

# Clinical Laboratory COVID-19 Response Call

## June 28, 2021

### Agenda

- **Welcome**
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- **Public Health Laboratory Support of Point-of-Care Testing Sites**
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- **Over-the-Counter Tests and CLIA**
  - Amy Zale, Centers for Medicare & Medicaid Services (CMS)

**JASMINE CHAITRAM:** Hello, everyone and welcome to the Clinical Laboratory COVID-19 Response Call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness here in the Division of Laboratory Systems at CDC. And for those of you that have been joining us for these calls since we started them in March 2020, you'll know that DLS is the division at CDC that has responsibility for supporting clinical and public health laboratories.

And we've been doing this before the COVID-19 pandemic and throughout. We have been doing this in specific areas such as training and workforce development, quality and safety, informatics and data science, and preparedness. And through the response, we've specifically been helping to serve as a liaison and a communicator of information to the clinical laboratory community and public health labs as well.

Today we have a shorter agenda than usual. So our call may not last as long. I do want to point out that FDA is normally on these calls. They're not here today. So any questions that you have for FDA, we may have to get back to you or answer them on the next call.

And before we get started, I will do the usual review of some housekeeping items and a couple of announcements. So my first announcement is that we have some information about [risk assessment for point-of-care testing sites](#). And this can be found on our point-of-care web page. It's showing the link right here. And it's a biological risk assessment resource that can help you with doing a risk assessment if you're doing point-of-care testing.

The next announcement is [packaging and shipping job aid](#) (find this Power Point file in the "Specimen Packing and Shipping" section) that was recently also posted on our website. And the link is shown here as well. So if you want to refresh on that or get information on packaging and shipping specimens, you can visit this link. And sorry it's taking me a minute to click through my sides.

OK, so where can you find all this information? One stop shop is the [DLS Clinical Laboratory Preparedness Portal](#). And here we have information about our [Clinical Laboratory Response Calls](#), our [LOCS messages](#), links to other resources that CDC has for COVID-19. So here is a good place to find information.

And all of our calls are archived here, transcript slides and audio. So you can always go back if you missed something, or you couldn't make a call, or you had to leave early. And the information will be available. As I mentioned, our LOCS messages are here too.

Our next call will be on Monday, July 12th from 3:00 to 4:00 PM. We host these calls every two weeks. I hope you can join us for that call. We have always asked and continue to ask for feedback and needs on training and workforce development. You can send those to [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov).

And then finally, just some information and instructions for asking questions-- we have the Q&A button in the Zoom webinar system. It's at the bottom of your screen. Or maybe it's at the top of your screen. Either way, it says Q&A. And we do prefer that you use that to submit questions to us. This helps us to track the questions and possibly get answers back to you if we're not able to answer them on the call.

We may not be able to answer your question on the call because we don't have the right subject matter experts with us. Or it may be too many questions to get through. Usually that's an issue when we have a lot of topics on the agenda, but more so today that we may not have the right experts in the room to answer those questions. And we can either get an answer back to you by email or table your question for an upcoming call and try to answer it then.

If you put your question in the chat box, we won't be able to track those. And we won't be able to get back to you. So please try and put them in the Q&A section along with your name and an email address. And that will help us to get a response to you.

Just a couple of other reminders with asking questions-- this is a call focused on clinical laboratory and testing issues. So we would like to have questions submitted that are related to those topics, either laboratory regulations or issues a laboratory is facing, safety questions, and then anything related to testing. We cannot answer questions about vaccines unless we're presenting a specific topic on that particular issue.

I think that's it for me. Just one more quick thing, just a reminder that the slide decks may contain materials from panelists that are not affiliated with CDC. And so they may not necessarily reflect CDC's official position. And that is the same for any of the slides that we post on our Preparedness Portal that you may reference later.

And with that, I think we will go to our very first speaker. And we're very excited to have him here with us, Sanjib Bhattacharyya. I think I said it right. It sounded good when it came out. He is with the City of Milwaukee Health Department. And he is going to talk to us about public health laboratories and their support of point-of-care testing sites. And I'm very excited that he's here with us today. Sanjib?

