Responses to Audience Questions
5/20/20

ANATOMIC PATHOLOGY

What are the intracellular and hematologic representations of Covid-19. aside of positive test results? Will Covid-19 present clues on a wedge smear?

It is unclear at this time. Please continue to check publications of histology and COVID as they arise.
Asymptomatic Screening

What CMS compliance issues are involved when using commercial assays in a screening context- particularly hospital programs to screen asymptomatic HCWs and pre-operative patients who are not suspected of having disease or exposure?

It is unclear at this time. Please continue to check the CMS website regarding guidelines for COVID testing.

How are you handling Asymptomatic testing? Do you have different guidelines or disclaimers that you add to results to discuss the fact that these tests are not validated for asymtpomatic patients?

Variable by site, practice, and availability of tests. The most important question is what is the data going to be used for.

Are you implementing any strategies to test employees? How are you using antibody testing?

JS: There are no return to work algorithms, only upon suspicion as ordered by occupational health

Please talk about employee testing algorithms.

Variable by site, practice, and availability of tests. The most important question is what is the data going to be used for.

Are you considering testing students (K-12) or university?

JS: We haven't specifically targeted these populations.

BIOSAFTEY

Is it safe to do in-house PCR COVID-19 testing without a safety hood? Some companies say a hood is not required.

JS: Consider heat inactivation or some other method of inactivation if you don't use a biosafety hood.

What measures does a technician take when testing for their safety?

All laboratory personnel should follow the CDC intermittent guidelines and OSHA guidelines. CDC: www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html OSHA: www.osha.gov/SLTC/covid-19/

Is anybody infected in the lab? Rate? Through contacting positive sample?

Though all data is not yet available to determine this rate, the best guidelines to use are from the CDC and from OSHA (www.osha.gov/SLTC/covid-19/laboratory.html)

Are there any special precautions the techs are taking while running the test?

All laboratory personnel should follow the CDC intermittent guidelines and OSHA guidelines. CDC: www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html OSHA: www.osha.gov/SLTC/covid-19/

What types of specialized protective equipments are the medical laboratory scientists performing the COVID-19 assays are using?

All laboratory personnel should follow the CDC intermittent guidelines and OSHA guidelines. CDC: www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html OSHA: www.osha.gov/SLTC/covid-19/

Is there any information available on how long GI biopsies need to sit in formalin before grossing to prevent possible spread of the virus?

JS: Virus should be inactivated by formalin, so whatever time is adequate for biopsy fixation should be sufficient.

So, in a lab that does not perform COVID testing, treat every sample as a potential COVID-positive, even if there is no indication from ordering physian?

A laboratory should follow standard precautions for all human samples, which includes respiratory pathogen risk.

How can we deal and handle samples, such as blood, body fluids from COVID-19 positive cases in laboratory section other than virology or bacterology? Do we have to use safety 2 or 3?

All laboratory personnel should follow the CDC intermittent guidelines and OSHA guidelines. CDC: www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html OSHA: www.osha.gov/SLTC/covid-19/

Has any laboratory scientist become infected during the testings?

JS: None reported at our facility.

is it safe to continue with frozen sections, regardless of lab findings, given the false negatives?

Please see our Biosafety Town Hall on June 9th!!

EXCESS LAB TESTING KITS

At this time, if public health labs are receiving excess consummables or reagents, what suggestion do you have on how to distribute to other labs in need of the supply chain?

We are not aware of a plan to officially distribute excess materials, but checking with your local other laboratories in your area about sharing supplies may be a good approach.

FUTURE PLANNING

There hasn't been a lot of discussion about what laboratories will do on the other side of the pandemic. Hopefully, that time will come sooner rather than later. Once this happens, many laboratories may have more diagnostic platforms than they will need for standard routine work. While we are ramping up now, should we be developing a ramping down plan now so we know how to respond when the time comes?

Excellent question and this will be addressed in the Town Hall on the "state-of-the-state" to be held in late June with several leaders from government and pathology.

GUIDELINES

Are there any resources/guidelines for small labs to cope with dynamic guidelines around COVID-19 tests and associated lab safety features?

