Agenda
Clinical Laboratory COVID-19 Response Call
Monday, November 15, 2021 at 3:00 PM ET

Agenda

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Introduction to Laboratory Risk Management (LRM) and Biological Risk Management for Point-of-Care Testing Sites**
  - Sabrina Debose, CDC Division of Laboratory Systems (DLS)
- **Laboratory Training: Virtual Reality (VR) and Syndication**
  - Joe Rothschild, CDC Division of Laboratory Systems (DLS)

JASMINE CHAITRAM: Hello, everyone. Thank you for joining the Clinical Laboratory COVID-19 Response call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in CDC's Division of Laboratory Systems. I've talked a lot on these calls. I usually do a little intro about our division and the work that we do.

Today's agenda, actually, includes two topics and examples of things that our division has done. Our first speaker is Sabrina Debose. And she is going to be talking about laboratory risk management and biological risk management for point of care testing sites. And then our next speaker is Joe Rothschild. And he is going to be talking about virtual reality training that was recently created by our division. And we've got two courses that are now available at no cost.

I'm going to, of course, before we have our speakers go through their information. I am going to do the reminders that I usually do. And so we are the Division of Laboratory Systems. And we support clinical and public health laboratories. And we've been doing that since the beginning of the pandemic in January 2020.

Our four goal areas that we focus on include quality and safety, workforce and training, preparedness-- and that's a topic I'll come back to in a minute-- informatics and laboratory data, meaning data science. So in the area of safety, like I said, we're going to have a presentation on risk management. In the area of training, where we're going to have this one presentation about our virtual reality training options, which will cover two topics.

And then in the subject area preparedness, obviously we're doing these calls in preparedness in response to the COVID-19 pandemic. And we do serve as a liaison to the CDC Emergency Operations Center providing information from CDC to clinical and public health laboratories. And we also have a Preparedness Portal, a one-stop shop for the information. This does have links to CDC related information about COVID-19.

What we also have here are archives of our clinical lab calls. And you can go back all the way to the beginning and see slides, transcripts, any information, agendas from previous calls. We also have here

an archive of all the LOCS messages that we've sent out. That's the Laboratory Outreach Communication System.

And that is where we send emails and announce these calls. And any emails that you may have missed, you can go back here and find the information. I do get a lot of questions about I missed the call and where can I find the slides of the transcript or an audio of the call? And this is the spot, this preparedness portal.

Our next CLCR call-- we call it "clicker," short for CLCR, Clinical Laboratory COVID-19 Response call. The next call will be on Monday, December 13. So that is a month from now. We usually have these calls every two weeks.

The next call would have been Monday, November 29th. That is following the Thanksgiving holiday. And I think a lot of people will be recovering from all the food that they've hopefully had an opportunity to have and good times with family and friends. And so we are going to cancel that Monday call to let you catch up with other things at work. And we will have our next call on Monday, December 13.

And just a reminder that if you have any specific needs around education and training to please contact us at labtrainingneeds@cdc.gov. And finally, how to ask a question-- please remember to use the Q&A button in the Zoom webinar system. We really want to record those questions that are coming in plus your email. Sometimes we get questions, and we don't have subject matter experts on the phone to answer those questions. But we will record them and try to get back to you or put those questions on a future call. If you put those questions in the chat box, they will not be recorded. And we will not have a record of them. So please remember to use the Q&A button.

And I think that today we'll probably be able to get through any of the questions that we have about the two topics that we're presenting on. But if we don't, again, we will try to get back to you at a later date. And if there are questions that are not related to these two topics, I'm not sure that we'll be able to answer them.

We will have some FDA colleagues on the phone, although they're not on the agenda. So if there are questions for FDA, we can try to squeeze those in at the end. And just a quick reminder also about the presentation materials that we put on our preparedness portal and that we present here, it says speakers are not affiliated with CDC-- just a reminder that they may not necessarily reflect CDC's official position on that topic.

And with that, I'm going to turn it over to Sabrina to talk about laboratory-- the introduction to laboratory risk management and risk management for point of care settings.

SABRINA DEBOSE: Hi, Jasmine. Thank you very much. Hello, everyone. My name is Commander Sabrina Debose. And I'm a Health Scientist in the Division of Laboratory Systems at CDC. So today I will give you an introduction just to show you where you can find our information to our new e-learning course

called Introduction to Laboratory Risk Management. And I'll also give you some information and highlight a new resource for those who perform point of care testing called the biological risk management for point of care testing site. And it's a web page. Next slide, please.

Thank you. So here's the next slide. And this one is called the Introduction to Laboratory Risk Management. For short, it's called LRM.

