Clinical Laboratory COVID-19 Response Call

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Panelists

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Robyn Temple-Smolkin, Association for Molecular Pathology (AMP)
Regina Van Brakle, Centers for Medicare & Medicaid Services (CMS)
Amy Zale, Centers for Medicare & Medicaid Services (CMS)
Joe Rothschild, CDC Division of Laboratory Systems (DLS)
Tim Stenzel, U.S. Food and Drug Administration (FDA)

JASMINE CHAITRAM: Hello, everyone. Thank you for joining the clinical laboratory COVID-19 response call. I'm Jasmine Chaitram with the Division of Laboratory Systems at CDC. The Division of Laboratory Systems has been hosting these calls since March, and we have a focus to help clinical laboratories on specific topics, including safety and quality, workforce and training, informatics and biorepository science as well as data science. We also work with clinical and public health laboratories on preparedness and response activities, and we have been serving as a liaison between the CDC Emergency Operations Center and the clinical and public health-laboratory communities, and one of our ways in doing that is by hosting these clinical lab calls, which we're now doing every other week.

I am showing here the agenda for today's call, and I want to, in advance, thank all of our speakers for participating. A couple of housekeeping things before we get started. First, as I already mentioned, the next call will be in two weeks from now on Monday, September 14 from 3:00 to 4:00 PM Eastern Time.

We love to hear your feedback, and so we're asking for anything specifically on training and workforce development. And you can send your questions, needs, wants, desires to LabTrainingNeeds@cdc.gov.

When you want to ask a question during the Zoom call, please use the Q&A button at the bottom of the screen there on your Zoom webinar system. Type your question into the Q&A box and then submit it. Please be sure to include your email address so that we can get back to you. If you submit a question anonymously, it is very hard, if we don't get to the question during the call, to get an answer back to you. So we do ask that you submit your email.

We will try to answer some questions live during the call. But because of the number of folks calling in and the number of questions we receive, we are not able to answer all of the questions. We do try to answer them between the time that you asked the question and the

next call. So if your question is not answered, we will try to have an answer for you within the next two weeks before the next call.

We also use these questions to help us formulate the agenda for the next call. So if we see a particular trend in the types of questions being asked, we use that information to help us decide what topics should be on the next agenda. So thank you for submitting those questions. It does help us to understand the needs of the clinical-laboratory community and focus our communications towards that.

And then just a couple of other notes. If you're with the media, please send your questions to media@cdc.gov. And if you're a patient, please direct your questions to your health-care provider. This call is intended for laboratorians.

So one other thing that we wanted to do today is a live audience poll, and I just want to give you just a little bit of background before we do the poll. Many of you are using emergency-use-authorized tests. These are tests that are approved by the FDA to be used for COVID testing during this time. And if you visited the FDA website, you would know that there's an instructions for use document along with other documents that are posted with the assay information. The other two documents are fact sheets. One is for healthcare providers, and one is for patients or individuals that are being tested.

FDA is trying to better understand how this information is being communicated, so we want to do a poll to see how these fact sheets are being used. So the first-- sorry. We're going to do the poll right now.

All right, so the first two questions, if you'll answer these live, we'd appreciate it. The first question, are you aware of the patient fact sheets that should be provided to individuals when providing a COVID-19 EUA test result? And I see the results are coming in. Thank you.

And the second question is if yes, does your laboratory provide these fact sheets or a link where patients can access the fact-sheet information online? I'll just give it a couple more seconds to have those responses recorded. As I said, this is useful information. We will be sharing this with the FDA so that they can decide how they're going to do things in the future.

And now we have our second question-- well, a second set of questions. Are you aware of the health-care-provider fact sheet that should be provided to the health-care provider when the laboratory returns a COVID 19 EUA test result?

So two different questions. One was about the patient fact sheet. This one is about the health-care-provider fact sheet. And if yes, you do provide this, do you provide it directly to the health-care provider or a link to the fact sheet? Is your laboratory responsible for actually sharing it?

All right, well, thank you so much for participating in that poll. We will keep on going with our agenda.

Next up is just some information that we usually provide, some links to important information on the CDC website or the DLS website. And as I've mentioned before, all of our slides are available after the call as well as a transcript from the call. So if you missed part of the call or you can't make it to a specific call, you can always go there to find the transcript and the slides, and you can also share with other colleagues.

And so these are the links that I've shown quite a bit in the past. The next set of links are newer, and these are related to the antigen-testing guidance that was posted on the CDC website recently as well as some updated frequently asked questions.