**SANJIB BHATTACHARYYA:** Sure. Good afternoon, everybody. And thank you, Jasmine, for introducing and for the opportunity to talk to you all. Let's go to the next slide, please.

So in my current role, I'm the Lab Director and Special Deputy Health Commissioner with the City of Milwaukee Health Department Laboratory. I'm also an adjunct faculty with the UWM School of Public Health and Biomedical Science. Next slide.

I thought that before I jump into the point-of-care experience that we'll be sharing today with our nontraditional testing site, just a very quick overview of our health department mission and approach here, as you can see, that advancing the health of Milwaukeeans, of science innovation, and leadership practices-- and of course, technology, data, and partnering includes a nontraditional approach of engaging partners in the community. In this situation, we'll talk about deployment of Abbott ID point-of-care COVID testing, but again, integrated into science, leadership, and quality. I'll talk about some of the quality and the safety consideration as well. Next slide.

And this is a quick snapshot. I know it's kind of a busy slide, but I thought that it will give you an idea that this is a local public health laboratory. We are focused on health-equity-centric practice of science in a local public health lab. Believe it or not, we are approaching 150 years very soon, and hoping to have a good celebration.

But at your left, as you see, there are many regulatory bodies that are overseeing us, including CMS CLIA and the aspects that we we'll be talking today for the point-of-care deployment, but there are many others, including many of the CDC program and World Health Organization sites being the [INAUDIBLE] pathogen and other roles. And we had many awards and recognitions, including the Healthiest Lab in 2017, and very recently from the Kimberly-Clark, recognition for the Environmental Health Impact Achievement. So with that said, I'll go to the next slide, please.

So based on the core practices for the quality control and quality management in our workforce, I think this is a very core public health laboratory practice. And it's inclusive of the diversity that was partnered in the staffing that we look for. To maintain the highest level of the quality performance with the systems partners, we assure the robust training and competencies are in place before we submit or perform any of the duties. So this is what the core function is. And that's eventually being supported as a systems role in this jurisdiction. Next slide. So next one.

So before going to the point-of-care, of course, you have heard and you had been hearing about is COVID response for the public health laboratories. But we are in a way kind of unique, that how we took the multi-stakeholders approach. And we couldn't be achieving all of those success so far without being part of the system. And the next slide.

I wanted to give you a structure that how this all COVID response came into play. And early on during our COVID preparation and lab getting ready for the COVID testing, we made sure that we had a very coordinated effort in the United EOC operation. And as you see, that's numbered in gray and brown, that all of those are highlighted here, where public health laboratories are playing critical roles. So we are the local health officials and very much involved in guiding the safety and risk associated with that.

And then operations-- so health department had been the largest local health department in this jurisdiction, very much involved in COVID testing, vaccination, community response areas. And in parallel, we continue to make sure that education and awareness is there, because no matter how much we do the direct testing, and support service, and the surveillance, we also wanted to make sure that all the lingo and the science behind doing the testing are being translated in a way that public and the communities are very much aware of that, including in the workforce as well as the targeted communities that we'll be talking today. Next slide.

So this is kind of a snapshot. If you look at that at the center, that this is primarily the Milwaukee city and the county areas. And all of those are in pink. Our purple are different areas that we continue to support COVID testing services, as well as including the community health centers and the health system. So you have three major health systems here that we coordinate pretty routinely.

So early on, we definitely realized that public health labs and the clinical labs were being part of the public response. We need to kind of expand beyond that so that we can continue to do a better outreach to those communities that are underserved or needed necessary support. So the community outreach and education and measurements of those with the adequate reporting opportunities is one of the key things that we looked at. Next slide, please.