This is an online e-learning course. You can access this course by going through CDC Laboratory Training page, which is the page that's on the screen. Once you log on to the site, you would follow the link to register for the course through CDC TRAIN.

This training is designed for new, public health, and clinical laboratory professionals who handle potentially hazardous material. Learners who complete this basic level course will acquire knowledge of risk management principles and will be able to describe the importance of risk management in laboratory settings. Next slide, please.

DLS is also proud to announce the launch of a new resource for those who perform point of care testing. This is called the Biological Risk Management for Point-of-Care Testing Sites web page. On this web page, it builds on the division's portfolio of risk management resources that are currently available. The link to the web page is currently listed on the screen.

Once you get to this website page, the content introduces basic concepts. It outlines the five steps of risk management process. It identifies terms to know for risk assessment and provides relevant resources to assist with developing a site-specific risk assessment process for your facility. Next slide, please.
So here's to recap. Here are the links for the new DLS biological risk management assessment resources. Thank you. And that's the end, Jasmine. Thank you.

JASMINE CHAITRAM: Thank you very much, Sabrina. I don't see any specific questions for you at this time. So if you want to stay on the line and just see if anything pops up in the Q&A box, and then you can feel free to go ahead and type an answer while we're going to the next speaker.

SABRINA DEBOSE: Will do.

JASMINE CHAITRAM: All right, thank you. All right, so our next topic is, as I mentioned, the virtual reality training that we have. And Joe Rothschild is on for that. And we are going to try to do some videos. So have patience with us if things get glitchy. Go ahead, Joe.

JOE ROTHSCHILD: All right. Can everyone hear me well?

JASMINE CHAITRAM: I can hear you.

JOE ROTHSCHILD: OK, perfect. Well, good afternoon, everyone. My name is Joe Rothschild. And I work for the CDC as a Health Communication Specialist in the Division of Laboratory Systems.

To be honest with you, I'm really more of an innovator and an artist at heart rather than a scientist. But I'm lucky enough to work in a branch where that innovation and creativity is really appreciated and utilized to train our clinical and public health laboratorians using virtual reality as well as the syndication of our really great e-learning courses. So that brings us to the topic of this presentation-- virtual reality and syndication. So let's get started. Next slide. All right.

So all that said, a little background for you guys-- our branch, the training and workforce development branch, we really specialize in all things laboratory training related. We have a really amazing creative team. And we try to pack as many 3D animations, graphics, and, really, eye candy where it's appropriate into our e-learning courses. And we really want to try to make them as engaging as possible and more effective as well.

We've been chasing virtual reality since around 2013, 2014. And in 2019, we really finally got our chance to start developing CDC's first ever virtual reality laboratory training course. So we pilot tested this course with internal CDC staff-- both active laboratories as well as people who had never stepped foot in a lab before and really discovered that it was universally accepted as a real valid training modality for our staff.

So really, the neat thing about that was we learned that we had staff that had really no video game expertise, no laboratory expertise. And really, right away within a minute or so, they got it. They understood and they sort of immediately naturally adapted to this virtual environment-- so really, really cool.

So in 2020, we completed and launched the course LabTrainingVR Biosafety Cabinet Edition. And this was for the HTC VIVE platform. And it's available both on TRAIN as well as STEAM. So moving to this year, we really ramped up our VR production team as well as our offerings.

We developed some multiplayer components to our VR courses so you could have multiple people in the same environment at the same time where they could communicate and sort of work together. And just last month, we launched a new VR course both on TRAIN and STEAM that's focused on personal protective equipment for laboratory staff. So in addition to this PPE VR course that we just released, we're also in development of a VR course that-- instead of the more expensive HTC VIVE headset, it's focused on a $300 Oculus Quest headset. So you don't need that heavy duty VR laptop to do it.

And this course is going to be an open world-- I guess they call it an open sandbox environment where you'll be able to do, hopefully, really anything laboratory related in this environment. We're also going to be doing this year and next year a pushpack program. And what that is-- we will actually be sending out Pelican cases that have a VR headset, the controllers, a VR laptop all preloaded with CDC training content-- so really, really exciting stuff. Next slide, please.

So let's talk about our currently available VR courses real quick. So our first one-- LabTrainingVR Biosafety Cabinet Edition. We teach learners how to properly set up, work in, and shut down a biosafety cabinet. And actually, instead of talking about it, let's show you a quick little-- we have like a one-minute little promo video. So if you could play that, that would be great.

