Clinical Laboratory COVID-19 Response Call

June 1, 2020

Panelists

Jasmine Chaitram, CDC Division of Laboratory Systems
Dr. Robert Redfield, Director, CDC
Brad Smith, Centers for Medicare and Medicaid Services (CMS)
Tammy Beckham, U.S. Department of Health and Human Services (HHS)
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Sara Brenner, U.S. Food and Drug Administration (FDA)
Chris Elkins, CDC Laboratory Task Force for the COVID-19 Response
Vicki Olson, CDC Laboratory Task Force for the COVID-19 Response
Kathy Nucifora, COLA

JASMINE CHAITRAM: Hi, everyone. Sorry for the delay, and thank you for joining the 10th clinical laboratory COVID-19 response call. These calls are hosted by the Division of Laboratory Systems at CDC. The Division of Laboratory Systems is focused on quality and safety, workforce development and training, informatics and data, and biorepository science.

We are also working closely with public health and clinical laboratories around the country to support preparedness and response activities. And, in particular, during the COVID-19 response, we've been serving as an interface between the Emergency Operations Center at CDC and the clinical laboratory community.

Today we have a full agenda, as always, and we have a special guest speaker-- the CDC director, Dr. Robert Redfield. And we were having some technical challenges getting him to sign on so we are going to just check and see if he's there now.

OK, so as we work to get that connection done, I'm going to actually go ahead and give you some other updates-- the normal updates that I give before these calls. Here are some important links. We usually show these each week. They are websites that CDC has with important information, including our CDC Laboratory Outreach Communication System, where you can find all of our posted messages that we've sent out since January.

We also have our LOINC in vitro diagnostic LIVD test code mapping for SARS-CoV tests-- we talked about that on a previous call. As well as interim guidance for collecting and handling and testing clinical specimens.

During these calls, we do ask for your feedback through a survey, and the survey link is here. Thanks to everybody who has participated and provided that feedback. We've been using that information to improve our calls and also help us with future agenda items.

And the survey should be open for you to take during the call or you can take it later. It's open usually for about a week. And we do send out an email after the call with information about how to do that survey. We also have asked for information and ideas on training and workforce development needs, and shown here on this slide is the email address where you can submit those suggestions.

And to ask a question-- I've covered this before, as well-- we ask that you submit your questions using the Q&A button in the Zoom webinar system. And there's some specific instructions here on how to do that.

One other thing I wanted to mention that during these calls, we do get a lot of questions, and we have gotten a lot of feedback through the surveys about answering questions. And we're doing the best we can to provide information and responses, and we do that through a variety of methods.

Sometimes we have speakers that are answering questions or other DLS staff answer questions in the Chat box as they come in. Sometimes we have speakers answer questions after the call, and we provide those answers by email. We also do that for some of the questions through DLS staff.

We share some of the questions with our partner agencies, specifically the ones that are for FDA and CMS, CSTE, as well. And they will either answer the questions or they will use those questions to guide their agenda items for future topics on these calls.

So keep submitting those questions. We will do our best to answer them. And we will, hopefully, get back to you quickly with those answers.

And so, I'm going to go back and see if we are able to get our first speaker on the line.

OK, so sorry, again, folks. There's always technical difficulties when you try to use technology. And so I'm going to ask for FDA to speak on-- give their normal update, as well to answer a few questions that we've received through these calls and through emails. And FDA does not have PowerPoint slides other than two slides where I will be showing some links to important information that FDA has.

So Tim, would you like to go?

TIM STENZEL: Yes, can you hear me OK?

JASMINE CHAITRAM: Yes, you sound good.

TIM STENZEL: Great. All right. Well welcome, everybody, again, on a Monday. So the FDA has now authorized 117 EUA assays, including three new serology assays. So we now have 15 serology, and we still have just one direct antigen test.

In the interim since the last call, we have begun implementing some of our new serology guidance. And as a result, there are now 31 serology kits that have been removed from the notified list. There is a new list on our website that lists those tests that have been removed. So you can see those on our website.

Some of them, I'll say, have voluntarily withdrawn their tests from the market. So you can check out that list at our Frequently Asked Questions web page for the FDA.

So we also have in the interim period, we've authorized more home collection and more saliva tests. So we're pleased to do that when performance is sufficient for those authorizations.