So again, a snapshot-- as you see, that it had been quite a busy time with hundreds of thousands of testing. But lately, things have gone down, like every other jurisdiction. But I think the focus has changed since then, that as you are doing more genomics, which you see at the center, at your left bottom, you see the community partnership, that we not only had multiple different PCR testing and sequencing opportunities to continue to look at the variants and the outbreak investigation, we also made sure that we partner with the corporate as well as in the local communities to find out their needs and assessment of those. Based on that, we approached our point-of-care deployment in our communities. Next slide.

I know the audience I'm talking to are very familiar with point-of-care, of course, but I just wanted to have this slide to give you all an idea, that some of those who are not very privy to the point-of-care, those who are coming from public health, that this is typically the testing performed outside of standard, high-complex laboratory testing. And focus today is, as you see the circle here, is that Abbott ID deployment for the COVID testing in the communities. Next slide.

So a little bit of a background again for deployment of point-of-care-- as we all know, that March is when the Abbott received the emergency authorization for the multiple point-of-care testing. And I think in April, HHS provided Abbott ID instruments to many of the state public health jurisdictions to meeting the priorities for the communities. And Milwaukee had been one of the largest hit in the state of Wisconsin. And we have the diversity in the population and disproportionately impacted minority population, early on, we kind of had this communication with Wisconsin DHS, state level of hygiene, and strategized the utilization of this Abbott ID instrument within many of the Milwaukee communities.

At your right, as you see, the testing was slow at the beginning, but very quickly, with all the clinical partners and the public health partners, we ramped up. But regardless of how the PCR testing ramped up, there was still a need to support our community sites. That's why I think it was very critical and timely to have access to those Abbott ID point-of-care instruments to be deployed to the communities. Next slide.

So just to give you an idea-- and of course, it's simple math here, but it's more than that, that increasing capacity means that we have to have the diversity in the testing. And when you are talking about diversity in the testing, not only the different PCR platforms that we had, that we started looking into how the rapid testing point-of-care-- in this situation, Abbott ID was the only access to us at that point-- that how that can eventually help expanding daily, weekly testing capacity. And that will add value to that. So in this particular situation, we had access to 15 Abbott ID to be deployed in our local jurisdictions, so just to give you an idea that how this was integrated with expanding PCR testing that we had been doing. Next slide.

And like we all know, that typically, public health is reference testing and the surveillance testing. But early on, understanding about the point-of-care ID deployment, we needed to really track down, that what are the different communities that we'll be serving. And as you see in this table, that we have the homeless shelter isolation facilities, student health center who haven't had ready access to all of those, correctional facilities and the jail.

And those are other areas of high-risk population. Interesting enough, that we had our fire and the police department that, working very closely with the health department and EMS, to look into supporting our own staff members and then all the clinical service provider for all the different communities. So all of those different jurisdictions or the location types are identified and with a targeted approach to find out which population we are serving.

And are those the population at high risk? And do they have the access, adequate access to near-real-time testing so that that can support our public health testing support? And the benefits are, of course, paramount, because supporting all those jurisdictions and the dormitory, for example, students' cell, the inmates needed to immediately get the testing done in a very quick manner. We couldn't be achieving those with PCR testing that we had in place, and then finally, providing the access to the underserved population that we needed to support.

But it doesn't come without any challenges, because the most important thing that we had faced at most of the sites that we were looking at haven't had the qualified staffing to perform the testing, and even the physical space, because they have no idea what a laboratory setup may be, even though it is not high-complex laboratory setting. But still, understanding about the workflow and the reporting requirements, and dedicating some of the staff members who will be championing to making sure they'll be playing critical roles in coordinating all the efforts, and then eventually the data submission, which had been our initial challenge. At your right, as you see, that these are different employment area, as you can imagine that it was really deployed to those diverse populations. The central city has more of those units, because

that's one of the highest hit areas and has limited access to some of the testing, traditional testing that we have been talking about. Next slide.

And the planning was not simple, even though based on some of the discussion that we had in many other state public health jurisdiction-- I know every jurisdiction is different. Some had the point-of-care readily deployed to many of the state-wide jurisdiction. But we really wanted to make sure that we do a thorough planning, because it is required to have the right approach to do success.