And we are now ready to turn to our first speaker, who is Robyn Temple-Smolkin from the Association for Molecular Pathology. And I think she's got a quick update for us. Robin, are you there?

ROBYN TEMPLE-SMOLKIN: Yes, I'm here. Can you hear me?

JASMINE CHAITRAM: Yes.

ROBYN TEMPLE-SMOLKIN: Great. Thank you, Jasmine, and thank you to the CDC for the opportunity to speak here today.

Throughout the COVID-19 pandemic, AMP has sought input from laboratories on their experiences and challenges with SARS-CoV-2 molecular testing. Data from our April survey was previously presented on one of these CDC calls, and at that time we indicated that a third follow-up survey would be conducted. We appreciate the opportunity to announce that the new SARS-CoV-2 molecular testing survey is currently open and available at the link shown here until early September.

As the pandemic evolves and laboratories prepare for the fall and the winter, AMP continues to seek data from the laboratories in order to understand and support their needs during this time. These results will allow us to better understand the contribution clinical and public health laboratories are making, the challenges laboratories are currently facing, and assist us in working collaboratively with key stakeholders to find solutions for those challenges.

The target audience for this survey is laboratory professionals in clinical and public health laboratories offering a SARS-CoV-2 molecular test. However, if you're not performing testing, we have included an abbreviated set of questions to address the reasons for your not testing within your laboratory. This anonymous survey will take about 15 to 25 minutes to complete, and the results will be used in aggregate.

Thank you to those who took the time to complete our previous surveys, and we hope that you will consider participating in this important follow-up survey. Just a note that this survey has not been endorsed or supported by the CDC. Thank you. Back to you, Jasmine.

JASMINE CHAITRAM: Thank you very much, Robyn.

So we are moving on in our agenda, and our next speaker is two people, but I think one will speak first-- the Centers for Medicare and Medicaid Services, and it will be Amy Zale and Regina Van Brakle.

REGINA VAN BRAKLE: Hi. Thank you.

JASMINE CHAITRAM: Go ahead. Oh, Regina's going first. OK, Regina.

REGINA VAN BRAKLE: Yeah, thank you, and thanks for the opportunity to speak.

The CARES Act requires that every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to report the results from each test to the Secretary of Health and Human Services. On June 4, the secretary of HHS provided further guidance on required data elements.

Reporting of results to state and local public health departments is not a current requirement under CLIA. In order to be able to require reporting SARS-CoV-2 test results for CLIA-certified laboratories, as outlined in the CARES Act, it was necessary to amend or add several CLIA regulations.

Laboratories performing SARS-CoV- 2 tests will be required to follow this guidance or any updates to this guidance. All CLIA-certified laboratories that report the results of any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 are required to report results regardless of the type of laboratory test they are performing. All negative and positive SARS-CoV results must be reported irrespective of the method used, whether it's a molecular, antigen, or serology test.

Any facility using point-of-care COVID-19-testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings, will be required to report this test result under these regulations.

CMS has made the following modifications to the CLIA regulations. We've added a requirement for all certificate types to report SARS-CoV-2 test results as required by the Secretary. We've added a requirement for accrediting organization and exempt states to report to CMS any laboratories that have not reported test results. We've made a change to enforcement regulations to allow for imposition of civil monetary penalties on Certificate of Waiver laboratories, and we've defined the CMP structures.

So now I'll turn it over to my colleague Amy Zale.

AMY ZALE: Thank you, Regina. So under the civil monetary penalty of the new rule, CMS will enforce to the results-reporting requirement. Failure to report SARS-CoV-2 results will result in

a civil monetary penalty of $1,000 for the first day of noncompliance and $500 for each additional day of noncompliance. This rule applies to laboratories holding any type of CLIA certification, Certificate of Waiver, Certificate of Provider-performed Microscopy, Certificate of Registration, Certificate of Compliance, and Certificate of Accreditation. All negative and positive SARS-CoV-2 test results must be reported to the facility's respective state or local health department. CLIA-certified laboratories will be assessed for compliance with the reporting requirement via routine or complaint survey.

CMS is continuing to assess automated methods to gather data for determining compliance with the laboratory reporting mandate. Use of the available data will be augmented by the following: Certificates of Waiver and Provider-performed Microscopy labs are not routinely surveyed by CLIA. As outlined in our rule, CLIA will be surveying 5% of these labs over the three years that the rule is in effect. CLIA-certified laboratories will be identified as not reporting via surveys and complaints.

Laboratories will have a one-time three-week grace period to begin reporting required test data. This requirement complements existing HHS guidance requiring laboratories to report test results and additional information such as demographic data.

