Clinical Laboratory COVID-19 Response Call

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Panelists

Jasmine Chaitram, CDC Division of Laboratory Systems
Sara Brenner, U.S. Food and Drug Administration (FDA)
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Bill Arndt, CDC Division of Laboratory Systems
Barbara Schwarzer, The Joint Commission
Robyn Temple-Smolkin, Association for Molecular Pathology (AMP)

JASMINE CHAITRAM: Hi everyone. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. Thank you for joining the Clinical Laboratory COVID-19 Response Call. This is the 12th call the Division of Laboratory Systems has hosted.

And we are-- the division, just for those of who that are new to the call-- I know I say this every week and it might sound like a broken record, but I always say it for the folks that are new to the call-- the Division of Laboratory Systems at CDC is focused on laboratory quality and safety, informatics and data science, biorepositories, and workforce and training. And so we also-- the purpose for these calls is we have a preparedness and response activities that we support for clinical and public health laboratories. And during the COVID-19 response, we have been serving as an interface between the Emergency Operations Center and CDC for the clinical laboratory community. And we've been hosting these calls weekly in hopes that we've been answering your questions and providing valuable information to you.

I am showing the agenda for today's call. We have a number of great speakers lined up. And I also have some housekeeping things that I want to cover with you before we get started. I always show some important links that we provide on our slides.

And this is also an opportunity for me to remind you that these slides are posted after the calls as well as the transcript from the call on CDC.gov/safe labs. And you can go into the Resources and Tools to find the slides and the transcripts there. And that's where you can find these links if we're going too quickly.

The other thing that we're doing this week instead of the survey is we're going to do a live audience poll. And this is to help us determine the frequency of these calls going forward. So the poll will be in progress for the next couple of minutes. And we would thank you for those of you that are already giving us your input. This will definitely help us in planning for the future.

And as I've mentioned before, we are interested in hearing your training needs and ideas. And so you can submit those to LabTraining@cdc.gov. . And as I've said before, we want to hear your questions. So please submit those through the Q&A button in the Zoom features.

And again, the reminder that we do our best to answer these questions both on the call, after the call, through LOCS messages, through future agenda topics. And so thank you for submitting them. We use them to guide the information that we need to provide on future calls. And it helps us to understand what the needs are of the clinical lab community and public health during this time.

And so thank you for submitting them. So keep submitting them. And just know that if we don't get to your question for some reason, either through the call and all of the feedback that we're providing, you can always submit your questions directly to DLSinquiries@CDC.gov; we will get an answer for you.

And with that, we are going to move into our first agenda item. And I think we're going to end the poll right now. And so our first speaker is Tim Stenzel from the Food and Drug Administration.

And he will give an update on FDA as he has done pretty much every week since we started these calls. Tim? Are you there, Tim?

TIM STENZEL: Thank you. Yeah, can you hear me?

JASMINE CHAITRAM: Yes, I can hear. You're good.

TIM STENZEL: OK. Yeah, so we had a few questions. Going to run through them now. So the first question has to do with RUO assays for cytokines?

You know, if you develop a test and offer it, does it require an EUA to be able to do that? And yes, EUAs for cytokines are required if claims for use with COVID-19 patients are made. And we have already authorized one IL-6 assay. And there were none to our knowledge that we're on the market prior to this emergency and pandemic. So we look forward to authorizing additional cytokine assays for use in support of COVID-19. patients.

Second question has to do I think more broadly, and not necessary more broadly, but it has to do I think, with-- it says Tim, still confusing, are LDTs from individual labs that are only being used in that institution in need of an EUA? Understood that kit manufacturers must have an EUA to distribute. Yes, LDTs for at least for viral detection diagnostic assays require an EUA, even if from individual labs, and only when used on their own patients at their own institutions.

However, serology testing is different. We have provided guidance that says for serology testing, LDTs serologies are not required, though they're encouraged for EUA submissions and authorization. So again, for say, molecular or for any viral detection diagnostic assay, yes, all

developers are required to get an EUA. There is the notification pathway, though. So read the guidance.

You can develop the assay, validate, notify. And then for molecular assays, you can submit an EUA if you're in a lab within 15 business days. For serology, again, laboratory developed tests for serology are encouraged, but not required to submit an EUA. They can also unnotify, if they wish.

