

# Clinical Laboratory COVID-19 Response Call

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### Panelists

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**JASMINE CHAITRAM:** Hi, again. This is Jasmine Chaitram. Hold on, let me get my video going. Sorry, folks. Here I am. Hi. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems at CDC. The Division of Laboratory Systems hosts the Clinical Laboratory COVID-19 Response Calls. Honestly, can't remember how many calls we posted to date, but we usually host these every other Monday. Thank you all for joining us today. I am showing today's agenda. We have a lot of good topics based on your feedback.

So as I already mentioned, the next call is scheduled for Monday, August 31, from 3:00 - 4:00 PM. This is some information for our clinical laboratories and public health laboratories that are joining the call. We have some links up here. These slides are available. If you are not able to sit through the whole call or you missed something and you want to go back to the slides, we do post these on [CDC.gov/SafeLabs](https://www.cdc.gov/SafeLabs) under Tools and Resources. So the information is there for you.

And I didn't mention, but I will take a break right now and go back to that-- the Division of Laboratory Systems is focused on supporting clinical and public health laboratories. We have done this previous to the COVID-19 response. We were doing this in areas of quality and safety, informatics, data science and repository science, training and workforce development. We were also doing this for preparedness and emergency response. And we are doing that now for the COVID response by helping to serve as a liaison between the laboratories and the CDC Emergency Operations Center.

So these calls are here to provide information to all the laboratories. We have links, like I said, on our website, on CDC's website, as well, to provide guidance. And we also put out LOCS messages-- that's the Laboratory Outreach Communication System-- with important information. And if you are not signed up for that, please sign up at [LOCS@cdc.gov](mailto:LOCS@cdc.gov).

Another thing that we are doing is trying to get feedback on training and workforce development needs. And here is an opportunity to submit those needs to CDC using the email on this slide, [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov). I also wanted to quickly mention that we recently

released a [packaging and shipping infectious substances course](#). And this course is available now on CDC Train. And participants will get two hours of P.A.C.E. ® credit if you participate. So you can find that at [CDC.gov/labtraining](https://www.cdc.gov/labtraining).

And a reminder about questions. To ask a question, we request that you submit it through the Q&A button in the Zoom webinar. I know sometimes, people put it in the chat box, but we really want to keep a record of all of these questions. We also want to be able to respond to these questions later if they're not answered on the call. We do our best to try to answer your questions live, but there are a lot coming in because of the number of participants.

And if we don't answer them on the call, we will try to email you after the call. Or we use the questions to help scope the agenda for the next call and try to focus our updates to answer some of those questions. So if you are the media and you have questions, please submit those to [media@CDC.gov](mailto:media@CDC.gov). And if you are a patient, please direct your questions to your health care provider.

And with that, I'm going to now go into the first topic on our agenda, which is antigen testing. And this is actually going to be a video update and you will hear more about that in just a second.

**REN SALERNO:** Hi, my name is Ren Salerno. I'm Director of the Division of Laboratory Systems at CDC. I've also been serving on the CDC's Laboratory Task Force for the COVID-19 Response. Today, I will present CDC's [new guidelines for rapid antigen testing for SARS-CoV-2](#), which was just published on our COVID-19 laboratory website yesterday.

This presentation is pre-recorded because unfortunately, I'm not able to participate during this particular call. I will not be able to answer your questions in real time, but please submit them and we will do our best to answer them as soon as possible. I'll now summarize this guidance.

As in our pooling guidance, our antigen testing guidance summarizes the three different [testing strategies for SARS-CoV-2](#)—diagnostic, screening, and surveillance. Diagnostic testing for SARS-CoV-2 is intended to identify current infection at the individual level and is performed when a person has signs or symptoms consistent with COVID-19 or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2. Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2.

Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Surveillance testing for SARS-CoV-2 is intended to monitor a community or population level outbreak of disease or to characterize the incidence and prevalence of disease. Surveillance testing is performed on de-identified specimens, and thus, results are not linked to individuals. Surveillance testing cannot be used for individual decision making.

Any laboratory or testing site that performs diagnostic or screening testing must have a Clinical Laboratory Improvement Amendments, or CLIA, certificate and meet all requirements to perform testing. Assays and test systems used for COVID-19 diagnostic or screening testing must have received an emergency use authorization, or EUA, from the US Food and Drug Administration, or be offered under the policies in FDA's policy for COVID-19 tests.

Laboratories or testing sites that conduct surveillance testing for SARS-CoV-2 are not obligated to comply with the FDA and CLIA requirements that apply to diagnostic and screening and testing. This past weekend, CDC posted new FAQs on the differences between surveillance testing, screening testing, and diagnostic testing.