So who needed-- why do we need that? And why should we do it? And then how the training needs are, all of those were looked at by the team who were involved in that.

And then providing all the standard training guidelines, that's very important, making sure that all the sites had the understanding about what the clinical reporting means and what the CLIA requirements are. This is an EUA unit. So we had to also make sure that the IBA guidelines are followed. So having a deployment of this point-of-care in non-traditional setting was no easy task. And then finally, the outreach-- we had to continuously reaching out to all the sites making sure they have all the support they need and then how they do the reporting back to us. So we had to do a lot of service, making sure the sites are ready and ready to deploy and accept some of the units. Next slide.

And next few slides, I'll be sharing some of the examples. This is actually a real example of how the site assessment was done. So first step of that is that the certification-- are the sites ready to have a testing site? So do they have a CLIA license? If not, how will we cover that? Should there be any concern of that? Because this is a test, or it's a CLIA, whatever is needed-- so understanding about the CLIA operation was critical. Do they have medical oversight? So who is leading the effort in the sites? And do they have the right credential to do it? And then operationally, we looked into the location consideration. Do they have the right facilities and safe enough? Is that workspace adequate? And access to the patient flow as well as all the basic QC that needs to be performed over the period of time. So next slide.

To continue with some of the tools, one of the key things-- and I think this is recently came up with CDC's new guideline that Jasmine showed earlier today, the safety consideration. There is definitely high risk associated with handling clinical samples. So we had to make sure that we provide appropriate PPE. Or do they have any kind of training needs assessment regarding those?

And are the facilities ready to handle the biohazards disposal? So again, this is a high-risk clinical handling. And even though the test system was more of a closed system, we wanted to make sure they have the right safety consideration.

And then the reporting-- and as you all know, early on, that this is a reportable disease. And in the state of Wisconsin, it's also a reportable in our Wisconsin disease surveillance system. We wanted to make sure that they have the right tools and opportunities to report it in a routine basis.

And I'll go to the next point for some of the portal that we had to create. But early on, we started email, our secured email, our secured fax option, and then eventually were able to work with our state and the city IT to support that portal system for the reporting. Next slide.

So some of the critical consideration for the site specification is partners understanding what they are getting into. And as you can imagine, being a nontraditional site, when you're looking into these to be deployed, so we have to make sure that if the sites are really not acknowledging or understanding the risk associated with that, they may not be the ideal site. So you have to work with the leadership and making sure their team and the people who are directly involved in that is trained and acknowledge all those things before we can go ahead. Next slide.

And training-- the first line of training was the training provided by Abbott ID and Abbott, because there were some training videos, that, some of you may be familiar with that. But when we looked into that, we thought that that's maybe very preliminary training. We need in-person training opportunities. So we had to pull our training coordinator and some microbiologist position who had been setting up the standard operating guidelines and SOPs and make sure that we coordinate those with our state as well as any kind of base reporting that's needed after the training.

So the training was pretty extensive, even though it was not long training. But we wanted to make sure that they have the correct way of documenting those, and a binder, instrument manual, and went through the Abbott training as well as in-person hands-on training for their staff. Definitely, some of the CDC guidelines for the CLIA documentation at your right, as referenced here, were very, very helpful to understand the way of testing, like, the point-of-care Abbott ID instrumentation. Next slide.

And then this is a snapshot of the workload. Even though compared to the high-volume PCR testing that we did, this is, I think, somewhere between 7,000 to 10,000 testing that was performed. But it was tremendously helpful for these communities.

And whether it's a homeless shelter or the student health, correctional facilities, it was so critically needed. And this was hugely backed by reference testing that we had been doing. So at the beginning, we had been actually confirming some of the positives. And depending on how things eventually panned out, we kind of wanted to make sure we continued support.