While CMS is only enforcing the SARS-CoV-2 test result, laboratories are still required to report the data elements as detailed in the HHS June 4 guidance. Per CLIA regulations, if your laboratory is not performing any testing for SARS-CoV-2 or your facility is only collecting samples and sending them to a laboratory for testing, there is nothing that must be done differently at this time. However, if your laboratory decides to start testing for SARS-CoV-2, you would need to follow the reporting requirements. Thanks, Jasmine.

JASMINE CHAITRAM: Thank you both, Amy and Regina. As you can imagine, we did get a number of questions, and I'm going to start with: on August 28, CMS posted a series of FAQs that indicate CLIA will use enforcement discretion. Has CLIA ever used enforcement discretion before? If so, when? Can you more clearly explain the terms and conditions of that enforcement discretion? Does that allow CMS to enforce CLIA rules on some laboratories but not enforce on others? What is the legal basis for CLIA using enforcement discretion?

AMY ZALE: Jasmine, if you could send us that one, that's probably one that we need to handle in writing if you wouldn't mind, please.

JASMINE CHAITRAM: OK, yes. We will follow up.

OK, here's another one. Sorry. Let me just scroll down. Hold on. In August, your office sent a memo out to the state survey agency directors about the new CLIA interim final rule on requirements for reporting. That memo says the interim final rule with comment requires laboratories to report SARS-CoV test results in a manner and frequency specified by the Secretary. Can you clarify what CMS CLIA will enforce under this new rule? Will CMS enforce

just test reporting or test reporting that meets all the requirements, the 18 specific elements of the HHS guidance of June 4? The memo to state survey agency directors is not clear.

AMY ZALE: Sure. Sorry. I was trying to get off of mute.

So while laboratories are required to follow the HHS guidance that was put out on June 4 that has the requirements to report within 24 hours and there are 18 data elements which are necessary for reporting, CMS is only enforcing the CARES Act and the CARES Act language. And the CARES Act language says that all laboratories have-- or any facility with a CLIA certificate who is performing SARS-CoV-2 testing has to report those to state and local health departments. And so that is what CMS is enforcing with this new rule.

So laboratories are still required to follow the HHS guidance and those requirements, but the enforcement coming from CMS will be whether or not positive and negative SARS-COVID-2 results are being reported to state and local health departments.

JASMINE CHAITRAM: Here's another one. How can CMS require reporting SARS-CoV-2 for nursing homes, including civil monetary penalties of up to $1,000, and then have an FAQ that allows universities to test for SARS-CoV-2 without any CLIA or reporting requirements?

AMY ZALE: Any laboratory that has CLIA certification is required to report SARS-CoV-2 testing. If universities are doing surveillance testing, surveillance testing is not covered by CLIA, in which case they will not be required under the CMS CLIA rule to report because CLIA does not have any oversight over surveillance testing.

JASMINE CHAITRAM: OK, here's another one. If there's a complaint against a non-CLIA-certified laboratory performing testing and reporting individual presumptive results for SARS-CoV-2, would CMS investigate that complaint?

AMY ZALE: So if there is a complaint, you can send it to your state agency, and all complaints are taken seriously and investigated. And absolutely if there is a non-CLIA-certified laboratory who is doing something of concern, we would definitely want you to let the state agency in that state know.

JASMINE CHAITRAM: OK, here's another one. Will labs receive CMPs only if they do not report SARS-CoV-2 test results or if they do not report all of the required data elements? Which I think you kind of answered, but it helps to say it one more time.

AMY ZALE: Reinforcement really helps because we really understand that this is something that people are confused about, and so we do want to make it clear that the only way that a CLIA-certified laboratory would get a civil monetary penalty imposed is if you are not reporting your test results. That is the only part that CMS is enforcing is the reporting of positive and negative SARS-CoV-2 test reports-- or test results.

JASMINE CHAITRAM: Here's one. Does reporting to your local health department count as reporting to CMS? I think there's some confusion about where these results need to be reported, so if you could help clarify that as well.

AMY ZALE: Sure. So CMS is not collecting any of the data. We're only enforcing the rule. So if a laboratory or facility is reporting to their state and/or local health department, then they are in compliance with CLIA and meeting the requirement.

JASMINE CHAITRAM: All right, here's one. So are the penalties for failure to report positive or negative results a failure-- so are the penalties for failure to report positive or negative results or for failure to report any of the additional elements? And again, I think you've answered that, but obviously there's still questions.