The next set of questions has to do with the category of at-home testing. So the question is quite long. Is there a focused activity to adopt long term and ongoing government approved at-home self-point-of-care testing for COVID-19 that is affordable, reliable, and available for all?

The lack of access to COVID-19 testing has obviously affected over 90% of our nation and the majority is the underserved population. Health care workers urgently need this as much as the public. Our nation needs this for us to get back to some kind of normal.

So the short answer as far as home testing goes is yes. This is a high priority for the FDA and our review process. If we get anything that requires an EUA, such as home collection or home testing, it automatically gets a priority review, because it cannot be launched until the EUA authorization happens.

Also, there is significant funding for this kind of test development. It was recently authorized under the RAD X, that's the R-A-D X, which stands for Rapid Acceleration of Diagnostics, under the operation warp speed efforts to bring accurate, safe, effective point of care test to market by the end of summer. This is a $1.5 billion initiative not led by the FDA, but led by NIH, of which $500 million is going into the RAD X Tech program focused on developing a point of care molecular diagnostics. The FDA is engaged with NIH and other stakeholders in this effort with the goal of delivering millions of tests per week to Americans before the fall.

So a next question has to do with pooling. And are there guidelines for pooling samples? Does it need an EUA submission if the test is already approved as an EUA?

So the current thinking for this is that-- well, first of all, we are still working on recommended validation for pooling. And we again, hope that it gets out very soon. I think there is an effort now to get it out very soon-- I can't promise when-- in which we provide recommended validation for pooling of samples. For kit manufacturers, yes, pooling is required to have an EUA. For labs, our current thoughts have been that authorization is encouraged, but not required.

We would prefer to see EUAs for all users for pooling. One of the opportunities in pooling is try to avoid false negatives. So however, almost any pooling scheme will end up resulting in some false negatives, at least as far as viral detection goes. Whether that viral detection has clinical significance or significance for potential transmission of that virus is yet to be determined, if it's

extremely low in that particular situation. But every pooling scheme we've looked at does have its downside of reducing sensitivity, especially at the very low end of LOD.

So we do recommend that you determine whether or not you will be missing any samples with your pooling scheme, even at the low positive range. We would encourage that if the number of say, positives is that you include in your pooling validation is somewhere around 30, that for that level of positives that you intend to not miss any with your pooling scheme. We also suggest that you have limitations and warnings that low negative sample could be missed in the pooling scheme. If you feel like your pooling scheme won't miss any, we'd love to talk to you about that. And if that's true, and we'd be happy to share with others.

Finally, the topic of self-collection. So we have obviously authorized a number of self-collection situations. We have also allowed health care worker observed self-collection of the anterior nasal passage when swabbed on both sides using an EUA authorized assays. So health care observed self-collection by laboratory systems and hospital and clinic systems is fine when you're using an EUA authorized assay.

However, if it's going to be unobserved, not directly observed by a health care worker, an EUA authorization is required. The most common situation obviously, is in the home collection situation. The reason we require this is we have seen poor performance of some developed assays when the collection is unobserved.

And I did have one other point of information. Someone else asked again, can you give the link for the calculator? This is the serology calculator, it is a theoretical calculation using one or two serology assays, and with positive and negative predictive values would be, depending on the prevalence. That calculator is on the Emergency Situations Medical Device web page under EUA Authorized Serology Test Performance. So oftentimes, the CDC provides these links.

But if you Google EUA authorized serology test performance and FDA, you should be able to find that calculator on that page. And thank you. I turn it back to you, Jasmine.

JASMINE CHAITRAM: Thank you so much, Tim. And we got a few questions online while you were speaking. I'm going to ask you one of them. Can a CLIA high complexity laboratory use a molecular test that is distributed by an international manufacturer who did not notify the FDA?

TIM STENZEL: If they perform their own validation of that test and notify-- if the lab notifies the FDA and submits their EUA validation data within the required time period, then they can use that test, that they're taking responsibility for the EUA authorization of that test.

JASMINE CHAITRAM: Thanks. And here's another one. If testing is done for surveillance and not diagnosis, do you need to have an EUA?

TIM STENZEL: So if purely done for surveillance, the FDA does not require an EUA. There are a couple situations that are very clear. If you have an EUA authorized assay, and you're doing surveillance, there's really no issues. If you're doing--

[CELL PHONE RINGING]

If you're doing-- pardon-- if you're doing an IRB study, you can also return results with that surveillance. But the FDA does not regulate purely surveillance activities.