There were some supply chain issues that, as we are all familiar with that, that we had faced. So we wanted to make sure that we have a backup plan to provide PCR testing during those periods of time. And this is another area of interest, that we have to make sure that when you look into the community testing site distribution and planning, we wanted to make sure that we have all the secondary planning to continue support, because they cannot afford to lose, not to have those supports that we had been providing. So it had been a tremendous opportunity, of course, working closely with our EOC as well as the community partners and our jurisdictional coordinators. Next slide.

So one of the key things which I think is very important to understand, the point-of-care definitely had some challenges, given the reference testing is primary for what we do and reference testing role in public health. So we wanted to make sure that quality activities, quality assurance is kind of the center of this. So we wanted to make sure the communication was adequate, confirmatory testing support, as I mentioned, and then reporting system. So we created some of the portal with some help from the state support, and then weekly reporting the test data.

So we had been reviewing all of those things very closely and providing additional feedback and support. And in person, we had been actually going back to the sites making sure they have adequate support and necessary questions are being addressed. So it was pretty much essential to assure the highest level of quality services that we can provide along with the sites were trained to do that. Next slide.

So definitely, you have to understand that the cost and the time consideration. And I think this is an opportunity for us to understand all of those, that, at the very beginning, there were some challenges in getting the equipment, hardware and the software service plans in place. Now I can say that, 15 months after the major heavy lifting for COVID, we are continuously working with them, making sure they have the right support and the supplies that they need. And then providing the training before we can go live was critical.

And at your right there is-- it's a real treat to show you some of the timelines that we had to work on. As you see, the planning, developmental training, and the tools availability and outreach were kind of throughout the whole process. And then we have to make sure that continuous quality improvement is one of the key things that we maintain. And of course, we provided all the information in advance, and making sure that they are ready to get those deployed and service started as we did the follow-up communication in frequencies, certain frequencies that they needed to be. Next slide.

And then finally, the lessons learned part of it-- I think it's a hugely lessons learned for public health laboratories, that when we are heavily engaged in reference testing and surveillance testing, point-of-care, making sure that the highest quality of the testing, even for the point-of-care, that plays a critical role in expanding and supporting public health as well as clinical coordination of testing that we can provide. So in this, here we identified a few things here, that we have to really establish some relationship with all the partners, making sure that the sites understand and they trust us, as well as routine communication during the training and beyond, making sure that they follow the compliances and making sure the success is achieved through those.

Ideally, we dedicated some point-of-care coordinator for the health department, even though it was a challenging task to do, because some of our staff member had to do some of those. But moving forward, if this is something that public health is planning to deploy, I think this will be a critical role. And understanding that this is a diverse community that we are talking about-- so it's nontraditional. Even though fortunately, for local public health laboratories, we have a pretty deep understanding about our communities. And we are heavily engaged to many programs.

And you know, next one, everything works best if there is a site owner. So again, we need a champion for this. In most situations, we were able to find it in staff in some community sites. But it was not easy, because again, you have to understand, this is a nontraditional testing site. They are not used to have any such testing.

And then finally, very important to keep in mind that there are definitely costs involved, even though bringing in the instrumentation and initial supplies of the reagents were at no cost, but are cost beyond

that, because like I said, that we are continuing reevaluating those community sites and their support needs. And there are associated costs even with the personnel and the training that we needed to do. So I think, overall, I think it was a very good lessons learned in terms of good success, but there are definitely improvement opportunities.

And luckily, with the well-planned opportunity that we had and then quality improvement and quality control in place, we have been very successful. And this is a really positive experience for us. And first time-- I mean, during our last pandemic for influenza, we haven't had this opportunity to work that closely with the communities. But I think this is the lesson plan moving forward, that how public or even the governmental laboratories can support point-of-care, and as long as we are providing a high-level quality controlled environment, to provide the best services we can.

I think this is the last slide. And thank you very much. And this is our-- living your best life is what is our slogan for the health department. Thank you, all. Thanks for the opportunity. And I'll be staying around for some questions, if there is any.

**JASMINE CHAITRAM:** Thank you so much, Sanjib, great presentation. There were a few questions that came through. So I can ask you those now.