OK, I'll move into the questions that were asked on the last-- that we've accumulated since the last call. I would say that usually the agency-- the FDA will get these questions if they don't get answered online during the-- later. And we always do prepare responses for them. We also look for opportunities in the interim at any of our public forums, such as the CDRH town hall, to address questions.

There were a number of questions about the Abbott ID NOW. You may have seen the FDAs press release on the Abbott ID NOW regarding false negative results. So as stated, we're working closely with Abbott to address those concerns and confirm performance of the Abbott ID NOW in post-market studies. Abbott is performing a couple of those studies already. And we are staying in close contact with them and monitoring the performance in those studies.

As stated previously, we will ask Abbott to and have asked Abbott to perform another post-market study that has FDA input on the design of that study. And we anticipate that will be formalized in the fairly near future.

There are questions about, when will performance testing post-market studies be completed? When we update the authorization for the Abbott ID NOW, it will include timing on that post-market study. It will also say-- it'll be publicly known. It will also include an update-- as previously stated in various forums and in the press release-- that the negatives with the Abbott ID NOW are now to be taken as presumed negatives and require a confirmation if clinically indicated by an alternate molecular test.

And regarding that reflex to another molecular test there, there were questions about how to process, since the Abbott ID NOW is authorized now for a direct swab only. The VTM has been removed. So that is a process-related question that labs who want to incorporate the Abbott ID NOW can take into account about if they do get a negative result with the Abbott ID NOW, how will they collect another sample and send that for an alternate molecular test?

All right, I think that, pretty much, sums up answering the questions for the Abbott ID NOW.

We've got a number of questions about non-respiratory samples, including saliva. One question is, should the labs have to submit their own EUA for saliva testing. They can if they wish, but it is not-- it's a voluntary program for that. Labs can get authorized for it.

We did update our molecular templates both for kit manufacturers and labs with information on how to do-- with recommendations on how to validate saliva. So for saliva for a lab, which is voluntary submission for authorization of saliva, we do recommend at least 30 paired positive nasopharyngeal swabs, along with saliva. So that's 30 paired NP swabs, along with saliva.

We have seen variable performance with saliva. We have not been able to authorize every saliva submission that has come our way. So we do urge caution and careful validation of saliva. We've seen that stability of saliva samples is very important.

And we have authorized two different saliva collection devices for use in EUA. And you can look that up online on our EUA authorization website.

We also have questions about other non-respiratory samples like CSF in blood. We have not authorized those other alternate sample types. We do ask that for new samples types that we have not authorized that if you're interested in performing regular testing on those sample types, making statements that you can test those sample types, that you come in and have a discussion with our FDA staff. And you can go through the templates email address to describe how you wish to validate that.

And we would ask for EUA authorization for each new unique kind of sample type, at least for the first one. Of course, kit manufacturers, if they claim additional sample types, like saliva or any others that they don't have, they are required to get an EUA authorization for those sample types.

We've got questions about comparative tests. There's one question which I may not have come through clearly. So I don't actually know what one of the tests is so I can't speak to sensitivity comparisons or to that. But we do list performance as best we can, depending on when the test got authorized during this emergency.

Early on, they were contrived samples. You should see helpful LOD information and whether or not that particular test on contrived samples can reliably detect a positive near their LOD.

More recent tests, we've been asking for actual patient samples. So sort of comparative performance to a known standard or another alternate molecular test or another test should be evident. The first antigen test had this, of course.

There's a question about the specificity of antigen tests. We don't have a direct specificity target. We do ask that the test be at least 80% sensitive to a high sensitivity molecular test. We do expect the specificity of those antigens has to be very high.

And if there are issues with any test, including antigen tests, with specificity or sensitivity, we'd love to hear from you through our templates email address, or you can link up on our FAQ page onto the MedWatch link, or you can do both. You can send us information via our templates email address and formally provide information on the MedWatch program, which is voluntary.

And finally, if I have enough time, there were questions about testing strategies. Specifically, what is the ideal testing strategy for serology that you suggest? I just looked up these numbers-- even if you have a very specific serology test using our calculator on our Serology Performance page, say 99%, if you have a 5% prevalence of disease, only 34% of the positives are going to be true positives.