AMY ZALE: Correct. So the civil monetary penalty is imposed if a facility is not reporting positive and negative results to their state and local health department.

JASMINE CHAITRAM: Sorry. I'm looking through some of the questions. They're similar in nature, so just hang on one more second.

OK, here's one. This is related to the FAQs on university surveillance testing. One of the FAQs says that CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 surveillance testing where patient-specific results are reported. Provided that the facility does not report the actual test results but only refers to individuals with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing. Isn't it CLIA's responsibility to ensure quality testing whenever an individual's specific test result is given? Why does telling an individual to go get testing at a CLIA lab not fall under CLIA? Why does telling a group of individual university students after testing that they may each safely go to school not fall under CLIA? It seems to me that there's an argument that this is an example of what a federal court might say is arbitrary, an abuse of discretion, or otherwise not in accordance with law.

AMY ZALE: I'm going to recommend again, Jasmine, that we have that one sent to us in writing, and we'll respond to it that way.

JASMINE CHAITRAM: OK. Thanks, Amy. Let me just see if there's any others that are new. I think you've covered them. Yep, I think you've covered them all. Thank you very much for joining today's call, both you and Regina. Appreciate it.

AMY ZALE: You're welcome. Thanks for having us.

REGINA VAN BRAKLE: Yes, thank you very much.

JASMINE CHAITRAM: OK, our next update is going to actually be from the Division of Laboratory Systems. Joe Rothschild is going to give us a laboratory training update.

JOE ROTHSCHILD: All right. Hi, everyone. My name's Joe Rothschild, and I'm a health communications specialist with the Training and Workforce Development Branch here at the CDC Division of Laboratory Systems.

So today, I'm going to be taking a couple minutes to provide a few updates related to our innovative training resources that have been recently released and also show you guys some that are on the horizon, really to make sure that everyone's aware of the training resources that are available to you guys, the laboratory community. So next slide, please.

So to serve as a recap, our chief for learning and workforce development, Senia Wilkins, presented during a previous call, and she shared our newly redesigned website, cdc.gov/labtraining. And there you can find the most up-to-date information on all of our active free training courses. Next slide.

So what's going on, right? So our most popular e-learning course, Packaging and Shipping Dangerous Goods-- What the Laboratory Staff Must Know just launched with a new and improved version. We completely redesigned the entire course to address changing regulations as well as improve the instructional design of the course. We also added much nicer graphics, 3D animations, video segments, and that all were sort of added to increased retention. And as a reminder for all you, this course was made for public health and clinical laboratory staff involved in any step of the packaging or transport process of patient samples or cultures. Next slide.

So I'm also really proud to announce the successful release of CDC's first virtual reality laboratory training course. We're super excited about this. I'm super excited about it. This course focuses on biosafety cabinets and setting them up. This course is currently available on both CDC TRAIN and on Steam. And if you have kids, you probably know what Steam is. If you don't, think of it sort of as iTunes but for games and programs. Steam has over a billion users and, on average, 20 million concurrent users. So it's a huge user base.

With the appropriate VR equipment, we designed and built this course to work on the HTC Vive and Oculus Rift headsets. And with the appropriate gear, it's going to really teleport you or transport you into a photorealistic laboratory where you'll learn all sorts of great stuff about biosafety cabinets.

In the first three weeks of it going live, we had around 150,000 impressions and downloads in basically 20 different countries. Next slide.

All right, so if you'd like more information on what we're doing in VR, you can shoot us an email at vr@cdc.gov or visit our VR web page at cdc.gov/labtraining/vr.html. Next slide.

So at DLS, we're really committed to keeping our training current and up to date with the most recent instructional-design advancements while also addressing current needs. And for these

reasons, we're already looking at updating our virtual reality biosafety course, and it's going to effectively double the amount of content and double the amount of learning objectives in it.

The version that's currently out there really just sort of focuses on setting up a BSC and preparing for work in a biosafety cabinet. The future updates that we're going to be implementing will move far beyond the setup procedures and allow users to really experience working in the BSC. Next slide.

For example, in this VR course, we've added sections on pipetting, on vortexing, on spill cleanup, on disinfecting specimens. Next slide. And we even added a section on procedures for emergency shutdown. And this is a really neat scenario because it takes place in the middle of a massive storm, and we really designed this to increase the adrenaline of the learner to simulate a potentially panic-inducing environment. And really the idea here is to help trainers apply the knowledge that they've already gained in the course even while under extreme duress. Next slide.