Antigen tests can be used in various testing strategies to respond to COVID-19. This interim guidance is intended for clinicians who order antigen tests, receive antigen test results, and/or perform point-of-care testing, as well as for laboratory professionals who perform antigen testing in a laboratory setting or at the point of care and report those results. The purpose of this interim technical guidance is to support the most effective use of antigen tests for different testing situations. This guidance applies to all uses of antigen test and is not specific to the application of antigen test to any particular age group or setting. This guide supplements and is consistent with CDC's overview of testing for SARS-CoV-2 guidance.

Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens including influenza viruses and respiratory syncytial virus, or RSV. Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal, oral or nasal swab specimens that are placed directly into the assay's extraction buffer or reagent. The currently authorized antigen tests are not restricted to use on persons of a certain age. Antigen tests are relatively inexpensive, can be used at the point of care, and currently authorized devices can return results in approximately 15 minutes.

As of today, the FDA is granted emergency use reauthorization for two antigen tests that can identify SARS-CoV-2. For both of these devices, the instructions for use indicate that they are intended for individuals who are suspected of COVID-19 by their health care provider within the first five days of the onset of symptoms.

The sensitivity of these two devices are 84% and 97% respectively compared to RT PCR. This lower sensitivity means that the antigen test may return a negative result while a more sensitive test such as RT PCR may return a positive result for the same specimen. Reporting negative results from the antigen tests may differ depending on the device. The specificity of these two tests are 100% compared to RT PCR, which means that false positive results are unlikely, and that positive test results can be reported as true positives.

With any in vitro diagnostic test, the likelihood of obtaining a false positive or false negative diagnostic test result is influenced by factors related to the testing scenario and the performance characteristics. For instance, the sensitivity and specificity of the test being used.

Diagnostic tests perform optimally for detecting an infection when the pre-test probability is high. Pre-test probability is the likelihood that the person being tested actually has the infection. Positive predictive value is the probability that a person who has a positive test result most likely has the infection.

Pre-test probability and test specificity have the greatest impact on false positive rates. When the pre-test probability is high, positive predictive value is high and the likelihood of false negatives increases. Negative predictive value is the probability that a person who has a negative test result most likely does not have the infection. Pre-test probability and test sensitivity have the greatest impact on false negative rates. When pre-test probability is low, negative predictive value is high, and the likelihood of false positives increases.

This past weekend, CDC posted separate [FAQs on this specific topic](#).

The gold standard for clinical diagnostic detection of SARS-CoV-2 remains RT PCR. It may be necessary to confirm a rapid antigen test result with a nucleic acid test, especially if the result of the antigen test is inconsistent with the pre-test probability. When confirming an antigen test result with an RT PCR test, it's important that the time interval between the two sample collections is less than two days and there have not been any opportunities for new exposures between the two tests.

If more than two days separate the two tests or there have been opportunities for new exposures between those tests, the RT PCR test should be considered a separate test, not a confirmatory test. If RT PCR testing is not available, clinical discretion can be used in determining whether or not the patient should isolate.

All testing for SARS-CoV-2, including rapid antigen testing, is directly impacted by the integrity of the specimen, which depends on specimen collection and handling. Improper specimen collection may cause some swabs to have limited amounts of virus genetic or antigenic material for detection. Inadequate quality assurance procedures could result in cross contamination in the specimen, which could cause an accurate test results and exposure to the staff.

Delays from sample collection to testing should be minimized. Biosafety measures and instructions for use should be followed precisely to ensure accurate testing and safety of those who perform the testing.

Evaluating the results of rapid antigen tests for SARS-CoV-2 should take into account the performance characteristics, sensitivity, and specificity, the instructions for use of the FDA assay, and the prevalence of COVID-19 in that particular community, specifically the positivity rate over the previous seven to 10 days or the cases per population, as well as the clinical and epidemiological context of the person who has been tested-- their signs, symptoms, and history.

The evaluation of a diagnostic antigen test result should consider the length of time the patient has experienced symptoms. Generally, clinicians can rely upon a positive diagnostic antigen test result, because the specificity of current FDA-authorized antigen tests is high, as long as the instructions for use have been followed. In many cases, a negative antigen test result may need to be considered presumptive.

This table summarizes how laboratories should report rapid antigen test results for SARS-CoV-2 to health departments and patients. A CLIA-certified laboratory or testing site must report rapid antigen test results to the local, state, tribal, or territory health department in accordance with the CARES Act and the June 4 HHS guidance. This is true for both diagnostic and screening test results.

Antigen test results that are reported to public health departments should be clearly distinguished from other COVID-19 tests, such as RT PCR tests and antibody tests. A CLIA-certified laboratory or testing site must report antigen test results to the individual or the individual's provider according to the instructions for use of the FDA-authorized assay. Depending on the stipulations of the authorization, the laboratory or testing site may be required to report negative antigen test results to patients as presumptive negative.