So we do suggest in the low prevalence population that you do perform two independent different antibody tests if it's important to know whether someone's truly been exposed. So I think with that, unless I have a little bit more time, I think I'll pause and let somebody else.

JASMINE CHAITRAM: Thank you very much. And that was Tim Stenzel from the US Food and Drug Administration, giving an update from FDA. And while he was speaking, I was showing some links. We did get a question last week-- there was a mention about the FDA town hall meetings. We've added a link in our slides now that shows where you can get information about these weekly town hall meetings.

And just a reminder, these slides are posted on CDC.gov/safelabs under Tools and Resources. So you can always go back and find a reference there.

Again, I apologize for mixing up the agenda today. We do have our special guest speaker, Dr. Robert Redfield-- the director of CDC-- has now been able to join us. He's in transit so we are just grateful that he was able to connect and be able to speak this afternoon. Dr. Redfield.

ROBERT REDFIELD: Thank you. Can you hear me?

JASMINE CHAITRAM: Yes, we can. Thank you.

ROBERT REDFIELD: Great. Thank you very much. And it's great to be here and be part of this call.

As the CDC director, I'm really proud that CDC's initiated this forum to share the information about the critical work that the clinical labs are doing to support our nation's response to this pandemic.

As we begin today, I just want to recognize each of you for your significant contributions to the laboratory community, to our nation's health and well-being. As a virologist and a clinician, but many of you may not know, I spent many years as a diagnostic lab director, I do appreciate the importance of the strong clinical laboratories to provide the foundation for accurate and timely disease diagnosis, prevention, and control to improve the public health and health and safety of Americans.

As our nation begins to reopen schools, businesses, places of worship, recreational facilities, and more, a triad of public health interventions that include early case identification, isolation, and contact tracing are going to be the core to these efforts. And laboratory capability is central.

And as our nation works to increase this early case identification through expanded, rapid, timely, actionable testing, we understand the challenges that much of our laboratory infrastructure and public health spaces. I recognize that the pandemic is stretching that capacity within many of the laboratories as we increase the volume.

But I want to emphasize-- this is an important time. When we are being given new resources to begin to improve the core capability of public health in this nation, which has been under-invested in for decades. This includes data analytics, predictive data analysis, and workforce development.

But it also includes central to increase the core capacity of our public health labs. To increase the laboratory resilience and their surge capacity. To increase the laboratory infrastructure so that it has multiple platforms for different tests as they're developed. So that they will to be able to respond to the clinical and public health needs that will occur. Now is the time to get that all in place.

I think, many of you know it's remarkable, the new resources that are being put in. And most recently, the $11 billion-- that's $11 billion with a B-- that has been provided by Congress to be distributed through HHS, much of which is distributed through CDC, to help build that capacity centered around laboratory testing capacity and data associated with it. Along with the actionable items of contact tracing, isolation, and quarantine. So this is really, I think, an important time for all.

CDC and HHS and our partner agencies are here to support. The work that you're doing is extremely important. And I want to thank all of you for your diligence and dedication during this emergency response.

And I want to encourage everyone to take full capacity of the opportunities we have now to, once and for all, not only build the core infrastructure from the point of view of public health and, in your area, laboratory capacity that this nation needs, but more importantly that this nation deserves. Thank you very much.

JASMINE CHAITRAM: Thank you so much, Dr. Redfield, for those remarks and for joining us today.

As Dr. Redfield mentioned infrastructure and resources, we are going to have our next speaker, Brad Smith, from the Centers for Medicare & Medicaid Services, talk about supply chain for laboratories. Brad, are you on?

BRAD SMITH: I am. Thank you so much.

JASMINE CHAITRAM: Thank you.

BRAD SMITH: Great. Well, thank you guys for taking time this afternoon. So I just want to give you a little bit of an update, along with Tammy-- who's also on the line with me-- around where we are in terms of supplies. And I will start with specimen collection supplies.

So we successfully, in May, distributed over 12.9 million swabs. And I believe, it was over 9 or 10 million-- I think it's over 9 million-- transport media to states across the country, as well as territories. All of these supplies in each state were typically shipped to a single location that was provided by the state.

We will be sending out details, either later today or maybe tomorrow morning, to states with plans for June. And what those will communicate is that we're going to continue to send the same amount of supplies that we sent in May to each state in June. As you guys know, we did about 10.7 million tests last month and 12.9 million of supplies in the states. The number of tests we sent exceeded the number of tests the states did. So we're planning to send out the same amount of supplies in June that we sent out in May, with the difference being we're going to increase the amount of transport media.