NARRATOR: Welcome to your virtual laboratory. CDC LabTrainingVR Biosafety Cabinet Edition creates a training space for learners to apply knowledge and build skills. CDC developed this course for clinical and public health laboratory professionals. And by the end of the training, learners will be able to identify the major parts of a class 2 biosafety cabinet, or BSC, demonstrate how to maintain positive airflow within a BSC, and demonstrate how to prepare for work in a BSC.

Future updates to this course will focus on building skills beyond setting up a biosafety cabinet such as how to clean up spills, safely remove materials, properly decontaminate and shut down a BSC, and conduct emergency shutdown procedures. We hope that you enjoy and benefit from CDC's first laboratory training in VR.

JOE ROTHSCHILD: All right, so I'll point out that that was totally the wrong video. It's the right course. But we've-- all those things that we had listed as coming soon, we actually have. We have the spill cleanup-- lots of great stuff. So my apologies. Can we go to the next slide, please?

All right, so you heard me mention about a VR course on personal protective equipment that we just released. This is another amazing course for the HTC VIVE headset. And in this course, we have our users going through a museum type of environment where they learn about different types of PPE, when it's appropriate to use those types of PPE, how to properly don them, doff them-- all that kind of great stuff.

We even used motion capture to capture laboratorians. And I'm sure you've seen it. That's the suit with all the little ping pong balls all over it. Super cool course, multiplayer once again-- and let's play that video.

NARRATOR: Welcome to CDC's second virtual reality training course. CDC LabTrainingVR PPE Edition takes place in a training museum and creates a space for learners to learn about personal protective equipment. CDC developed this course for clinical and public health laboratory professionals. By the end of the training, learners will be able to identify the routes of transmission of infectious agents, don and doff the appropriate PPE for daily use at the bench, and don and doff PPE during an emergency. Broken into several exhibit halls, LabTrainingVR PPE Edition features motion captured laboratorians that demonstrate the correct and incorrect ways to utilize PPE and proper lab procedures in order to reduce the chances of exposure.

Learners will be able to step into exhibits and practice what they've learned prior to entering a realistic anteroom and laboratory for a final exam. We hope you enjoy and benefit from CDC's latest laboratory training in VR.

JOE ROTHSCHILD: All right, next slide, please. So last up on our current virtual reality platter, we're calling this OneLab Training VR or OneLab VR. And now, before I get into more details on that, it's being developed for the $300 Oculus Quest.

So we switched to this piece of hardware because of the-- instead of the HTC VIVE, this one is so much less expensive. It's easier to set up. It doesn't require any type of VR computer. And we're trying to reach as many people as possible. And this really feels like the right tool for it.

Let's see. Let's go to the next slide, please. So here's just a little sneak peek. We have this really-- it's basically-- it's 50,000 square feet, virtual square feet. We have an amazing lobby. We have over 100 different types of laboratory pieces of equipment, from just standard centrifuges to microtomes to autoclaves and really tried to put every conceivable piece of equipment into this laboratory environment-- so really, really exciting. Next slide, please.

So as I mentioned earlier, we're planning on completing our pushpack program. And for this, we're going to be sending out deployable Pelican cases that have all the VR fixings inside to around 40 different clinical and public health laboratories. They just have the headset, the controllers, cables, sensor, stands, and even a VR laptop that's been sort of preloaded with all of our training courses.

We include job aids-- both video job aids as well as hard physical copy job aids that really cover everything from here's how to open the case, here's how to plug in all the cables, here's how to configure it. So we're really excited to see how this program goes because we know-- or we think that VR is a fantastic modality for training laboratorians. We need to get these into your hands so we can sort of get that feedback. Next slide, please.

So along that same topic of increasing our reach, we're syndicating are e-learning content. This really great tool enables external learning management system administrators to actually load CDC e-learning onto their LMS. We're doing this because we're frequently contacted by these external partners that say, hey, I want to put your e-learning content on my LMS so I could manage and monitor my staff.

And in the past, we had to say no because at that point we sort of lose control of our content. And so with this, you're able to do that. And so as rules and regulations get updated, we update the training on our end. And that automatically gets pushed to everyone else's end.

We're currently syndicating-- I believe it's 16 COVID relevant e-learning courses to approximately-- at last count, I think it was 33 different partners that include colleges, hospitals, businesses. And yeah, if you'd like more information on that, http://www.cdc.gov/labtraining/syndication.html. Next slide, please.

And same thing for all of our great VR stuff. If you'd like more info, http://www.cdc.gov/labtraining/VR.html. And, Jasmine, how are we on time? Would you like me to do a quick demo of walk through that OneLab VR environment?

JASMINE CHAITRAM: Sure, we can do that. Do I need to give you control to share your screen?

JOE ROTHSCHILD: That is correct.