JASMINE CHAITRAM: OK. Thank you so much, Tim, for the FDA update. We're going to move to our next speaker. It's going to be Bill Arndt from the CDC Division of Laboratory Systems. And he is going to give us the laboratory biosafety update. Bill?

BILL ARNDT: Thanks Jasmine. Good afternoon, everyone. So my name's Bill Arndt. And I'm the Biosafety Program Lead in the Division of Laboratory Systems at CDC.

Over the last couple of weeks, the CDC has made several changes to the COVID-19 Laboratory Biosafety web page, as well as the biosafety FAQs. The updates to the interim laboratory biosafety guidelines include new guidance for anatomic pathology and point of care testing. And for the anatomic pathology guidance, it's really intended for specialties such as surgical pathology, histotechnology, cytology, and autopsy. The new POC testing guidance provides more detail on the locations for the potential use of POC testing, as well as some additional things to consider when implementing POC testing at your laboratory or other locations outside of a traditional laboratory setting.

The major update to the laboratory biosafety FAQs was that they were combined with another set of laboratory specific FAQs. So now, all the laboratory FAQs are located in a single location on the website that is the Frequently Asked Questions for Coronavirus COVID-19 for laboratories. Now all the laboratory associated FAQs are located in a single location and cover a variety of different topics, which include general testing guidance, ordering a supply, serology, and the biosafety FAQs that we previously had.

We've also added some additional biosafety FAQs to the new FAQ page for anatomic pathology, POC testing, and the use of pneumatic tubes for transporting specimens. I would recommend those interested to review these pages, these updated web pages, to ensure that you are aware of the most recent recommendations provided by the CDC. That's the updates that I have at this point. So thank you for your time. And I will now turn it back over to Jasmine. Thanks.

JASMINE CHAITRAM: Thanks, Bill. I do have another question for you that came through here online here. It says do blood specimens from COVID-positive patients need to be shipped as Category B specimens?

BILL ARNDT: So at this time, the guidance for packaging and shipping samples is the same. So all patient specimens associated with a suspected or confirmed COVID-19 patient should be shipped as Category B. That's still the current recommendation guidance provided by the CDC.

JASMINE CHAITRAM: OK. Thank you. And I'm not showing any other biosafety questions right now. So we will move to our next speaker.

And the next speaker is from The Joint Commission. And it is Barbara Schwarzer. And thank you Barbara for joining us. And we are ready for you whenever you are.

BARBARA SCHWARZER: Thank you Jasmine. And good afternoon, everyone. I'm the Field Director for the Laboratory Accreditation Program at The Joint Commission.

And today, I would like to talk to you about how The Joint Commission is getting back to conducting on-site laboratory surveys, and how the COVID-19 pandemic will influence laboratory surveys of the future. And then I want to show you how laboratory surveyors are ready, relevant, and responsive as they return to survey.

Next slide, please. First, I would like to share with you a message from Dr. Chassin, President and CEO of The Joint Commission. And we want to thank you. Joint Commission leadership wants to thank you for allowing us to visit your organization. We know that you are working tirelessly to keep your communities, patients, and each other safe during this coronavirus pandemic.

And we're sure that your communities know how hard you have been working. And then we commit to you. In this time of uncertainty, when the rules seem to change every day, we are committed to working with you to continue to create safe, highly reliable health care, and to share lessons learned by other organizations just like yours. And then we will all come together stronger than before. We will overcome the unprecedented challenges that we face.

In addition to conducting accreditation surveys and reviews, we have been advocating for the safety and well-being of health care workers at the highest levels of policy-making. We are here for you. We are here to help you. And then our extensive training and infection control practices will ensure safety for your organization during the survey process, and provide valuable guidance for you to improve care when the survey is over. Next slide, please.

So we are ready. And I want to tell you about how we prepared. All during the quarantine and downtime, Joint Commission laboratory surveyors have been working very hard to get ready for the day to return to survey with your safety and surveyor safety at the top of our list. We created a COVID-19 algorithm of safety for survey locations. And it's based on data from available news sources and CDC guidelines.

And we are able to measure the safety of a geographical area primarily by county on a daily basis to determine if it is safe to send our surveyors there. And we've been doing outreach calls.