And if individual states need additional supplies, they will be able to reach out to us to request those supplies. And if they make those requests, what we will be doing is we'll be looking back at what their testing volume has been over, say, the past week, extrapolating that forward, and making sure that supports the need for increased supplies going forward.

In addition to continuing to work on specimen collection supplies, we're also very focused on the lab testing supplies. I'll talk through three of them specifically.

One, we are providing to each state, 5,000 Abbott ID NOW tests. These are being sent to the state public health lab to distribute and use in the state however the state leadership and the governor determined to be most appropriate. We are hoping to be able to extend and maybe potentially grow that Abbott contract to a larger size over later in the year, but that's still something that's in process.

In addition, we have been working and have procured a small number of Thermo Fisher tests that we're distributing out to state public health labs. We believe this is one of the tests that

can most help ramp up the volume at the state public health labs. Other folks including states and commercial labs and others are also purchasing directly from Thermo Fisher. And our procurements are primarily for the state public health labs.

And then the last piece that we've been working on has been with Hologic. We have been encouraging them and helping them allocate tests across the country, ensuring that each geography is receiving an appropriate amount of Hologic tests. That when we add that together with all the additional kind of lab testing supplies that they're receiving, in every state, it exceeds the state's testing goal for the month of May and now for the month of June,

We are leaving it up to Hologic within this state, how they distribute those tests across the different labs in the state. But we are making sure that each state is getting an appropriate amount of tests to hit their testing goal. And then we are providing the data on which labs the Hologic is going to, to the state leadership, and then giving the state leadership an option if they want to redistribute those in any way based on that specific needs they see in their state.

But I think on the whole, what we're seeing is an increase in supplies across the country. We believe and we know that there are going to be more than ample supplies to support the June testing numbers and the testing goals that each state has. And we know even in May, we sent states more supplies than tests got completed.

And what we are really turning our attention to now, in addition to supporting the work in June, is really preparing for the summer and really, for the fall. And making sure that our supply chains are ramping in advance of that time. But with that, let me pause there, and, Tammy, see if there's anything you'd want to add.

TAMMY BECKHAM: No, Brad, I think you did, pretty much, summarize what I would add. But I'm happy to take any questions.

JASMINE CHAITRAM: Thank you, both. This is Jasmine, again. So we did get a few questions through the chat box that I'm going to ask you a couple of those.

So one of the questions is, what about Cepheid tests. And the comment is, we have a very hard time getting them. So I'm assuming the question is about whether or not Cepheid tests would be available through the supply chain.

BRAD SMITH: Yep. This is Brad-- I can start with that. So Abbott ID Now and Cepheid test have been the two most in-demand tests, relative to their supply. There's only about a million of each of those per month across the country. What we've been working with Cepheid on is what's unique about Cepheid in a number of rural areas, especially-- they're the predominant instrument.

So what we've provided to Cepheid is-- because we have all the instruments whereas Cepheid only knows where their instruments are-- we provide them a list of MSA's, where more than

50% of testing capacity for COVID in the MSA is on Cepheid machines. And in addition, we've provided them a list of Cepheid machines where there is no other high throughput machine, or no high throughput machine, within 50 miles.

And we have asked Cepheid to ensure that these locations in particular are receiving Cepheid tests because they're very dependent upon the Cepheid machines. That only represents about 10% or 15% of Cepheid's total volume-- the rest is going out to their normal distribution channels across the country.

And so know we know that folks would like more Cepheid tests, but we're really making sure that we're prioritizing the geographic areas where they have to have Cepheid tests. Because those are the only machines within a certain radius, or the predominant machine in an MSA. But Tammy, anything you want to add on that one?

TAMMY BECKHAM: No, I'm good. That's perfect.

JASMINE CHAITRAM: Thanks, Brad. Another question we got-- we have not seen an impact on specimen collection supplies in Southwest Texas. Who can we reach out to?

BRAD SMITH: If that person wants to email Tammy or I directly, each state has a point of contact in the state. It's typically either the state public health lab or the state emergency management response director. And that's typically who's helping distribute those supplies. So we have supplied all of the states with the supplies. It's now up to each of those states to distribute them. But if anyone has an individual question, they can reach out to Tammy and I. We can make sure they have the appropriate contact for their individual state to reach out to.