**SANJIB BHATTACHARYYA:** Sure.

**JASMINE CHAITRAM:** The first one was, was the instrument installed free of charge at testing sites?

**SANJIB BHATTACHARYYA:** Yeah, so there was no cost to the testing sites. So again, it's a coordinated effort through the Wisconsin DHS that were able to readily access the instrument. It was more of a preparation for the site to be available and willing to. So yes, it's no cost. It was all taken care of through the public health systems as the instruments came from HHS, to DHS, to the local jurisdictions.

**JASMINE CHAITRAM:** OK, thank you. And are you offering no-cost asymptomatic COVID-19 testing for all members of the public now?

**SANJIB BHATTACHARYYA:** I think from the public health standpoint, yes, because we continue to consider us in a COVID mode. The asymptomatic testing is a little different based, of course, we are-- our primary is to make sure that we focus on symptomatic and high-risk patient. But with the combination of coordinated effort with DHS for the antigen testing, I think those are still available, but again, primarily the high-risk symptomatic. And depending on the need, we have been providing some additional support for asymptomatic, depending on how that was defined and how that was needed. So again, it's not all of those cases, because there are many partners in the testing or clinical laboratories are also here who had been providing those supports.

**JASMINE CHAITRAM:** OK, great. And I guess related to the first question I asked you, are the test kits, were they also free of charge for the testing sites?

**SANJIB BHATTACHARYYA:** Yes. There is no cost at all to the testing sites.

**JASMINE CHAITRAM:** OK, and then two questions that are very similar about sensitivity-- how did you address the potential reduced sensitivity of this method? And what is the false-positive and false-negative rates with this test?

**SANJIB BHATTACHARYYA:** Yeah, in fact, we are really close to get one publication out. I know this was a very big issue at the very beginning. And there were some studies out. But we realized some of the

studies at the beginning were not really well-planned studies. So we did actually a significant first three months, very in-depth comparing the point-of-care testing data with our PCR reference testing. So those were an eye-opener for us. And we wanted to make sure, like I said, that training, and the quality control, quality assurance were critically embedded in all the sites as well as heavily backed up by reference testing. So we had full confidence that-- of course, there are very few situations that we had discrepant results. And those were addressed with the reference testing. But our findings were fairly well. And the point-of-care compared very well with our reference testing as well.

**JASMINE CHAITRAM:** OK, great. And how would a homeless person go about receiving a test if they don't have symptoms?

**SANJIB BHATTACHARYYA:** Yeah, so those were-- again, those were coordinated to the sites. And then if it's an asymptomatic situation, I think there are certain guidelines where they can go and other community testing sites. But again, at the beginning, it was definitely high-risk symptomatic. And based on each and every individual, situation was different how they're being coordinated. And right now, we have other clinical sites and public health clinic sites. Those are also open to have the testing access. And I know that local pharmacists are also helping with the testing. So I think we provided adequate guidance to those and constantly being done in terms of education and awareness for the community, where to go for testing and what kind of testing they are talking about.

**JASMINE CHAITRAM:** And one more, does the state allow temporary or mobile testing sites for CLIA-waived COVID-19 testing?

**SANJIB BHATTACHARYYA:** Yeah, it was actually coordinated with the Wisconsin DHS with our local. And we continue to provide mobile testing as well. But early on, as you can imagine, all those resources are not readily available. And even in those situations, targeted population reach out to have a broadband approach for the mobile testing was not really either available or adequate. That's why, I think, this approach was more targeted towards the communities in need.

**JASMINE CHAITRAM:** All right, Sanjib, thank you so much for being with us today on this call and answering all these questions. We really appreciate your time.

**SANJIB BHATTACHARYYA:** Thank you. I'll be around.

**JASMINE CHAITRAM:** And we are going to move now to our last topic, our next speaker and our last topic for today's call. Amy Zale has been with us before. She's with the Centers for Medicare and Medicaid Services, talking about over-the-counter tests and CLIA. Amy, take it away.