Our account executives have reached out to you to answer your questions and to assess your readiness to have us come to survey your laboratory. They will ask if you were still under your emergency operations plan, if you had any new staff COVID cases in the last 14 days, if there were any visitor restrictions, and if you felt ready to have us come to survey you.

And then we have been training. Prior to going out on a survey, all surveyors have been trained in emergency management and infection control by subject matter experts to ensure your safety and the safety of your patients. We have learned when we should wear masks, the importance of maintaining physical distancing at all times to protect both surveyors and your staff, how to disinfect laptops between areas, how to use technology to maintain physical distancing when doing tracers and reviewing documents.

We're going to focus on emergency management and infection control during the laboratory survey. With a focus on emergency management and infection control, we will assess compliance with all of The Joint Commission laboratory standards since the last survey, including the period of the public health emergency. We'll review EUAs, quality control, proficiency testing, calibration verification and correlations, during the public health emergency.

During a public health emergency, we are at our most vulnerable point. And we want to help you assess risks and validate good practices with sensitivity, with wisdom, and with providence. In addition, we have hired new surveyors and several new pathologists to help us serve you. Next slide, please.

As we return to survey, Joint Commission laboratory surveyors are relevant. As always, we want to make sure that we focus on quality and safety of patient care in this new environment. We want to help you get to zero harm in this new ever-changing pandemic environment. Few of us ever thought to include COVID-19 in our risk assessments. We want to help you get through this time.

We also recognize your tireless work. We recognize the selfless commitment that you have made to take care of your patients, to get supplies, to implement new tests quickly and safely, to work short-staffed. And we appreciate all the work that you have done.

As we go out on laboratory surveys, we will share best practices that we have seen across organizations, recovery efforts, wins, and lessons learned by laboratories just like yours. And we are excited to say that we'll be beginning virtual surveys. We have been approved by CMS to perform virtual surveys. And we have submitted our plan and will soon begin them in those areas where it is not safe for our surveyors to travel. The virtual survey can be conducted in the near future with a follow-up site survey when it is safe to return.

We will promote safety and efficiency during this survey. We'll maintain physical distancing to protect all staff and surveyors. And we are combining the sessions for opening conference,

emergency management, infection control, and leadership, so that we are very conscious of your time constraints during this time.

We may ask for fewer participants in the survey in order to maintain physical distancing. Our laboratory surveyors will wear masks. We will practice diligent hand hygiene and maintain physical distancing. Next slide, please.

We are responsive to you. We will seek to understand. And we want to hear your story and your plan to move forward, because we are here to help you. We want to listen to how things have changed for you.

And we want to help. The Joint Commission website is continually being updated, and it's there on your screen now. It's updated with FAQs, resources, and webinars specifically for lab.

In conclusion, as laboratory surveyors return to survey, we will be masked. We will be six feet apart. And we will not reach out to you to shake your hand or give you a hug. But we are still your Joint Commission laboratory surveyors. And we will be happy to see you and work with you again.

And the last slide, please. We can take questions and there's also an email address there that you can use to send questions in directly to The Joint Commission regarding laboratory.

JASMINE CHAITRAM: Thank you and I expect that you will probably get some questions to that email address. I did get a few questions for you while you were speaking. The first one is what percentage of U.S. laboratories are inspected by The Joint Commission?

BARBARA SCHWARZER: Ooh, that's a very good question. I don't have the specific answer to that. But we do survey laboratories all across the United States within hospitals, independent laboratories, everywhere in the United States.

JASMINE CHAITRAM: Thank you. And are you limiting the travel of your surveyors to driving distance only?

BARBARA SCHWARZER: We are at the beginning. We started back very carefully, only sending surveyors out within the driving distance. But we are expanding to being able to fly so that we can increase our geographic area.

JASMINE CHAITRAM: OK. And are you going to schedule lab surveys? And what would be your notification timeline?

BARBARA SCHWARZER: The account executives will be calling organizations starting at about two weeks out from when they would be surveyed. We will not give the exact date. The exact date of the survey is still unannounced. But we will be calling you ahead of time to assess your readiness and make sure you are ready to have us come survey your lab.

JASMINE CHAITRAM: OK, great. And I had another question for you. When do you think you'll start virtual surveys?

BARBARA SCHWARZER: Well, we're hoping to within the next month. We've been approved. And we've submitted our plan. And we're just waiting to hear back before we can start those surveys.