The best approach is to follow the developing guidelines from CDC at this website: www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html

METHOLOGIES

For nucleic acid-based tests, what is the role of RNA extraction protocol? How much RNA is lost in the extraction process?

JS: This step helps enrich RNA, when RNA is uncoated, much can be lost. Therefore, we would suggest using control material of encapsulated viral nucleic acid as described in a previous blog post: labmedicineblog.com/2020/04/08/tips-for-covid-19-testing/

Are current molecular assays able to determine Covid viral load, e.g., relative Ct? If so, is this information used clinically?

JS: If a standard curve were established, this is possible. There is no known clinical correlation to viral load, so this information is not used clinically. Thus most molecular tests are qualitative and not quantitative.

MULTIPLE PLATFORMS

How do you manage reporting the different LOD's from different platforms used to test for the same target?

JS: We give the disclaimer in the initial notice to the hospital, but have not had much variability among our platforms.

What correlation needs to be done across assays?

JS: Correlation can be done when validating a new assay. However samples are not routinely run on more than one platform unless there is concern for a false negative and the sample is run on a more sensative platform (RT-PCR).

I am wondering how are these instruments calibrated and quality controls performed? Do you have CAP-authorized reference ranges, considering this tests of COVID-19 is performed on different platforms?

JS: All of our tests are qualitative (positive or negative result), so no calibration is performed. We use enveloped artificial RNA from SeraCare as our control material. This is also the case for our antibody testing.

How have you dealt with obtaining validation samples for COVID testing, specifically antibody serum samples?

JS: Validation samples are obtained from area labs such as public health labs, which are glad to help out. Serology specimens had to be collected from patients who tested positive for COVID-19 already by PCR based tests. This was more difficult to obtain.

Are you binning test orders using LOINC codes?

Please see this link regarding LOINC and COVID: loinc.org/sars-coronavirus-2/

Is it better to have multiple (commercially available) testing platforms, or to focus on LDT supplementation to ongoing service?

It depends on the volume of practice, the patient mix, and the acuity of results that are needed. Each lab must also consider personnel needs, costs, and turnaround time.

REGULATIORY

Have there been any complications or issues in regard to regulatory agencies and developing Covid-19 testing in your labs? If not do you forsee any?

JS: This has not been an issue, we applied for an EUA, but the FDA decided it wasn't necessary in the end as our instrumentation was sufficiently similar to other instruments validated for the CDC assay.

SALIVA TESTING

In saliva, I thought I heard that there was concordance in negative results between nasopharyngeal and saliva. Is that true for false negatives as well?

JS: The study with saliva was performed using an RT-PCR method, which has fewer false negatives. The issue of false negatives is probably related to platform more than sample type.

Does it look like the saliva tests will be used more for children going back to school?

JS: Saliva testing could be useful for places with poor access to specimen collection supplies or at home testing. Not specifically developed for children, but no reason to preclude its use there.

SAMPLE COLLECTION

Are you getting patient collected swabs/ saliva vs nurse/med personnel collection?

Please see our Biosafety Town Hall on June 9th!!

How are swab collection requirements relayed to collecting staff? Some platforms require a dry swab, others require placement in VTM. How is this handled on the collection side?

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Is anyone using induced sputum?

Excellent question and this will be addressed in the Town Hall on the "state of the state" to be held in late June with several leaders from government and pathology.

Are your phlebotomists collecting nasopharyngeal or oropharyngeal swabs in your outpatient laboratory drawing sites?

Please see our Biosafety Town Hall on June 9th!!

SEROLOGY

What is your opinion of the value of antibody testing, and which is the best approach? A total IgG/IgM test, IgG or IgM by itself?

Please see our Serology Town Hall on June 3rd!! www.ascp.org/content/learning/ascp-virtual-town-hall-series.

if you have instruments from Abbott, how accurate is Abbott's antibody testing specific to COVID-19?

JS: Our study using this platform showing very good specificity (n>700, 0% false positives), but sensitivity is best after 14 days.

How do laboratories and clinicians use antibody testing right now without a standard or recommended algorithm from CDC or ASCP?

Please see our Serology Town Hall on June 3rd!! www.ascp.org/content/learning/ascp-virtual-town-hall-series.

Are you doing the antibody testing to see if someone has had this?