So I'm pasting right now. I just pasted into the chat a link to this YouTube video. So feel free to copy and paste and watch that later. That's like a minute-long promo video that really will allow you to just see and hear and really get an idea of what it's like to be in that course in VR. Next slide.

So we're never content to just releasing something, set it and forget it kind of thing. We're always looking at improving and getting stuff better. So we have two more virtual reality courses that we're working on.

Our first that we're currently in development right now is focusing on personal protective equipment, and really it goes into what is PPE? What situations does it protect you from? When you should use it, proper donning and doffing order, that sort of thing.

And a really neat thing about this one is this is the first CDC e-learning course where we've used an actual motion-capture suit. So it really captures actual movements of laboratorians.

And our third course that we're just right now working on sort of from a technical standpoint, we're referring to it as the CDC multiplayer lab. And what this is is we can set it up now where we have a laboratory in VR where we can have a user in Taiwan with a VR headset on. We can have a subject-matter expert here in Atlanta at CDC with a virtual headset on, virtualreality headset, working together in a VR lab looking over each other's shoulders where we can have literally an instructor watching someone in VR doing a process and be able to say, well, hold on. You forgot to eject the pipette tip. Or hey, look, your boxes are obscuring the grill for airflow in a BSC or something like that. So we're really looking at that as an amazing technological feat that we'll be able to do some great stuff with. Next slide, please.

And, really, we want to hear from you. We want to keep our training resources relevant and timely, and it's really important for us to keep a pulse on the needs and gaps in education and

training that all you guys are experiencing. So if you have any training needs or ideas, please reach out to us. You could shoot us an email at LabTrainingNeeds@cdc.gov, and that's about it. Thanks for your time.

JASMINE CHAITRAM: Thank you very much, Joe. Appreciate that. I do have a question for you, and it is do you have to have a virtual headset to participate in the virtual training?

JOE ROTHSCHILD: Yeah. So this virtual realitytraining was designed specifically for virtual reality. The biosafety cabinet course, for example, it does have a sister sort of prerequisite e-learning course that you can find on CDC TRAIN or, better yet, go to cdc.gov/labtraining and find it there and get a lot of the same information.

But with an e-learning course, you can't test the hand. You can't figure out, are they moving their hands too quickly in and out of the BSC? Are they blocking airflow and stuff like that? And so that's sort of really the difference between the two.

JASMINE CHAITRAM: OK, one more for you, Joe. The question is when would a virtual reality course be available for testing workflows? And that's very specific to a laboratory, so I think that would be challenging for CDC to develop, but maybe you could say something about-- and I know I think you've already said this, but to repeat what CDC has in the queue as far as virtual reality courses under development.

JOE ROTHSCHILD: Yeah. So for example, our multiplayer lab could be a great fit for testing workflow where we could build out an entire laboratory. We're going to be building out an entire lab with centrifuges and incubators and the kitchen sink, everything in there. And then you could almost guide your own training in there where you could have multiple people in there. You can have a subject-matter expert with the headset guiding the workflow and watching and testing other people that are in that virtual environment. But with that one, we're still months out from being able to show anything.

JASMINE CHAITRAM: OK, great. And another question. Is there a published list of VR hardware or software that is supported?

JOE ROTHSCHILD: Yes. So if you go to the cdc.gov/labtraining, you can find the listing for LabTrainingVR-- Biosafety Cabinet Edition. And if you scroll down to the bottom of the page, you'll see a list of sort of the recommended hardware and then the absolute minimum hardware that will run on it as well as it will say, hey, you need a HTC Vive or Vive Pro or Oculus Quest headset-- or Oculus Rift. Sorry, not Quest.

JASMINE CHAITRAM: Thank you very much, Joe. That's it for the questions we're going to answer at this time.

Before we move on to the last scheduled speaker for today, there's two things I just wanted to let everyone know. Number one, we've gotten a couple of requests to share the poll results, and we will do that. I'll do that at the very end before we sign off.

The other one is that we are still getting a lot of questions about the CMS and enforcement for laboratory reporting. So I'm pretty sure that we are going to have time after FDA speaks to go back to some questions. So please hang on, and we will try to come back to that in just a few minutes.

I'm going to introduce our next speaker which is Tim Stenzel from the Food and Drug Administration, and Sara Brenner's also on the phone. We'll start with Tim.

TIM STENZEL: OK, thank you. A pleasure to join you again today. What I'm going to cover briefly may have been covered before offline, but I just want to make sure that everybody hears it. And that is there was a previous question about if a kit manufacturer submitted an EUA authorization for pooling, do labs have to wait until authorization? And the answer is no, that once the manufacturer of a kit has validated pooling and they've notified the FDA, they can offer that test under the notification policy.