We are doing hospital virtual surveys and ambulatory care. So the model has been set. And we're very excited to start as soon as we get the go ahead.

JASMINE CHAITRAM: OK. There's one more question I'm going to ask you. Um, sorry. I'm just scrolling through the through the list here, trying to find it. I saw it a second ago.

I'll ask you this one in the meantime. There's a question about what happens if they're past the due date for the survey, I guess, for submitting information? So what happens past The Joint Commission due date?

BARBARA SCHWARZER: Yeah. We have gotten approval to give extensions because of the COVID-19 pandemic. But we are prioritizing those with the earliest dates and also along with the areas that are safe to come to survey, so that by getting the virtual surveys going, we should be able to get a lot more caught up in areas where we cannot travel yet.

JASMINE CHAITRAM: OK, great. And the last question I'm going to ask you-- and I think you've already answered this, but just one more time to make sure folks understand it. How far in advance will the organization be asked about their emergency protocol, new staff cases, visitor restrictions, et cetera?

BARBARA SCHWARZER: Probably within starting it two weeks prior to when we would be coming out. So the account executives will give us the laboratory organization a call, assess the readiness, and then two weeks and more beyond that would be the time that the survey would be scheduled if everything is OK.

JASMINE CHAITRAM: All right. Thank you so much Barbara for joining us and for the great presentation. We're going to move to our next speaker and our last speaker for today who's going to be Robyn Temple-Smolkin from the Association of Molecular Pathology. And she'll be talking about a summary of the SARS-CoV-2 molecular testing survey that was recently done by AMP. Robyn?

ROBYN TEMPLE-SMOLKIN: Thank you Jasmine. And thank you to the CDC for the opportunity to present today. The Association for Molecular Pathology, or AMP, is an international medical and professional association representing approximately 2,500 pathologists, and doctoral scientists, laboratory directors, scientists, medical technologists, and trainees who perform or are involved with molecular and genomic laboratory medicine.

Our membership includes professionals from academic medicine, hospital-based and private clinical laboratories, government, and in-vitro diagnostics industry, our mission is to advance the clinical practice, science, and excellence of molecular and genomic laboratory medicine to enable highest quality health care. AMP members continue to be on the frontlines of clinical laboratory response to the COVID-19 pandemic. Next slide, please.

In order to better understand the contributions laboratories are making and the challenges they are facing during the COVID-19 pandemic response, AMP created a robust survey to document their efforts and experiences. This survey covered topics related to clinical molecular diagnostic testing only for SARS-CoV-2, and does not address serology or antigen testing. This anonymous survey was conducted from April 23 to May 5, and was open to all laboratory professionals, offering a clinical SARS-CoV-2 molecular diagnostic test, both AMP members and nonmembers. In terms of demographics, we had 118 responses from US-based laboratories with broad participation across the country. 95% of survey takers were either currently offering clinical SARS-CoV-2 tests, or in the process of validation. Therefore, the overwhelming majority of survey respondents were actively involved in the COVID-19 response.

Approximately 40% of laboratories categorized themselves as academic medical centers, 30% community hospital or health system laboratories, and 35% commercial reference laboratory. In the laboratory industry, academic medical centers and community hospitals generally have their own on-site CLIA-certified laboratories to conduct general and time-sensitive testing for the patients within their health care system, particularly hospitalized patients, whereas more specialized, less time-sensitive testing is shipped to often out of state or cross-country commercial reference laboratories. In the terms of test's methodology, our results indicate that 50% of laboratories are solely using commercial test kits with emergency use authorization, 10% are using laboratory-developed testing procedures for LDPs only, and 40% are using a combination of both LDPs and EUAs. Laboratories also report that more than 60% of those surveyed are running at full staffing seven days a week to perform SARS-CoV-2 testing. Next slide, please.

Once laboratories were able to develop SARS-oV-2 tests, they responded rapidly. However, while laboratories quickly launch tests, supply chain disruptions have had, and are continuing to have, negative impacts on providing SARS-CoV-2 testing. Laboratories report that supply chain interruptions have had a significant impact on their testing capacity, with over 85% reporting that interruptions have delayed and/or decreased testing.