JASMINE CHAITRAM: OK, hold on.

JOE ROTHSCHILD: Yep. All right. Let's see how this goes. Always tricky. Let's see. We're going to put on the good old VR headset, fire it up. We're going to cast. All right, let's see if this works-- not quite yet. And cast to the computer. In a second now it should start. All right, so can you guys see that? I think you can.

JASMINE CHAITRAM: We're seeing it. Thank you.

JOE ROTHSCHILD: All right, great. So this is our VR environment. Let's see. How do I get rid of-- we could go to OneLab VR.

So we have sort of this nice lobby environment that you might find outside a hotel, sort of a check-in area. I'll just teleport right back here to show some of the equipment that we have. We have a place where specimens can sort of come in and be received. We have centrifuges over there.

Let's see-- dry ice, incubators, refrigerators. Let's see-- all kinds of really fancy equipment that I'm sure everyone online knows what it is. But yeah, so it's just-- we've really tried to make this as realistic as possible for everything. So we have microbiology, chemistry. Let's see-- what other stuff do we have down here?

We have office space. Let's see. Let's go check out autoclaves. So we have pretty realistic autoclaves. So really, yeah-- and I'll get out of this right now because I know we have lots of other stuff to do.
But yeah, we've really tried to make this as realistic as possible and really tried to sort of be forward thinking. So because this is a multiplayer environment, hypothetically we could have people from all over the world in this laboratory. You could have a CDC subject matter expert in this laboratory literally looking over their shoulder as they're doing a procedure and be able to say, hey, you forgot to eject your pipette tip, or, hey, you're blocking airflow in that biosafety cabinet, or really anything.

So we're really excited about the future of VR, especially this OneLab environment as well as our syndication tool. It's all about getting that content into your hands. That's about it. Any questions?

JASMINE CHAITRAM: Hey, Joe, actually we do have a couple of questions for you. And thank you so much for that demo and the videos. I think that was really fun to watch. Hopefully nobody got dizzy.

The first question we got is for VR. I was really interested when this came out. But it's been a challenge trying to convince people of the purchase of the equipment needed. Would the CDC be doing any type of demos? I think other than the one you just did.

I don't play video games. So I have no idea what any of these terms are. I love the idea.
And I would agree that some of the terms are not familiar. The only reason why I know what an Oculus is is because I have teenagers. But can you make a comment about the availability to do demos and how someone might schedule that?

JOE ROTHSCHILD: Yeah, absolutely. So first of all, this is a headset. Usually, most of your VR equipment you have a headset and then you have these little sort of hand controller things. Demos-- so first of all, we have this pushpack program where we're going to be sending everything right to you. And if that's something that you'd be interested in, I think maybe a great way would be send an email to labtraining@cdc.gov. Or just hit us-- there's a link on our VR page. So that's one really great thing. Two, demos-- Jasmine, are these going to be internal or external demos that we're talking about?

JASMINE CHAITRAM: I think you probably schedule a call just like you've done.

JOE ROTHSCHILD: OK, yeah. Sure. Yeah. Yeah, I think if you're interested in learning more about that, absolutely reach out to us. I think vr@cdc.gov is also an email that will make its way to me and to our branch. We'd love to do demos.

I know we had originally planned to do lots of trade shows and conferences pre-COVID. And obviously COVID sort of put the kibosh on that. But I know that's also something that we're really looking forward to do is really sort of bring this, bring it to you, and let you get your hands on it.

And as far as the cost for purchasing this, absolutely. And that's sort of the whole reason why instead of the $1,000 for an HTC VIVE headset and $3,000 for a VR computer, we're moving towards this other headset where it's $300 and that's it. So we're really trying to do everything that we can to make it obtainable by you guys.

JASMINE CHAITRAM: Thanks, Joe. So there was a question about cost. And I think you answered that one. But do you know if these VR courses provide continuing education credit?

JOE ROTHSCHILD: Absolutely. Our first one on biosafety cabinet actually does offer PACE credit. I think it may have been the first VR course to offer PACE credit. I think we're in process of obtaining PACE credit for the PPE one. And sort of moving forward, absolutely. It's our hopes and dreams to have all of our training offer PACE.

JASMINE CHAITRAM: OK, thanks. And then I know you kind of mentioned this already. But are you saying that if there are labs that are interested in getting a VR pack, all they have to do is send an email to CDC? Or is there more to it?

JOE ROTHSCHILD: There's more to it. We're working on this pilot test where we have 40 of these kits that we're going to be sending out. And I think in part of designing our pilot test for that is we're going to be looking at trying to get really a wide range of state and local clinical public health laboratories.