JASMINE CHAITRAM: Great thank you. And then another-- I guess, somewhat similar-- question. How do labs that serve nursing homes get more supplies?

BRAD SMITH: So again, we're working through the states. And so as states bring us issues-- around specimen collection supplies, it's really we're sending them to the state, and then the state is distributing those within the state. So they would, for example, prioritize folks serving critical populations, or high-risk populations.

In addition, for lab testing supplies, the states are flagging for us any issues they have. And so we are responding to requests that are coming from that state leadership team and working with them individually to resolve them. And many, if not almost all, of those state leaders are focused on their nursing home populations-- one of the populations they're building testing strategies for.

JASMINE CHAITRAM: OK. Thank you so much in the interest of time, I'm not going to read any more questions. But there are several in the chat box if you wanted to take a look, Brad or Tammy. And thanks to both of you for providing that update. And once again, that was Brad Smith from CMS and Tammy Beckham from the US Department of Health and Human Services.

Before we move to the serology testing update from the CDC Lab Task Force, I did want to mention that, this weekend, we sent out a very important LOCS- Laboratory Outreach Communication System-- message about molecular transport media. In particular, the media that was supplied from PrimeStore-- manufactured by PrimeStore-- contains guanidine thiocyanate and has the potential for dangerous chemical reaction that releases cyanide gas when this media is exposed to bleach.

And there are some specific testing systems out there that use bleach during a disinfection step. And so laboratories should be aware of the media that they're using and the ingredients that it contains. And also, we will be sending out an updated LOCS message here probably this afternoon. But I also wanted to clarify that this particular media, the PrimeStore media-- is being provided by states, and it's similar to the description that Brad just gave about how these supplies are being provided through the states.

And when the state health department receives them, it's in one large box. And then those boxes are un-packaged and the media is then provided out to laboratories. And those particular tubes may not be labeled appropriately with information about the ingredients that are contained. So if you're a laboratory receiving media from your state health department and it's not clearly labeled, please ask those questions before using the media, especially on systems that use the bleach step for disinfection.

And so now, we are going to move to the CDC Laboratory Task Force. And our first speaker will be Chris Elkin. And the lab task force does not have slides similar to some of our other speakers today. So do not expect to see any slides while they're talking. Go ahead Chris.

VICKI OLSON: Actually this is Vicki Olson. I start today.

JASMINE CHAITRAM: Oh, sorry, Vicki.

VICKI OLSON: Thanks, Jasmine. So Jasmine asked us to come and talk a little bit about a recent guidance on use of serologic assays that has been published on May 23rd on our website-- this was done in collaboration with FDA-- to really address a lot of the questions as serologic assays for SARS-CoV-2 have been getting more and more interest.

So we all know that serologic assays can provide very valuable information in the investigation of transmission dynamics, which can inform prevention strategies. However, they are not recommended for use in diagnosing acute infection. The assays designed to detect the viral nucleic acid confirm that active infection while serologic assays are detecting antibodies, which can be produced one to three weeks after the infection occurred. And they are maintained for some length of time.

This is a relatively new virus, and so our knowledge is rapidly evolving. And we are constantly trying to update our guidance documents to really include this new information as it comes to

light. Serologic assays show that a person likely had a previous infection, but cannot exclude or confirm acute SARS-CoV-2 infection, currently.

Our current guidance that was just put on our website on May 23rd recommends the use of assays that do have FDA emergency use authorization. As Tim Stenzel already mentioned, there are currently 15 assays that have this approval. They are different. Some of them detect different classes of immunoglobulins, some detect all classes, some only IgG, others IgG and IgM. To date, we have no information that suggests one type of immunoglobulin class detection is preferential versus another.

The test performance characteristics-- again, Tim mentioned earlier-- are available on the FDA website. And there is a collaboration between FDA, CDC, BARDA, and NIH National Cancer Institute to really evaluate these different antibody tests. And FDA, as Tim mentioned, is putting this on their website as the data becomes available.