The types of supply chain interruptions that laboratories experienced were vast, and include test platforms, test kits, reagents, swabs, transport media, laboratory consumables, and PPE, with swabs being the largest limitation across laboratories. Interestingly, the types of supply chain interruptions were similar across laboratory types with the exception of test kits. Over 40% of academic medical centers and community laboratories report currently experiencing test kit supply interruptions, with only 13% of commercial laboratories currently experiencing this issue.

Survey responses across all laboratory types indicate that multiple types of additional resources are needed to implement and/or maintain testing, with specimen collection materials identified as the most needed. We will be interested in serving over time whether agencies supply chain management steps are effective and sufficient to alleviate these challenges. Next slide, please.

One laborious work-around laboratories have undertaken to alleviate the supply chain challenges is to deploy multiple test methodologies. This is unusual in laboratory medicine, as most clinical laboratories utilize a single platform for any particular test. Commercial reference laboratories reported using predominantly one or two methods, while academic medical centers and community hospital laboratories reported predominantly running three, four, or more methods. And subject matter experts in infectious disease have expressed that employing multiple methodologies is not business as usual, even during epidemic or pandemic responses. Having to source, validate, and support multiple test methodologies and sample collection types in a resource limited environment with unusual and increased pressure on an already extended testing enterprise.

Results not shown here indicate that for academic medical centers and community hospitals a key deciding factor to which test method is prioritized and used is the availability of testing reagents and supplies. In contrast, key deciding factors for commercial reference laboratories include whether the method was high throughput or if the platform was already available for clinical testing. We want to reiterate that this is not the normal course of business for laboratories and represents how hard it is for laboratories to function in a world with an inconsistent supply chain. Next slide, please.

When asked whether demand for SARS-CoV-2 testing was higher lower or approximately equal to their current capacity, approximately 30% of all laboratories reported demand higher than capacity. However, variability was observed amongst the types of laboratories when we look at demand for testing that was lower than capacity. On the left, you can see that a larger percentage of academic medical center laboratories and community hospital laboratories reported demand lower than current capacity, in comparison with only 37% of commercial laboratories. This was interesting.

However, many laboratories reported that they expect demand will increase with reopening plans, in particular, when approaching the new normal of medical and surgical care. Survey respondents also anticipated additional testing needs as we returned to work, school, and the widening for criteria for testing. However, despite significant barriers, the survey responses showed that 90% of laboratories plan to increase their testing capacity over the next one to three months. They are working towards significant capacity increases, with 75% of reference laboratories, 50% of community hospitals, and almost 80% of academic medical centers scaling up to greater than 500 tests per day. Over 80% of responding laboratories reported that they plan to add more platforms or tests to reach increased capacity.

An important takeaway here is that laboratories are working very hard to scale up. However, that increased capacity remains heavily dependent upon external factors. In addition to

questions about demand and capacity, we asked laboratories their current average turnaround time for their primary SARS-CoV-2 testing method. Overall, laboratories reported a turnaround time predominantly between 12 and 24 hours or 24 and 48 hours.

On the right, this turnaround time data is broken out by laboratory type, with almost half of academic medical centers and almost 40% of community hospitals reporting a turnaround time of less than 12 hours, shown here in green and outlined in red. In contrast, reference laboratories report a less than 12 hour turnaround time 14% of the time. This distinction is important when considering the importance of a timely result to best manage patient care and hospital throughput. Next slide, please.

Based on the survey findings, AMP has developed five key recommendations which aim to effectively leverage the United States' large and diverse laboratory network to best respond not only to the current coronavirus pandemic, but potential future pandemics. Pandemic response requires all of us in the laboratory community, regardless of our laboratory setting. And to unlock their full potential they must be sufficiently resourced with stable supply chains.

Each community's needs will be different. However, this is an opportunity for the public health and clinical laboratory communities to further expand efforts to work collaboratively as we continue to move into the re-opening phase of the pandemic response. Next slide, please.

This has been a very abbreviated presentation of our COVID-19 testing survey results. For more information, please access for free on demand, our COVID-19 virtual town hall recording, or review additional resources using the link shown here. AMP plans to continue to survey as the COVID-19 pandemic develops to assess the evolving needs of the laboratory community. Key questions we will follow over time include monitoring of and assessing changes in supply chains, ongoing workforce needs, and impacts of reopening activities.