**AMY ZALE:** Thank you, Jasmine. And thank you for inviting CMS to present on the CLCR Call today. I'm happy to have the opportunity to share some information with you.

I hope to provide some clarity around the need for a CLIA certificate and COVID tests that have received emergency use reauthorization from the FDA for over-the-counter use. CLIA has gotten many questions about the use of these over-the-counter tests and CLIA. The last time I did my research, it may have changed.

So please don't quote me. But I believe that there are seven over-the-counter COVID tests that have received an FDA EUA. If the test is self-administered, then a CLIA certification is not required. If an entity is performing the over-the-counter test on an individual or interpreting the test result for an individual, that entity is required to have a CLIA certificate, a waiver at a minimum.

I wanted to share a real-world example to help illustrate this issue for you. We received a question about a summer camp that is using over-the-counter COVID tests. And it wants to use it on its campers. So in the first example, the camp staff provides the test to each camper. So they arrive to the camp in the morning with their mom driving them in there. And the camp hands the camper the test itself. The camper returns to their car, performs the test on themselves, interprets their own test, and then returns to the camp staff to let them know that they are positive or negative. This is an example of over-the-counter testing that does not need CLIA certification.

The next example is the CLIA staff has an over-the-counter test for each camper. The sample is collected by the staff or the camper. The camp staff performs the test on the camper sample. Camp staff interprets the test and determines whether or not the camper can attend camp. This is an example of an entity using an over-the-counter test where that entity is required to have CLIA certification.

I thank you for your time. And thank you for all of your hard work and dedication to laboratory medicine and ensuring accurate and reliable results. And I'm happy to answer any questions about this that you may have.

**JASMINE CHAITRAM:** OK, thank you so much, Amy. I think that's very helpful information that you just shared. And I forgot to tell everybody that you did not have slides.

But anyway, so I'm looking now to see if any questions are coming through. And I don't see anything specifically for you. I know someone asked at the beginning of the call about the Delta variant and if it's known if the over-the-counter tests can detect that variant.

And I will just comment that FDA has been on this call before and has mentioned that they are working closely with manufacturers to continue to assess their tests for these variants. I don't think CDC has looked at the Delta variant specifically with over-the-counter tests. But FDA is coordinating these efforts with the manufacturer.

Here is a question. Let me see if this one is for you, Amy. So some of these over-the-counter tests are the same brand that the lab has to use. What does it do to the numbers that are reporting for tracking if over-the-counter are not required to report to anyone?

So it's a good question. And you know, I think this is why we are actually in the process of looking at the [reporting requirements](#) and making some updates for those. In general, the information that's presented on the CDC website for percent positivity is only calculated on real-time PCR or [NAAT](#) tests. So that helps to not skew it with any of the [antigen tests](#) that are not being reported consistently or all the screening that's going on. All right, I'm still looking, Amy, because now questions are coming through. Let's see. Hang on one second.

**AMY ZALE:** I see one that's for us. Do specimen collection centers that send specimens to a third-party high-complexity lab for testing need a CLIA certificate? No. As long as you aren't performing testing, CLIA does not have oversight over specimen collection. And you do not need a CLIA certificate in that instance.

**JASMINE CHAITRAM:** And there is another one for you, Amy. It says, can you explain why that distinction exists? If my kid performs the test, no CLIA, if the camp does, CLIA. I don't see the reason for the difference. What's the policy?

**AMY ZALE:** So the reason is from the definition of a laboratory for CLIA, that if a facility is performing a test on an individual, then that-- and it has a very long definition for the health assessment and all of those things-- then that laboratory needs a CLIA certificate. So for these tests, if it is self-administered in a way that the over-the-counter designation on the EUA is in that letter of authorization and the manufacturer's instructions, then it does not need a CLIA certificate. But if it's an entity who is performing it and it is not done on a self-administered test, but it is an entity who is performing the testing on someone else, then that meets the definition, the CLIA definition of a laboratory. And that entity needs or that facility needs a CLIA certificate.