And so there is at least one manufacturer who has notified. And I don't know if it's public, so I'll let them contact you. But once they've notified us, you're good to go with their validation and their protocol.

And then there's another question of what manufacturers are working on pooling for their test kits. Quite a few, actually, several. And as soon as they complete their validation and notify, then labs can use those protocols when they approach you if you're a customer. So we look forward to those pooling protocols making it even easier for labs to initiate pooling.

And then there's been a lot of questions about SalivaDirect. So this was the EUA authorization made to the Yale School of Public Health and Department of Epidemiology of Microbial Diseases. And it is going to be performed at the Yale School of Medicine Department of Pathology Lab.

And then they have the ability to designate under the authorization other labs who want to follow that same protocol. And labs simply contact Yale, and I'll give you that contact information at the end of this discussion on SalivaDirect. And there are certain conditions that labs must meet to fall under Yale's EUA, specifically the authorized instructions for the use in performing the test provided by Yale, and you're to acquire the components per those instructions. If you have questions about performing the SalivaDirect test and using it as an EUA-authorized test, please contact Yale.

So just some interesting caveats about this. It is a very unique thing. We treated it more from the FDA perspective as a test kit even though it's just basically instructions for use. But they are the distributor, say, of using instructions for use, and those instructions and the kit

components, if you acquire them, have passed EUA authorization. And Yale, by designating you if you want to do this saliva test, can offer it as a fully EUA-authorized test in your lab.

So the EUA holder in this case is the lab that developed a test. It is similar, therefore, to a commercial manufacturer.

And they distribute the IFU-- the labs to which they distribute it to are designated authorized labs. So the FDA provided the authorization, and Yale designates the labs who then acquire all the components as specified in the IFU.

So we welcome this sort of a more, shall I say, open-source testing. I'm told that acquiring the reagent components per the instructions for use is very inexpensive. So this can really make testing perhaps that much less expensive for labs who want to offer this kind of test.

You can go to either the Yale website, which is salivadirect.org, and there is a form for laboratories to fill out if they're interested. You can also email Yale at salivadirect@gmail.com.

And, Jasmine, that's all I had for today. And if there are other questions, happy to try to answer them.

JASMINE CHAITRAM: OK. We do have several questions for you. The first one, since you were just talking about the Yale test, Yale is swamped, I believe, with responses. Can we create an EUA using their published information, or do we need to be a designated lab with Yale?

TIM STENZEL: Yes, to be covered by-- to use it as an EUA-authorized test, yes, Yale will-- you need that designation. A lab can develop their own laboratory-developed test based on that published protocol, but it won't be covered by the Yale EUA authorization.

JASMINE CHAITRAM: Can a waived lab only do pooled testing if the manufacturer gives directions for it in their instructions for use?

TIM STENZEL: Well, there are none, to my knowledge, that have that in their instructions for use. I think there are several who are looking at that, but none have been authorized yet.

And then the second part of that is probably more of a CLIA CMS question as it's my understanding-- and I defer to CMS CLIA-- that if you make an alteration to an authorized test, that automatically moves it into a higher-complexity category. But again, I defer to CMS and CLIA on that.

JASMINE CHAITRAM: Amy or Regina, did you want to comment, or did Tim cover it?

AMY ZALE: This is Amy. I think Tim covered it, but just to sort of reinforce what he said that, yes, if any laboratory modifies an authorized test, then it defaults to high-complexity.

JASMINE CHAITRAM: OK, thank you.

All right, Tim, I have more questions for you. A recently posted FDA FAQ says highly sensitive tests are not feasible. Health-care providers may consider the use of less sensitive point-of-care tests even if they're not specifically authorized for that indication. Are we saying that the IFUs only apply to PCR highly sensitive tests that are feasible and turnaround times are not prolonged? In this case, how does FDA define feasible and prolonged?

TIM STENZEL: Yeah, so again, this had to do with, screening, right, and actually testing of asymptomatic individuals? Is that correct?

JASMINE CHAITRAM: Yes. Yes.

TIM STENZEL: OK. So all tests authorized today are by prescription, meaning that a clinician can order this test, and they are allowed to order tests off label. And so it can be for truly patients who are asymptomatic and not at risk.

These include the lower-sensitivity test. For example, some may consider direct antigen test as lower sensitivity. This includes them as well.

So from an FDA perspective, that's fine. I know that CMS has been working through some things related to that, and I'll let them speak to those other issues. And I know there is an attempt, if not already cleared, to work through some of those things.