And so if you get us information, we will sort of add you to the list. And then our evaluators, I think, are going to go through that list and really try to figure out who makes the most sense to send these to. So no, it doesn't mean if you email us we'll send you one. But it will increase your chances more than not emailing us.

JASMINE CHAITRAM: Right. And the pushpack that we're sending now, if they email and are able to get one, there is no cost associated with that, right?

JOE ROTHSCHILD: That is correct.

JASMINE CHAITRAM: OK. And someone has mentioned that they have an Oculus headset. And can they use that and just download the program from CDC? Will that work?

JOE ROTHSCHILD: So currently, we have the two courses that are available that were designed for the HTC VIVE. If you already have an Oculus headset and are savvy, you could probably find a way to sideload it or do some sort of funky stuff that I don't really understand but my kids do. That could make it work, especially if you have the original Oculus or maybe the STEAM headset-- so yes and no.

JASMINE CHAITRAM: And then can you review-- I think you mentioned it. But can you review just generally what the equipment is needed to view the VR courses.

JOE ROTHSCHILD: Yeah, absolutely. So our present two courses were designed for the HTC VIVE. And there's a handful of different models of the VIVE.

There's just the VIVE, the VIVE Cosmos, the VIVE Pro. There's a handful of those that will work. So you'd need that. And then you would need a computer that can run VR.

Unfortunately at this time, your run of the mill laptop that your IT department or desktop that your IT department supplied you with probably can't run it. It needs sort of more of almost like a gaming type of computer, but as the time goes on, those gaming requirements will just sort of become standard on more and more computers. And it won't require a more sort of specific type of computer. But yes, you need a fairly high-end gaming computer to run VR.

JASMINE CHAITRAM: All right. The next one, learners have different styles of learning. Are there parallel non-VR training modules to go with the VR courses?

JOE ROTHSCHILD: Absolutely. That was sort of one of the things that we did is we started from some of our courses that we had previously developed as e-learning courses. For example, our biosafety cabinet

e-learning course that is available for syndication and sort of took that content, brought it into VR, and then added some sort of more VR-centric elements-- for example, measuring how fast or where you're moving your hands because that's a really important thing for working a biosafety cabinet, is if you move your hands out too fast, you could draw air out of the cabinet.

So we wanted to test and train for that. And that's sort of something you can't do in e-learning. But yes, for all of our courses, we're really trying to have an alternative and equivalent e-learning course that can be taken.

JASMINE CHAITRAM: Thanks, Joe. I think this is the last question for you-- and a comment that is really cool. And who is the intended audience for this type of training?

JOE ROTHSCHILD: So the intended audience for this type of training is going to be clinical and public health laboratorians. Me personally, I love it that we're seeing lots of gamers take it. My kids and all his friends have taken it. And hopefully it will encourage them to pursue potentially a future as a laboratorian once they get to experience what it's like working in a lab.

JASMINE CHAITRAM: All right. Again, Joe, thank you so much for joining us today and providing this information and walking us through the actual courses. It was something different to show on our calls. We do appreciate your time.

We do have Tim Stenzel from FDA on. And I do see one question in the Q&A box for FDA. Tim, I'm just checking that you can hear me.

TIM STENZEL: I can, Jasmine. And Toby [Lowe] is here with me. So if I can't answer, certainly Toby can.

JASMINE CHAITRAM: OK, well the question is, will anyone be able to discuss the return of LDT oversight by the FDA?

TIM STENZEL: Yeah. So I think we're prepared. The communication came out today. And so I think Toby and I can give a brief overview. We will be spending considerable time on Wednesday at the CDRH Town Hall on the communications that went out today.

So as is obvious probably to most everybody on the call today, there were two key announcements-- one from the Secretary of HHS and then one from the FDA. And the HHS announcement-- and I'm just going to read it. It's very brief in case people hadn't seen it. The US Department of Health and Human Services and the Food and Drug Administration are committed to ensuring that COVID-19 tests are accurate, reliable, and available today.

As part of that commitment, HHS is withdrawing a policy established during the previous administration that limited FDA's ability to address certain problematic COVID-19 tests. Policy first announced on August

19, 2020, related specifically to laboratory developed tests. An LDT is a type of test that is generally designed, manufactured, and used in a single laboratory.

Policy directed FDA not to require premarket review of LDTs including premarket approval, PMAs, or clearance 510K in emergency use reauthorization, even in situations where they have poor performance. By withdrawing the policy, HHS is helping to ensure that COVID-19 tests work as intended. Effective today, HHS no longer has a policy on LDTs that is separate from FDA's long-standing approach in this area.