**JASMINE CHAITRAM:** OK. Thank you, Amy. Let me see. So there are two questions that are really-- it's not so much for you Amy, but I guess coming up because of the topic. And it's about reporting for an antibody-antigen tests and what happens to those numbers, since I just mentioned the CDC is using PCR for percent positivity. There is another question about, is reporting obligatory for antigen tests?

And so all I can say is, currently, under the current HHS reporting requirements, any diagnostic testing-- so that's whether that's done in a lab or a point-of-care testing site-- is required to be reported to public health departments. And it's for contact-tracing purposes, for understanding the current conditions and outbreak situations in jurisdictions. I will say, though, that as I mentioned, we are looking at the reporting guidance.

And I'm hoping that, either on the July 12th call or the July 26th call, we will have some updated information to you about how those reporting requirements may be changing. And so that's all I can comment on at this time. So hopefully that's sufficient.

I don't see any other questions for you, Amy. So if you want to hang on and just see what's in the chat box and possibly answer them as they come in-- but I did see one question that Sanjib offered to answer live. So if Sanjib is still there-- Sanjib, are you still there?

**SANJIB BHATTACHARYYA:** Yep, I'm here.

**JASMINE CHAITRAM:** OK, did you want to answer the question about pooling? Is there swab pooling going on, testing?

**SANJIB BHATTACHARYYA:** Yeah, so currently we're not offering the pooled testing for many reasons. I know it's a jurisdictional decision. But at this point, we are not offering it. But there are some benefits, definitely, depending on how jurisdictions plan to use it, whether it's in a school setting and some other. But at this point, that's not our immediate plan, and neither being offered by the state as well.

**JASMINE CHAITRAM:** OK. And then another question that you had offered to answer is, are you seeing an increase in the Delta variant?

**SANJIB BHATTACHARYYA:** Yes, we are. And we are using pretty or expanding significantly our genomic, which expanded. We started, I mean, immediately after COVID since last April.

And yes, we are seeing that. And we are keeping a close monitoring. But there is some definite delay. When a positive test happens, and then eventually Delta sequences are being done. But yes, like everybody else, we are seeing increased number of Delta variants as well as other variants.

**JASMINE CHAITRAM:** OK. Sanjib, this is not related-- well, maybe, to the information that you provided. But the question is, how can a point-of-care testing site collect and send positive samples for variance surveillance? And I think, as a public health lab, you might be able to provide some guidance on this.

**SANJIB BHATTACHARYYA:** Right. So I think what we are trying to do-- and that came in last several months, is that any of the point of testing care sites, that we wanted to make sure that, if we can access any of the positive samples, because we have been doing in parallel additional PCR supports to them. But this is a tricky part, that if we do not have the clinical material available, we cannot do that. But we are making some coordinated efforts, at least from some sites who are able to do a parallel swab and then send any positives to us so we can perform sequencing.

**JASMINE CHAITRAM:** OK, I'm still looking to see if there is anything. I appreciate all of the questions that are being submitted. I'm not asking all of them because we don't have all of the experts here. Like, some of these questions are specific to either FDA or other parts of CMS. So I am just scanning those quickly to see if there is anything else here that we can answer today.

In the meantime, I do want to thank you all for joining the call, and for continuing to participate, and for continuing to ask great questions, for continuing to submit topics for speakers or future agenda items. We do appreciate that. And we do hope that these calls are useful to you. You can give us feedback in lots of different formats through the [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov) or [LOCS@cdc.gov](mailto:LOCS@cdc.gov) mailbox. And for any of the questions that were not answered today, we will do our best to try to get an answer for you or have somebody speak to those on the next call.

And I think with that, we will go ahead and end just a few minutes early. For those of you that are going from meeting to meeting, this might give you a few minutes to take a breather or do other things, read some email. And I don't know, but hopefully those 10 minutes will be helpful to you. And thank you again for joining us. And we will talk to you in two weeks.