Also-- Tim mentioned many of the points that I was going to bring up-- one of the concerns with serologic assays is that, even though the pandemic is nationwide, there's still a low prevalence of virus within the majority of the population. These situations increase the risk of a false positive for medical use. The guidance that we have put on the use of serologic assays defines multiple methods that could be used to increase your positive predictive value for the serologic assays.

So each assay has its own sensitivity and specificity, and these are characteristics of that specific test. However, the positive predictive value of the test-- the probability that that subject with a positive test truly has antibodies against SARS-CoV-2 is tightly related to the prevalence of the disease in the population.

Again, Tim provided an example before. Just to reiterate, if the prevalence of disease is assumed to be 5%, and if you're using an assay with high sensitivity and specificity-- let's say 95%-- you're still only going to have a positive predictive value of 50% because it's so low prevalence in the population. But there are ways to increase your positive predictive value. You can do this, first off, by choosing an assay with high specificity. But then you can also focus on testing persons with a higher probability of having an exposure, such as those within an outbreak setting.

And finally, as Tim mentioned as well, you can employ alternate orthogonal testing algorithms. So you can use your first algorithm to screen individuals. And then, those who are positive, in a manner, have actually increased your prevalence of disease. Since you're only focusing on those who are positive in the first assay, you've increased your prevalence. And then the second assay, which uses a different technique, would then be used to confirm that the individual actually did have antibodies reacting to SARS-CoV-2.

And I just wanted to end with reinforcing that our guidance currently does not endorse the use of these antibody tests to determine the immune status of individuals for cohorting or return to

work. Those type of uses have to really wait until we understand the presence, durability and duration of immunity for this new disease. And now, I will turn over to Chris, who's going to speak more about some of the ways we are using of serologic assays at the CDC to answer important questions surrounding COVID-19.

CHRIS ELKIN: Thank you, Vicki. And Jasmine, are we short on time, or are we good to go? Do I have a limit of five minutes or--

JASMINE CHAITRAM: Yeah, go ahead. We did get started a little bit late because of technical difficulty. So just go ahead with your update.

CHRIS ELKIN: OK. So it's good. I just wanted to clarify that so that I can run through these and try to keep it reasonable time. So I'm happy to give a little bit more detail on our laboratory work and how it is used to support CDC surveillance studies. Along these lines, it's important to highlight that we coordinate with various stakeholders and partners such as our support for FDA with emergency use authorization validation, NIH, NCI, and state and local partners.

But we also are very much engaged in assay development. And part of that development is to generate some level of correlative protection. So understanding simple antibody detection versus the functional role and immunity. And of course, how do we use this for guideline development? So some of the studies that we do-- we're conducting sero prevalence studies to gather important information. And we want to answer a lot of questions.

How much of the US population has been infected? What is changing over time? Are there different characteristics or risk factors? How many US residents have experienced mild or asymptomatic illness? And how long can antibodies be found? The questions we currently cannot answer through serology surveillance involves immunity. And are we able to get infected again? And how many antibodies are needed to protect somebody? And can we be re-infected? And how long will somebody with antibodies be protected?

So we're hoping that some of these data will be able to answer and inform these questions going forward. So starting from a high level-- at CDC, we have some large geographic serosurveys that range from retrospective to prospective. So retrospective in looking at archived specimens, blood specimens, and prospective from residual clinical specimens, from commercial labs. And then longitudinal serosurveys in major metropolitan areas.

We also leverage our commercial laboratories and have data on greater than a million different IgG tests. And looking at overall positivity and how that is stratified across the country, especially with very high-hit areas. We also have been involved in special population and local serosurveys. So some of these surveys are representative of the community and have interview participation, determine the risk factors for infection and presence of illness.

Others are convenience samples that add to our national picture. So in some major metropolitan areas, we have 120,000-- tens of thousands-- samples out there to test that

involve acute care hospital staff, medical examiners, emergency department ICU staff, health care workers, and then local seroprevalence to look at the local burden and the risk factors for infection. So we have a good strata there.

As far as our longitudinal cohorts and natural history studies, those studies are intended to assess antibiotic kinetics function, again, the neutralization aspect, risk factors for infection, but also determine if there are antibodies that prevent or attenuate re-infection. And, of course, persistence. And persistence has a couple of different connotations with PCR persistence and then understanding exactly what is the serostatus of those individuals, and related to cross protection.