Today, FDA also updated its policies for COVID-19 tests, including COVID-19 LDTs. These policies take into account the importance of test availability, reliability, and accuracy. And I would like to stress that test availability remains a key priority for the FDA.

Our clear priorities as outlined in the communication haven't changed as far as the most important elements of our COVID response. And that is we will continue to make it a high priority for review and reauthorization of at-home and point of care diagnostic tests. And these are antigen and molecular tests and also certain high-volume lab based molecular diagnostic tests. These are our kits-- and certain lab-based and point of care high volume antibody tests that measure the amount of antibodies.

And then of course, anything that is supported by US Government stakeholders, such as BARDA or the NIH Rapid Acceleration for Diagnostics Program will be a priority. So that's a very high-level overview. There are some changes. And as mentioned, there are changes to the LDT situation.

So we want to give everybody who has developed and LDT and validated it and is using in an opportunity to stay on the market in a couple of different ways. And that's probably where the interest lies in this group. Toby, do you think you can take it from there and outline some things that you think are important to mention on this call?

TOBY LOWE: Sure, absolutely. Can you hear me?

JASMINE CHAITRAM: Yep. I can hear you.

TOBY LOWE: Great. Yeah. So as Tim mentioned, we did update our policy partially related to the announcement that HHS made this morning and also about our priorities. The updated guidance goes into detail about exactly how we intend to work with test developers on tests that have been offered prior to or without FDA authorization.

So there's-- the key section of the guidance that will probably be of most interest to the folks on this call are section 4C and 4D. Section 4C goes into a discussion about distributing and offering COVID-19 tests during FDA review. So that covers both the category of tests that have already submitted an EUA request, typically following notifications. So we've had the notification lists on our website for a year and a half or so now.

And there's a process for-- depending on when those EUA requests were submitted for confirming with FDA that it's still a current application that you want us to review and then being able to continue offering the test while FDA reviews. And then for lab developed tests that had not submitted an EUA request but are being offered for clinical use, the guidance talks through a process where we would expect a lab that's a developer to submit an EUA request within 60 calendar days from today. And the guidance discusses that we do have optional EUA templates that talk through the information that we think is helpful to submit as part of an EUA request.

But the guidance does also clarify that those are optional. And labs may submit an email with the supporting information in whatever format is available for FDA review. And so there's that 60-day period where we would expect to hear from test developers that you either do or don't want us to continue to review or that you want to submit a new EUA request rather.

And then we would-- for anyone who does submit an EUA request, we would review that. And if an EUA request is not submitted, we would expect the lab to stop offering that test. The next section that would be of interest 4D talks about modifications to EUA authorized diagnostic COVID-19 tests.

So this is specific to diagnostic tests, not serology, and to tests offered in a high complexity CLIA certified lab-- so not point of care or-- unless that falls under the high complexity certificate, not home testing, not home specimen collection. But this section talks through the types of modifications that a high complexity lab could make to an EUA authorized test and continue to offer that modified test without coming into FDA. So that's another area that I think this group is likely interested in.

And then along with the guidance update, we issued a new umbrella EUA. So an umbrella EUA is an EUA, an emergency use authorization, that covers multiple products at one time. So this umbrella EUA that we issued is for tests that are for RT-PCR molecular tests developed by laboratories for use with a anterior nasal respiratory specimens, generally for use as part of a serial testing program. So this is meant to support the increase in serial testing programs for back-to-school programs, back to work programs, things like that where an individual needs to be tested once a week.

This provides a more streamlined and faster way for a laboratory to get their test authorized by FDA. The umbrella EUA lists out very specific validation and metrics, performance metrics. Because of the way that an umbrella EUA has to work, they are very prescriptive. And there's not really wiggle room in there because if a lab certifies that they meet all of the things within that umbrella EUA, they are automatically authorized and just need to submit documentation to FDA to get added to the website for that umbrella EUA.

So those, I think, are the biggest things that were in today's announcement that this group is likely interested in. And we're happy to answer questions if there's time for that.

TIM: Thank you, Toby. And there's a couple of really helpful flow charts in the updated guidance at the end that may hopefully provide greater clarity of this. And again, there are two pathways for an LDT that hasn't already been authorized to get authorized. One is continue with an original application or submit a new one or follow this umbrella policy. Thanks, Toby.

JASMINE CHAITRAM: Thanks, Tim and Toby. We did get a couple of questions as you guys are speaking. The first is, does this LDT policy apply to any LDT or just LDT for COVID-19 testing?

TOBY LOWE: So the guidance document-- go ahead, Tim.

TIM STENZEL: No, no. Go ahead. Go ahead, Toby.