We welcome any contact request for our future laboratory surveys. Long term AMP intends to review impacts to clinical laboratory practice, regulation, and reimbursement, and provide recommendations on how to better prepare for the next pandemic. AMP and its infectious disease subject matter experts welcome continued conversations in collaboration with clinical and public health laboratory stakeholders, governmental agencies, and policymakers to help improve not only this pandemic response, but future emerging pathogen responses on behalf of our patients. Please feel free to reach out to me at the email provided with additional questions. And thank you again to the CDC for the opportunity to speak on behalf of AMP today.

JASMINE CHAITRAM: Thank you Robyn, for joining. I've got two questions for you that I hope we can squeeze in here. The first one is the AMP survey question on turnaround time. Did the turnaround time definition include a transportation time to the lab?

ROBYN TEMPLE-SMOLKIN: It was self-reported turnaround time. We intend to dissect that out a little more clearly on future surveys. But it's a great question.

JASMINE CHAITRAM: Great. And then does AMP have a list of molecular pathology labs by state that the state lab can support with specimen collection supplies such as swabs, tubes with transport medium, and specimen transport bags? I'm in charge of a client service. And we're not supporting molecular pathology labs at this time. We would like to help.

ROBYN TEMPLE-SMOLKIN: I appreciate the offer to help. And I would encourage the person who wrote this question to reach out to me on email. We do of course, have a member listing, so we know which of our members are operating in which state or territory, of course. We don't maintain necessarily something on our website at this time. But that's something that we can discuss.

JASMINE CHAITRAM: All right. Well, thank you so much again for the great presentation. It-- really interesting results from that survey.

And we're so glad that you were able to join us today. We have about three minutes. Oh, sorry. Yeah? Go ahead.

TIM STENZEL: This is Tim. I was wondering if I could make just a brief statement before the end? But I'll let you do whatever else you want to do.

JASMINE CHAITRAM: No, sure. Go ahead, Tim.

TIM STENZEL: All right. Just want to clarify a comment I made earlier about pooling. I think it's best for the lab community to wait until we've released the recommendations for validation regarding to the regulatory pathway there.

So I hope I didn't misspeak. But I just want to clarify that for pooling, we still encourage labs to come to us with their validation plans. Thank you.

JASMINE CHAITRAM: Thanks Tim, for the clarification. We've got two minutes left. And I like to maximize my time. So I'm going to use those last two minutes to ask Bill if he's still on, a couple more biosafety questions. Bill, are you still there?

BILL ARNDT: Yep, still here.

JASMINE CHAITRAM: All right. Awesome. So the first question is about the Abbott ID Now. And does it need to be used in a biosafety cabinet?

BILL ARNDT: No. So that's a good question. So we've gotten that question several times. And the guidance we posted for the new guidance for the POC, for POC testing that was recently posted to the website as well as the FAQs would apply to the Abbott ID Now.

We currently do not have a specific recommendation that says the Abbott ID Now must be-- or is recommended to be used in a BSC. However, the facility should do their own site-specific risk

assessment to make that final determination. I would just refer them to the current guidance that's on the Interim Biosafety Guidelines for POC Testing, as well as the FAQ page.

JASMINE CHAITRAM: Great. And two more questions that are similar. So I'm going to ask them both at the same time. If it's still required not to use a pneumatic tube system for respiratory swabs? And do all specimens need to be hand-delivered to the lab and avoid the pneumatic tube transport system?

BILL ARNDT: Great. Good. Thank you. There is a new FAQ for use of the pneumatic tube system.

The current recommendation by the CDC is that the respiratory specimens should not-- should still not be transported through the pneumatic tube system. That does not mean all specimens, but just the respiratory specimens. And if you refer to the FAQ page under the one that talks about the use of pneumatic tubes, it'll give you-- it'll give you a general idea of respiratory specimens we are referring to with that recommendation.

JASMINE CHAITRAM: All right. Well, thank you very much. We are going to wrap up today. I'm going to remind you that if you want to receive messages from CDC, especially information about joining these calls, to send an email to LOCS@cdc.gov and we will put you on our distribution list.

As I said before, the slides and the transcript for these calls will be posted at cdc.gov/safelabs under Tools and Resources. Our next call will be next Monday, June 22, at 3:00 PM. And based on our poll results, we will announce what our call schedule will be going forward on the June 22 call. And I want to thank you all again for submitting your questions, for participating in the surveys for the last few weeks, for joining us on these calls, and for everything that you're doing to support the COVID-19 response. And that concludes today's call.