JASMINE CHAITRAM: Thanks. Here's another one. Yesterday on Twitter Admiral Giroir said that the Abbot BinaxNOW now can be used to test asymptomatic individuals for screening. Off-label use often may be appropriate. Can you comment on the purpose of the instructions for use that are included with FDA EUA authorizations? Should IFUs be followed or not?

TIM STENZEL: So, yes, we do encourage following the instructions for use, especially as how to perform the test and how to interpret the results of the test.

As we accumulate information about performance of these tests in the asymptomatic screening population and as data is submitted to the FDA and reviewed and we're able to authorize for screening, a pure screening claim in asymptomatics who are not at risk, then we'll update those. But we are attempting to provide flexibility for use.

One of the mitigating factors is that these are clinician ordered, and therefore clinicians involved can help interpret the findings. And we found that to be a very important mitigation for allowing this in these situations while the regulatory science and data catches up with what we really want to do here.

So I understand the question, and I understand the conundrum here. And we're just trying to provide a way to best benefit patients and those who may be at risk of being carriers and

therefore at risk of sharing or spreading the virus to others, particularly in the nursing-home population right now.

JASMINE CHAITRAM: Thanks. Here's another one. LDTs do not require EUA any longer. If a lab validates a new specimen like stool using an LDT, does the lab still require an EUA, or does this go under no-EUA LDT umbrella?

TIM STENZEL: So right now, we're asking for those kind of specific questions that they be sent to our CDRH-EUA-Templates@fda.hhs.govemail, and we'll endeavor to answer specific questions as quickly as possible.

JASMINE CHAITRAM: Great. And actually I'm showing that right now on the slide set, very same email address that you just gave.

I do have a couple of other questions for you. Can you give an update on the ID NOW? Could it be used on asymptomatic patients, and should all negative tests results be sent for confirmatory testing?

TIM STENZEL: So as far as the presumptive negative language, which I'm not going to be able to directly quote at the moment-- I'm going to paraphrase the ID NOW language. But not all negatives need to be reflexed. Clinical judgment should be used on which ones should be reflexed.

And as far as use in the asymptomatic population, it is current labeling and data suggests that its performance is currently acceptable within certain limitations, and therefore-- and it also is by prescription. So if a clinician wishes to order the Abbott ID NOW test on asymptomatic individuals, it could be used.

There's clearly an opportunity here to try to detect as many carriers as quickly as possible, and we're interested in being as flexible as possible to identify those carriers as quickly as possible.

JASMINE CHAITRAM: OK, Tim, I've got two more questions for you. Can you clarify with the Yale test, is it an LDT or is it a commercial test?

TIM STENZEL: It is considered a commercial test, a commercial kit test. It's just an unusual situation where the instructions for use are there. Its validation is there, but all the components and equipment are required but not provided. That's a very unusual sort of thing.

But being that all of the components and the equipment is readily available to many labs, this does offer a unique and attractive way to help a lot of labs. And I salute Yale for doing that.

JASMINE CHAITRAM: OK, and I think the final one for you today is going to be does the new HHS LDT guidance apply to laboratories using home collection?

TIM STENZEL: So that's another one of those answers that we would like to get an email from the question holder to our cdrh-eua-templates email address (CDRH-EUA-Templates@fda.hhs.gov) , and we'll endeavor to respond as quickly as possible.

JASMINE CHAITRAM: OK. So just a reminder to the folks submitting these questions, if you're submitting them anonymously and we're not answering them now, it will be hard for us to get an answer back to you. So please include your email when you can if you feel comfortable doing that.

In the last about 10 minutes that we have, I am going to go back to the CMS topic because I know there's a lot of questions still related to that and a lot of concerns, I guess you could say, from the lab community, so we want to try to address some of those concerns.

So, Amy and Regina, I'm going to come back to you and ask you a couple more questions. Hang on. Let me find some. Let's see. OK, and this one I can probably take for you.

AMY ZALE: Just so you know, we have to drop off at five of. We have another call that we need to go to, so we have five minutes. Just want to make you aware.

JASMINE CHAITRAM: All right. Let me ask you the questions that only you can answer. How will CMS be expected to ensure reporting to state and local health authorities?

AMY ZALE: So we are going to be coordinating with CDC. It is our understanding that state and local health authorities are then taking that information and sending it to CDC. So we'll be coordinating with CDC and HHS to ensure that laboratories are following the reporting requirements.

JASMINE CHAITRAM: OK, and here's one. We send our tests out to reference laboratories, but we also do point-of-care testing. Are we only responsible for reporting point-of-care testing?