TOBY LOWE: Sure. The guidance document that we, FDA, issued today, or reissued today, is specific to COVID-19 tests. The statement by HHS is not limited.

TIM STENZEL: Yeah, that's perfect. Thanks.

JASMINE CHAITRAM: All right, great. For LDT EUAs already authorized, do these tests need to be reviewed again?

TOBY LOWE: No. This does not impact any tests that are already authorized.

JASMINE CHAITRAM: OK.

TIM STENZEL: Yeah. Tests are already authorized. And they haven't made any substantial changes that would affect performance. Toby, you may want to add about that. They're still enforced.

JASMINE CHAITRAM: OK, the next one is, does the change mean that FDA is requiring all LDTs to submit within 60 days?

TOBY LOWE: For any COVID-19-- sorry, can you still hear me?

JASMINE CHAITRAM: Yeah.

TOBY LOWE: OK, for any COVID-19 test that is being offered as an LDT without FDA authorization, we would expect a submission within 60 days. Yes.

JASMINE CHAITRAM: And if an LDT has not yet been submitted to FDA for EUA but is currently in clinical use, does the lab need to stop performing the test while the FDA is reviewing? Or is it okay to keep the testing while the FDA is reviewing?

TOBY LOWE: As long as the EUA request is submitted within 60 days, they can continue to offer that test until or unless FDA tells them they need to stop. And that would only be if we review it and find a concern with the test. But generally, we'll review it and work with the lab if there's any concerns.

JASMINE CHAITRAM: OK, great. And have you guys already posted any guidance on your FDA website related to this?

TOBY LOWE: Yes, the guidance posted this morning-- the HHS statement as well as FDA's statement posted this morning, FDA's statement does have a link to the guidance. And there's also updates on the FAQ page-- so our FAQs on testing for SARS-CoV-2 web page is fully updated as of this morning as well.

JASMINE CHAITRAM: Okay. For COVID molecular fitted for EUA in summer 2020 then was declined in October 2020 and converted to an LDT, does it need to be resubmitted to FDA?

TOBY LOWE: If nothing from the original EUA request package has changed in terms of validation, data, et cetera, then we would just ask for an email within 60 days asking us to review that submission and referencing the original submission. You don't need to resubmit all of the data unless it has changed. And then please do submit the current information.

JASMINE CHAITRAM: And can you comment on how FDA will take this new policy path non-COVID-- is it non-COVID LDT assays? Or are you guys ready to comment on that now?

TOBY LOWE: So there's not really any change to our previous practice regarding LDTs outside of the public health emergency at this time. We do continue to work on legislative efforts in that area.

TIM STENZEL: Yeah. And I'll read one of the sentences from the secretary's statement effective today. HHS no longer has a policy on LDTs that is separate from FDA's long-standing approach in this area.

JASMINE CHAITRAM: And what about non-molecular LDTs such as antigen and serology? I think you guys commented on this already.

TOBY LOWE: Right, so we don't have an umbrella EUA for those the way that we do with the new one that was issued today for molecular. But we do-- we can accept EUA requests for those certainly. And they would fall under the same 60-day time frame that I mentioned.

JASMINE CHAITRAM: OK. For LDTs that were validated using the CDC test kit, which has been validated under EUA, is the lab now liable for ceasing testing and bringing their LDT to FDA?

TOBY LOWE: So the CDC single analyte assay I think is probably the one that you're referring to. That is still an EUA authorized test. And so the modifications policy that I referenced would apply to that. However, as CDC has publicly stated that they intend to withdraw that at some time in the future when that EUA is no longer active, when it's revoked, and that test is not an EUA authorized test, then those

labs would need to take responsibility for that as their own LDT, yes-- if they continue offering it. They can also switch to a different EUA authorized test.

JASMINE CHAITRAM: OK, thank you. We have a few more questions. They're not on LDTs. So we can change topics. But these are questions for FDA. Many of the Abbott BinaxNOW antigen tests are approaching expiration. Is the FDA looking at the ability to extend the expiration date again?

TIM STENZEL: We're constantly working with all developers, including Abbott, on extension of expiration dating. And that's entirely dependent on the data being submitted by the manufacturer and reviewed by the FDA. So I don't have the absolute latest on Abbott. But we've really shown a lot of flexibility for products where date extensions could be made and using product that's already been distributed in the field. So I'll take that back for the latest update on that.

JASMINE CHAITRAM: Thank you. During the last APHL Zoom call, OSHA indicated that they support using a single antigen over-the-counter assay for unvaccinated employee testing as opposed to twice weekly testing. Is that problematic for compliance issues with respect to package instructions to do testing weekly?