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There have been multiple serology assays that are available from various vendors. IgG, IGM, IgA, Total ab (IgG+IgM) and Antigen assy. Can you provide insight based on current CDC and FDA guidelines with focus to serology which assays would be useful in the test utilization ground?

JS: It is still very early without sufficient data to answer this question well.

Any experience with Antigen tests far COVID-19 testing?

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What population are you testing for antibody? Employees, or just determining prevalence in patient population?

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Can any of the doctors provde guidance on what they did to validate the antibody tests? There is difficulty in getting specimens.

JS: We used residual specimens from patients hospitalized with COVID-19 or from employees who had previously tested positive >14 days ago.

Do you a preference to Abbott serology kit over Roche? Also, what is your thought on manual ELISA TESTS targeting S1 s2 antigens?

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What is your input on serology multiplexing platforms?

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Which of the antibody tests in your labs has been most sensitive and specific? What is the lowest titer range you have been able to detect?

JS: Our platform does not give a titer. It only gives a relative signal to noise ratio that gives a result of positive or negative.

Conventional wisdom is to use serum specimens for serology; any thoughts on expanding to plasma and EDTA plasma?

JS: We explored alternative specimen types including EDTA, Citrate and Heparin anticoagulated specimens and all had very equivalent test results. We would be interested in testing for antibodies in saliva (gingival swabs like in at home HIV tests).

What do you believe are indications for performing COVID-19 antibody testing? It seems to be a laboratory test desperately in search of an indication for individual patient care.

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Has anyone had experience with the new viral antigen testing?

Please see our Serology Town Hall on June 3rd!! www.ascp.org/content/learning/ascp-virtual-town-hall-series.

Should a rapid serology covid testing be necessarily done under a BSC level 2?

JS: Studies have shown absent to very low viral loads in the blood of patients.

How exactly are you using the serological testing - total antibody or IGG vs. the PCR testing for diagnosis/treatment or how are they being used in conjunction? My lab now has the PCR Cepheid and m2000 platforms and now total antibody testing on the Vitros 5600.

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Should a serology Covid rapid testing be necessarily done under a BSC level 2?

Variable by site, practice, and availability of tests. The most important question is what is the data going to be used for.

STRESS MANAGEMENT

What are some coping and stress management resources helpful for those in the lab?

www.ascp.org/burnout

SUPPLY CHAIN

Will the reference labs start to validate 3D printed NP swabs?
Unknown.

SURGICAL TESTING

What decision will you make if a patient is Covid-infected and yet requires a mandatory surgical procedure?
Depends on each individual units infection control policies, ability to sequester patients, and urgency of surgery.

You mentioned a rise in the number of routine surgeries. Do you feel that there may be some sort of risk of possible contamination of COVID-19 in the transfer of specimen samples sent from routine surgeries to the surgical pathology laboratory?
As long as standard procedures for handling infecitous specimens are followed, there should not be transfer.

With the increase in elective surgeries, has there been any determination on the amount of time a small surgical biopsy should remain in formalin to inactivate the virus before grossing? I want to keep my employees safe from possibly spreading the virus.
The virus is inactivated by formalin but the best guidance is to review the CDC's guidelines on tissue found here: www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html

TASK SHIFTING

Can cytotechs run these molecular platforms (with appropriate training) or is it restricted to med techs? Our cyto department has seen a big drop in pap smears, and cross-training may be our way to keep people productive while learning new skills.
Trained laboratory professionals with a medical laboratory science degree like cytotechnology may be eligible depending on the state and licensure requirements as well as the discretion of the laboratory director. Task shifting for the cytotechs may also be a way to backfill other lab services.

Is there any move to reach out to medical laboratory technician programs in states to help with staffing in the labs for licensed and non-licensed positions?
This has been done in several different ways and we encourage innovative approaches to staffing challenges.

TESTING ACCURACY

What do you think about accuracy of rapid COVID-19 test? I heard 15-45 percent false negative.
JS: The testing methodology of the ID NOW is different from RT-PCR based assays, so there any limitations in sensitivity likely arise from the different methods used.