AMY ZALE: Yes.

JASMINE CHAITRAM: OK, and does--

AMY ZALE: I'm just going to say only the testing that the laboratory does itself are they responsible for. Anything that's sent to another CLIA-certified laboratory, that laboratory is responsible for reporting.

JASMINE CHAITRAM: OK, another one is some of the labs are concerned that if they submit results to the state health department and those results are-- there's technical challenges, so sometimes the results are not uploaded for whatever reason. So they're trying to understand how will this be assessed and will there be a penalty if they're not able to get their reports through?

AMY ZALE: The biggest thing that laboratories should be aware of is that if a surveyor comes into your laboratory and they ask to see whether or not you are reporting your COVID results, your SARS-CoV-2 test results, and you have the ability and documentation to show that you have been submitting those to state and local health departments, then you're going to be in compliance with the CLIA regulation.

JASMINE CHAITRAM: OK, thanks. Here's another one. One of the FAQs that you've posted, CMS says they will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency for the use of antigen tests on asymptomatic individuals. In CMS's view, how are the instructions for use that are included with an authorization applied? Should CLIA laboratories follow those instructions for use to the T?

AMY ZALE: I would request that that be sent to us in writing, please.

JASMINE CHAITRAM: OK. Let me see. I know I had another one in here that was a good one for you to-- OK, here we go. Can you clarify if the CMS rule means that we must report to our state only if we must report to residents in other states as well? We currently report all results to our state health department. And they are supposed to be reporting for the-- CDC has provided guidance. They are supposed to be reporting to multiple states if they are servicing patients from multiple states. So it's the resident-- wherever the patient resides, that's where they're supposed to be reporting their results to, and I guess CMS comment on that.

AMY ZALE: We would just be looking for documentation that those results were being reported. And so as long as you are following the-- I blanked on my words. I'm sorry. As long as you are reporting those results and you had documentation that you were reporting those results, then you would be in compliance with the CLIA regulations.

Whatever is, again, in the June 4 HHS guidance, laboratories are still required to follow that guidance. It's just not being enforced by CMS.

JASMINE CHAITRAM: When does the three-week grace period start?

AMY ZALE: That's a great question. So the three-week grace period starts when the rule is published in the Federal Register, and the rule is supposed to be published in the Federal Register on Wednesday, June-- June-- September 2. So three weeks after it's published in the Federal Register is when the grace period will end.

JASMINE CHAITRAM: OK, and does the requirement apply to Veterans Affairs facilities?

AMY ZALE: That's a good question. I believe they have CLIA numbers. Regina, you can probably help me with this one, but any laboratory that has a CLIA number has to be in compliance with the rule.

REGINA VAN BRAKLE: Yes, you are correct. And it will be good, Jasmine, if you can also forward that question to us in writing. Thank you.

JASMINE CHAITRAM: OK. I know you guys have to jump off. It's about five to. So just thank you again for being on the call with us today and for answering all these questions. And we have some more, so we will be sending those your way after this call.

AMY ZALE: That's great. Thanks for the opportunity.

JASMINE CHAITRAM: And I believe there was a question that-- sorry. I'm going to scroll through these really quick in the last five minutes because I think there was one on here that I was going to answer.

I saw a lot of questions about reporting positive and negative. The answer is yes, you should be reporting both positive and negative results. I think some have commented that their state health department told them that they don't need to report negative results. The CDC is interested in having both positive and negative results for all testing being done to be reported. You are welcome to send an email to DLSInquiries@cdc.gov, and we can reach out to the state health department for clarification if necessary.

And I think there was another question. Hold on. I'm looking to see if I can find it really quick in all the questions here.

We'll show the poll results for the time being because I know a lot of people asked for that. So this was the results for the first question. And here are the results for the second question. Thank you, again, to everyone who participated in the poll.

And with that, I think we're going to wrap it up on time today. I want to thank, again, all of our speakers for being here with us today and answering questions. I want to thank all of you for being on the call and submitting great questions. There's a lot of information that's out there. I know there's a lot of confusion on some of the guidance that's being provided. We do appreciate all the questions to help us understand how to better communicate to all of you.

The next call I said is on September 14, I believe. That's two weeks from now. The slides are posted, so review the slides and the transcript if you want to. And that can be found at cdc.gov/safelabs under Tools and Resources. We will be moving that in the future into a preparedness portal, but for now that's where you can find it.

And I think that concludes our call for today. Thank you again for all that you're doing out there to support the COVID-19 response.