There are planned cohorts and studies in spectral populations-- households with children, health care workers and practitioners, first responders, older adults, pregnant women and, of course, cohorts of the previously infected. At this point, I'd like to talk a little bit about some of our actual laboratory work and assay development that I mentioned before.

So our laboratory has the capacity to perform serological testing that really ranges from antibody detection to virus isolation. So when we think about antibody detection, we're really talking about two things. One is detection of antibodies that bind to SARS-CoV-2. And then there's functional assays that really allow us to understand what is that correlate of immunity. Does it produce a neutralizing antibody detection? So we have capacity to do that with our in-house ELISA test that we've developed, CLIA assays that we've brought in, Ortho Diagnostics so we have that platform to report back results. And then, we also have some non-CLIA diagnostics involved, primarily with the Abbott Architect system.

As far as our neutralizing antibody detection, those are labor-intensive. So we're looking at other alternatives that involve reporter-based systems, as well as some pseudo-neutralization assays that is based on a reporter's system that's hybrid and returns a time to result within one to two days. And of course, our virus isolation work, it is BSL 3 capacity, and that allows us to get isolation of new variants, But also understanding of what does persistent PCR mean? Is there a correlate infectivity there in those samples?

So that gives a good general overview of some of our laboratory capacities. In terms of our in-house ELISA, to think about our stakeholders, this in-house ELISA was a gold standard that was used to characterize reference panels for NCI and FDA. So to develop those panels and test them so that they can be used, then, to evaluate some of these platforms that have been submitted to FDA. As far as being used for some of our other samples that have come in, these are convenience samples and have tested on the order of about 30,000, with the capacity to test about 15,000 per week.

The two commercial platforms I mentioned-- the Ortho Vitros assay that I mentioned is being used to return results back to specimens that have been submitted to the submitter. And this system uses, as its detection platform, the S1 domain of the SARS spike protein. And this is

important because it's less concerned than some other parts of the spike protein. So that does generate some more specificity.

The Abbott Architect system that we use, which is non-CLIA but is a commercial platform-- was brought in-house for a very specific purpose because the target there for detecting antibodies is the N protein. And it's a conserved immuno-dominant protein within SARS-CoV-2. But it's also important, when we think about it-- it's not being used for the SARS-CoV-2 vaccine. That will be mostly the S protein, spike protein. So the advantage here is to have that system and help us differentiate antibody response so we can understand vaccination versus infection.

And I don't want to spend too much more time on the neutralization assays other than to say we are looking into some various platforms to get us out of BSL3 so we can do it in a less constrained environment, but also put it into something that can be done a little bit more quickly so we can get it to those correlates of immunity, or that correlate of infection that I mentioned earlier. So with that, I think I will stop and turn it back over to Jasmine.

JASMINE CHAITRAM: Thank you so much. That was Chris Elkin and Vicki Olson from the CDC Laboratory Task Force. Unfortunately, due to time, we won't be able to answer any of the questions that have come through the chat box, but we will try to get responses to those after the call. While Chris and Vicki were talking, I did show some links to the information that they presented. So you can check those out. Our last speaker is from COLA and her name is Kathy Nucifora. She'll be talking about maintaining collections and supporting laboratories during the COVID-19 pandemic. Apologies, Kathy, for running over on time, but we still have quite a few participants on the call. So we are going to go ahead with your presentation.

KATHY NUCIFORA: That's fine, Jasmine. Thank you. Again, my name is Kathy Nucifora. I'm the Chief Operating Officer at COLA. COLA is a laboratory accreditation organization, accrediting many types of laboratories, both large and small, across the country. And I'd like to thank the CDC for allowing me to spend these few minutes to give a voice to the many laboratories who have been seeking information about COVID-19 testing.

So first, I'll be sharing with you the types of questions that we're getting from our laboratories over the last three or four months. Then, I'll briefly talk to you about the resources that we've been connecting laboratories to, to help them get the information that they're seeking. And finally, I'll spend a little time sharing with you some of the activities that COLA has undertaken in order to support our laboratories and keep them informed during the pandemic.

Next slide, please. So first of all, I'll say right off the bat that we have promoted participation in these weekly calls. This is really the best place to go to get the latest, updated, current information from the CDC, CMS, and FDA. So every time the agenda comes out for these weekly calls, it goes out to our more than 7,000 laboratories, along with instructions on how to connect. So I just wanted to say that connecting laboratories to these weekly phone calls is really important.