What is the value of running rapid POC tests with such high false negative rates? If results can't be trusted, shouldn't that platform be abandoned?
JS: These tests are very widespread and used in doctors offices and large hospitals. They have a good positive predictive value, but clinical judgement should still be excercised in a suspicious but negative case. Samples could be reflexed to a more sensitive assay.

Do you have any data on the sensitivity of middle turbinate specimens? As NP swabs dwindle, we are using E-swabs and patients/clinicians are pushing back against nasopharyngeal collections with the larger swabs and they are collecting middle turbinate instead. We've had at least one patient with two middle turbinate negative results who then tested positive with an NP swab 24 hours later.
Please see our RT-PCR testing Town Hall on June 17th! www.ascp.org/content/learning/ascp-virtual-town-hall-series

Are there any issues or problems with the same lab test having different sensitivities and specificities when testing patients in different parts of the country with different levels of COVID-19 prevalence?
Please see our RT-PCR testing Town Hall on June 17th! www.ascp.org/content/learning/ascp-virtual-town-hall-series

Several of the RT-PCR assays are based upon the "Washington" genome. Are the different mutations close enough that these assays in effect all the mutated versions?
Please see our RT-PCR testing Town Hall on June 17th! www.ascp.org/content/learning/ascp-virtual-town-hall-series

Can you comment on the sensitivity of molecular testing using nasopharyngeal vs. oropharyngeal vs. nasal swabs vs saliva as the specimen type?

Please see our RT-PCR testing Town Hall on June 17th! www.ascp.org/content/learning/ascp-virtual-town-hall-series

What is percentage of false positive? Is there any other measure to verify false positive or any other alternative for testing COVID19?

JS: I discuss this some in this blog post: labmedicineblog.com/2020/05/11/extraction-free-and-saliva-covid-19-testing/

Do any of you have experience with the Roche assay and the detection of the pan-SARS target on low level positive samples? We tend to see T2 only positives on previous positives.

Please see our RT-PCR testing Town Hall on June 17th! www.ascp.org/content/learning/ascp-virtual-town-hall-series

TESTING AVAILABIILITY

Since reagents are so limited, have you had to ration testing within the hospital? How do you decide how to ration testing?

Great question and we will address these in the next town hall. www.ascp.org/content/learning/ascp-virtual-town-hall-series

I do not understand why Cepheid limited marketing to their kits to only hospitals, when I am a reference lab for seven critical access hospitals with a daily courier service. In Illinois, before surgery, patients must have a negative COVID-19 test 72 hours before surgery. The state is really not set up for this testing, but it is, for some facilities, the only option. I have used the Cepheid for GC and Chlamydiae and have not done Flu testing since all of the facilities are doing this testing.

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Where do you feel test capacity is going to level off at, considering maintenance and QC needs?

Excellent question and this will be addressed in the Town Hall on the "state of the state" to be held in late June with several leaders from government and pathology. www.ascp.org/content/learning/ascp-virtual-town-hall-series

TESTING STRATEGIES

How are facilities accounting for bias with this kind of triage testing? Would you have to inform the public that you are screening them specific demographics?

Excellent question and this will be addressed in the Town Hall on the "state of the state" to be held in late June with several leaders from government and pathology. www.ascp.org/content/learning/ascp-virtual-town-hall-series

Why does ASCP not release a white paper on Covid-19 testing? Seems hourly that CNN, FOX or whoever is asking who should be testing. What should they be tested for and with what test? When should testing be done and at what frequency? Answer these questions and release to the press. It will help a lot of people.

Excellent question and this will be addressed in the Town Hall on the "state of the state" to be held in late June with several leaders from government and pathology. www.ascp.org/content/learning/ascp-virtual-town-hall-series

What is the current algorithm you're following in testing for CoVID?

Excellent question and this will be addressed in the Town Hall on the "state of the state" to be held in late June with several leaders from government and pathology. www.ascp.org/content/learning/ascp-virtual-town-hall-series

Now that the molecular equipment is in place, is there any thought to expanding the list of test we can run in the lab, like more diagnostic testing for various viruses?

JS: This will be a discussion once the COVID-19 testing needs have decreased. It will be based upon how many viral PCR tests are sent out. Transplant and cancer centers like ours have needs for BK, CMV, EBV virus at higher frequencies than other centers.