consider posting your findings to public forums of other experts for additional input.

The total US population is approximately 328 million. How many people need to be tested, either current infection and/or antibody, to consider a good strategy?

A national strategy for testing should address these issues.

How many times of testing for each individual is reasonable? I can be negative today, or tomorrow and can be positive next week. Any thought?

For RT-PCR for a sick individual, one test properly collected is likely sufficient. A negative test with a strong suspicion could be repeated but supply chain logistics should be considered. Serology testing depends on the intended use and the sen and spec of the assay.

Where is testing of saliva? It is convenient because it requires no swabs.

The first saliva test for EUA was approved on April 14th. Additional data forthcoming: <https://www.fda.gov/media/136875/download>

When will the inavailability of Covid 19 tests for everyone be addressed? The federal government had promised drive-through testing at Walgreen's, CVS, Target, Walmart, etc., but I don't see a single one so far.

At the state level, availability of local testing facilities is often addressed by leadership briefings and/or websites. Checking with your local government resources on available COVID-19 testing is a best first start.

How many labs nationwide have instrumentation (Cepheids, COVID swabs PCR, also Ortho Vitros, antibody testing) and CANNOT receive reagents because they are not in a "hot spot?" The companies state we are not on their lists for shipments in April? shipments in May?

Supply management and allocation of reagents and supplies is being provided by vendors following regulations to which they have been held.

I am a manager from the private sector hospital laboratory. One of our hurdles is our supply chain for testing kits, as they are allocated for government-owned institutions and public health labs. How can private or community labs who have the capacity to test be able to attain testing kits as they are prioritized for government-owned and public health labs?

Supply management and allocation of reagents and supplies is being provided by vendors following regulations to which they have been held.

How can laboratories who have sample-to-result testing, such as Genmark, Diasorin, and Cepheid who have invested in acquisition of these COVID-19 testing platforms, compete with international diagnostic testing kits that are being distributed to state and government-owned laboratories? There is a faster distribution of international test kits than there are of our own testing kits that laboratories have invested in.

As testing kits are validated by manufacturers and ramp up their supply chain and distribution methods, market share availability will shift.

We here that there is a shortage of lab testing, even though quite a few manufacturers have developed these these testing platforms. Is the shortage due to acquisitions of the instrumentation, specimen collection swabs, personnel to collect the specimens, reagents for these different platforms, need for training on these platforms, shortage of testing personnel? All of the above? One more than another?

Note that the availability of tests has only been since the first of March (a little over 2 months as of May 5th). Manufacturers who have developed these tests are still challenged with ramping up supply chain and distribution. More progress is being made every day.



I have been told by numerous vendors that sample collection kits and testing reagents are on federal allocation. Have you heard more information as to when these supplies will be available to laboratories who are ordering them?

Supply management and allocation of reagents and supplies is being provided by vendors following regulations to which they have been held.

With the shortage of media/NP, have you been able to ramp up testing for outpatients or are you limiting testing to hospitalized/severe patients only? It seems that we should focus on isolation of those who are walking around and are contagious with the preferred NP specimen, rather than OP specimens that may not be as accurate.

Each facility offering testing develops a testing strategy based on their resources and availability of supplies. Such an algorithm may not be the ideal approach but is necessary due to shortages. Prioritization of sick patients (for isolation and treatment) is preferred. Outpatient testing should have a clear purpose within the scheme of the community's plan for reopening.

How do you envision dealing with the issue we hear about on the news namely public health experts' warnings that the U.S. needs millions of additional tests each week to safely reopen the country.

State reopenings are at the discretion of the leadership of that state and these decisions are being made independently of a national strategy or approach. Each state's leadership should be informed by their local epidemiology, case load, and direct advice from their public health and other healthcare providers networks. Depending on the re-opening strategy, there may or may not be sufficient testing.

Basic Laboratory Medicine, a test is only as good as the specimen. Patients do not collect their own test very well. I'm very concerned about the saliva test and even drive-by specimen collections.

High complexity testing should be performed by medical laboratory professionals.

Many of these testing/collection sites are being managed in pharmacy parking lots. How do we respond to the tests that are being done in parking lots by pharmacists or pharmacy techs?

High complexity testing should be performed by medical laboratory professionals.

BIDMC recently completed a 3D-printed swab clinical trial for 3 manufacturers: Origin, EnvisionTEC, and Carbon3D. The paper is available via preprint. The swabs were indistinguishable from the control Copan swab. These companies have ISO-compliant manufacturing facilities and swabs are now available to purchase. The designs are all open source and available. Have any of the panelists tested any of these swabs themselves? Are any of you considering printing your own? (Formlabs is a fourth company that completed its IRB through USF and is now selling swabs)

Novel approaches to meeting supply shortages are valuable as long as they are compliant with regulatory measures.

Given that my lab has developed a relationship with Rutgers for the saliva test and I feel that that discussion got curtailed can you address the benefits and disadvantages of that mechanism of testing?

More data is needed to understand the value of this test in both the clinical and the epidemiological setting.

Governor Cuomo plans to sign an executive order to allow pharmacists to run antibody testing in New York. What are your thoughts about this process?

High complexity testing should be performed by medical laboratory professionals.

How do we fix the supply chain "allocation" of test kits and reagents so that all hospital and clinical labs have access to test kits? Does it seem reasonable that pharmacies are able to acquire test kits but hospital laboratories cannot? Just from a PPE conservation perspective, wouldn't it make sense to make sure hospital labs are able to have access to these resources?

A national strategy for testing should address these issues.

With issues with availability of media, is the recommendation of having 2 negative PCR tests going to change?

The evolving status of testing algorithms should be informed by availability of all supplies but that may not be true in all locations. Each healthcare system should ultimately decide what type of testing they can offer.



It sounds like the regulatory structure for testing is responsible for the shortages we see. Viral transport media is just a simple saline solution, but CLIA regulations make it difficult to validate a particular saline solution and ESPECIALLY share a validated protocol between competent labs. Doesn't our country's regulatory structure need to be overhauled?

Regulatory structure for testing is required for high quality, accurate patient testing. Pandemic preparedness planning which can include relaxation or changes to structure temporarily are what is needed to assist with testing surges.

Can't pooled testing help alleviate shortages (while enabling an estimate of prevalence)?

Maybe. It decreases sensitivity, and requires there to be a low prevalence to make it effective (i.e. if the prevalence is high, then every pool is positive).