TIM STENZEL: I don't know if Toby, if you're familiar with that, and have examined that question or not. Otherwise, we may have to take that one back as well.

TOBY LOWE: Yeah, sorry, Jasmine. Could you repeat the details of that one?

JASMINE CHAITRAM: I think the question is asking that OSHA is basically saying that an antigen over-the-counter assay can be used as a single test for unvaccinated employees instead of having to do the twice weekly testing. And then the question is about compliance with the IFU. But I think there are multiple antigen tests out there. So it's choosing the right test right for that scenario.

TOBY LOWE: Right. So I can't speak to what OSHA has said other than what I have read in their ETS. I know that it does say to use an EUA authorized test as authorized. So there are some over-the-counter antigen tests that are authorized for single use for asymptomatic individuals. And there are others that are authorized for twice over three days.

I think that's going to be a matter of finding a test that meets the needs of an individual based on our authorization. And I don't know the OSHA ETS incredibly thoroughly. It's over 500 pages long. But I don't think there's any preclusion from testing more frequently than weekly.

JASMINE CHAITRAM: OK. And then we've got another LDT related question about a lab using an LDT. And they are considered high complexity until authorized. As long as the lab meets CLIA requirements for high complexity testing, they have 60 days to submit to for an EUA. And I think you've answered this already and said yeah.

TOBY LOWE: Yes. Yep.

JASMINE CHAITRAM: OK. OK, a non-LDT question-- according to the manufacturers I've used for SARS-CoV-2 PCR test, nasal specimens of self-collection under professional supervision are acceptable. The question is, can we run an unsupervised self-collected nasal swab on that platform? So I think the test is authorized with self-collection but with supervision. And they're asking if they can run an unsupervised self-collected nasal specimen on that platform.

TIM STENZEL: Just a point in general-- we evaluate things on data. And if companies, say, only submitted data for supervised and not unsupervised, we only can authorize tests for that. Or it could be that unsupervised didn't work so well. So, Toby, I don't know what if you want to add anything else at this time to respond to that question.

TOBY LOWE: Yeah, I think that's exactly right. I think that it's important to note that, as Tim, said, we authorize based on the data. And we wouldn't think that it was appropriate for a lab to promote a test to be used for unsupervised collection, which in a lot of ways is akin to home collection when it's not authorized in that manner. But we do have language on our website, FAQs noting that we don't think that specimens should be wasted.

So if a lab is presented with a specimen that's collected in a manner that's not part of the reauthorization, it may still be appropriate for the lab to accept the specimen for analysis and just note the circumstances on the report. So a lab that is receiving those specimens could still run them. But the lab should not be marketing their test as a home collection or unobserved self-collection test.

TIM STENZEL: A good point, Toby. And we don't limit what developers do in this area. If they want to submit an unsupervised data set, we'll review it. And we obviously have authorized so many unsupervised home collection kits already.

JASMINE CHAITRAM: Thank you so much, Tim and Toby, for joining us and giving that update on the LDTs and answering a number of questions. I think this is definitely a hot topic right now. There were a few more questions I'm going to try to answer too, quickly, before we hang up. The first one was more of a comment, I guess, about point of care testing and the quality of the testing and concerns about that.

And CDC also has expressed concerns that mostly because these are facilities-- a lot of new facilities that are doing point of care testing that don't have experience in this area. And that's why we created the point of care testing web page with a lot of resources for these facilities, including testing tips and training and just general information about risk management and how to report results. And so I encourage facilities to that are new and are doing point of care testing to please visit that web page.

We also had CMS come on and talk about the CLIA regulations around point of care testing. And we've had some other presentations. But if there are specific topics that we need to cover in this area, please send an email to locs@cdc.gov. And we can plan to have something on a future call.

The other question we got was about testing employees in the workplace and whether or not that falls under CLIA. And so here I'm just going to quickly say-- and CMS is not on the phone-- but with regards to this, if the facility is performing the testing on an individual and then providing results to the individual, then that does fall under CLIA. If the facility is buying tests and handing it to the individual to take home and perform the tests on themselves, then that would not fall under CLIA.

But we have had this topic covered. So I encourage you to go back into the archives of the last couple of months and see the updates given by CMS where they've provided a lot of detail about point of care testing and over the counter tests used in the workplace. And with that, I think we're going to end today's call. I want to thank all of you again for joining us today-- a reminder that our next call is canceled.

So it will be four weeks-- so about a month-- before we meet again. Until then, Happy Thanksgiving. Hope you all enjoy the holidays and stay safe. Talk to you soon. Bye.