But we do get a steady stream of phone calls and emails every day from laboratories who are trying to understand the EUA process. They have questions about PCR testing, about antigen testing, and a lot of questions about antibody testing. Many laboratories are interested in providing testing to their communities, but they need help sorting through the many EUA tests. They need to know what equipment is needed, what swabs can be used, what is the complexity of the tests, how do I verify performance, how can I get my laboratory on a priority list to get supplies, and so on.

We've also received many questions from laboratories who currently have a CLIA Certificate of Waiver and are interested in applying to upgrade their CLIA certificate to a CLIA Certificate of Registration so that they can implement COVID-19 testing. Of course, then there are the associated questions about personnel qualifications and other requirements for nonwaived laboratories. Many laboratories have also had questions about on-site survey delays. How will this affect my accreditation and how will it affect my CLIA certificate?

Next slide, please. So our goal is to connect the laboratories with this very useful information coming directly from the CDC, from the FDA, and from CMS. We do have a COVID-19 update on our customer portal, which includes links to the FDA FAQ, which has been a very popular resource. And of course the EUA information with the list of EUA tests. We've also referred many laboratories to CDC's recently published interim guidance on antibody testing, which has been very helpful. And we've provided links to CMS's CLIA FAQ and the CLIA guidance during the COVID-19 emergency.

Very importantly, we have publicized these weekly meetings so that laboratories can hear the latest directly from the CDC, from the FDA, and CMS. We've also engaged with the Laboratory Outreach Communication System, or LOCS, and we have shared those alerts with our more than 7,000 customers as we receive them. There have also been several webinars sponsored by laboratory professional organizations and we will continue to share that information with laboratories.

Next slide, please. So in order to keep up with the needs of our accredited laboratories, we do have a designated team of very talented technical advisors to field incoming questions and to direct the customers to the resources that I've mentioned. We've published a technical bulletin that outlines available resources and addresses questions about reporting COVID-19 test results, quality control performance specifications, test complexity, and biosafety.

Last week, during specified times, COLA launched a chat feature on our website that allows us to answer questions and to direct customers to the resources and references that they need if this turns out to be a useful way for laboratories to get information, we will continue to expand the chat feature.

I'd just like to say a few things about surveys. Similar to the CLIA program, and to other accrediting organizations, COLA suspended routine surveys on March 16 in order to protect the safety of our surveyors, laboratorians, and their patients. And after careful evaluation, and in

the interest of continuing to support our accredited laboratories, COLA resumed surveying laboratories on a limited basis on May 19. We've provided our laboratories with a list of precautions that our surveyors will take during the survey. And we have explained our expectations of the laboratories for keeping our staff and surveyors safe during the survey.

Currently, we are surveying laboratories only in locations that are within driving distance of a surveyor, as we do not yet feel comfortable with air travel. Another way we are supporting our laboratories is our newly launched pre-survey documentation review process whereby we will review a small subset of compliance documentation uploaded by the laboratories prior to the survey. This is optional for laboratories, and it allows us to evaluate compliance in areas such as personnel and PT and to give laboratories the necessary feedback. Now, this does not replace the survey, but it helps keep us, as well as our laboratories, stay on track during the time when surveys have been delayed.

At COLA, we understand that this has been a stressful time for our laboratory community. And we will continue to support laboratories as they navigate this difficult environment. I want to thank the CDC for hosting these very important calls, and we will continue to promote them to our customers. Thank you.

JASMINE CHAITRAM: Thank you, Kathy, for that great presentation. Again, sorry, for the shortness on time there. And, unfortunately, we won't be able to take any questions because we are short on time. And I'm just going to wrap up really quickly with a few notes. Remember to sign up for the Laboratory Outreach Communication System so you can receive important messages from CDC, as well as reminders of these calls. The next call will occur on Monday, June 8th, I believe it is. Losing track of time.

And as I said before, if you missed any part of this call, the transcript is posted on CDC.gov/safelabs under tools and resources. The transcript, as well as the slides with all of the links. And another way to submit questions, if you didn't get your questions in today during the call, is through the DLSInquiries@cdc.gov. Thank you again for joining us today. Thank you for all that you're doing. And that concludes today's call.