Surveillance testing results cannot be reported as to the persons whose specimens have been tested, nor to their health care provider or employer. Surveillance testing results also should not be officially reported to the local, state, tribal, or territory health department as diagnostic or screening test results. If a local, state, tribal, or territory health department or another institution requests access to the results of surveillance testing for SARS-CoV-2, those results may only be reported in aggregate to the requesting institution. And a statement should be included that indicates the data or surveillance tests are results that do not represent COVID-19 diagnostic or screening test results.

We hope you will visit our new antigen testing guidance that is now available on the CDC COVID-19 laboratory website. When you go there, just click on the "Using Antigen Test" tab. Thank you very much. I hope you have a great day,

**JASMINE CHAITRAM:** OK, well, that went well. I'm glad we were able to hear Ren's presentation. And next, I just wanted to give a couple of updates. Ren did mention FAQs that have posted recently. And we also sent out two-- I'm sorry-- [one combined LOCS message](#) this past weekend. I believe it went out yesterday on these FAQs that recently posted.

The first was about testing. And specifically, it helps to differentiate between the three types of testing Ren also mentioned-- diagnostic, surveillance, and screening. And CDC in general has received many questions about issues with screening versus surveillance testing and how it should be reported. So the FAQs delineate between intended use, regulatory requirements, and reporting expectations for the three types of testing.

CDC hopes that these FAQs will improve the understanding of what screening testing is and how it is different from just traditional diagnostic or surveillance testing. The other FAQ that was mentioned in the LOCS message and was just mentioned by Ren through his video recording here is on false positives and false negatives, and the role of pre-test probabilities, positive predictive value, negative predictive value, and how these affect the false result rate.

These FAQs are an attempt to help the clinical community appreciate that every test has a risk of false results and that there are ways to understand those risks, whether they are low or high. CDC would also like to remind laboratories that it's the responsibility of the lab to report any potential false positive and false negatives to both FDA and the manufacturer so those issues can be addressed quickly.

And so with that, I think we're ready for our next speaker, who is going to be Sara Brenner from FDA. She was on a couple of calls ago, where she gave an update on reporting requirements. And she's back to give us some more detailed information. Sara.

**SARA BRENNER:** Thanks, Jasmine, you can go ahead to the next slide. So this is a very brief background, then I'm going to move through this pretty quickly. On June 4, as pretty much everybody I'm sure recalls, under the CARES Act, laboratory data reporting guidance was released, and that applies to all testing performed in CLIA labs and home use settings. The data elements that were outlined in the [June 4 guidelines](#) were further detailed through the release of an implementation guide that went out on the afternoon of Friday, July 31, the day before the implementation deadline. So that guide is available at the [FAQ link](#) that is listed in this slide. And the direct to the [PDF](#) is the second link there. Go ahead to the next slide.

So just to kind of umbrella the discussion. The laboratory reporting guidance is very, very important that I know folks have been working really hard to implement to the best of their ability but these efforts are really helping to ensure a rapid and thorough public health response, enabling the maximization of utility of real world evidence, contributing to real time epi contact tracing. We're also using reporting data to inform the distribution of tests and resources, and bolster supply chains where testing is needed. And also, reporting data back to patients, of course, empowers them with access to personalized test results, knowledge, and guidance. Next slide, please.

So these are the data elements that are outlined in June 4 and further described in the implementation or technical specifications guide released on the 31<sup>st</sup>. Go ahead to the next slide. This is a screenshot-- I apologize, the browser used to capture the shot was not compatible with the actual PDF, so the color is a little weird. But hopefully, folks are now quite familiar with this implementation guide, which is a several page PDF, and outlines the data elements, the reporting requirements, technical specifications, as well as some notes, examples, and HL7 fields with numerous hyperlinks throughout the document.

So I'm going to pause on this slide here and talk a little bit more about what is intended with these different columns and the information here. So essentially-- and we've talked to many

different stakeholder groups at this point and various inquiries are coming in through a number of different channels, including directly in the DLS inquiries-- so I very much thank my colleagues at CDC for helping to triage those questions. I'm just going to hit a couple of categories of questions that have been coming in in terms of highest volume.

So one of the questions has to do broadly with how the implementation specifications guide relates to what's in the June 4 guidance. If you were to hold them side by side, essentially, all of the data elements that are listed with the column, 1 through 30 something, are the data elements that are listed in June 4. They're only listed once here. And the reporting requirement to the state or the federal or back to the ordering provider or whatever entity that is, is listed in the next columns.

So there's been some confusion that I hope to clear up here about reporting. So reporting should happen in the way that it does in your state and the way that CDC has described on their website. We just wanted to make it obvious that certain data elements go to the states and are held there, and only a subset of those elements are then reported to the federal government. And those are, of course, not identifiable, not PII, et cetera. So this is really meant to just outline that there is a difference in the set of data elements received at the state versus the federal level-- not an indication that they should be reported in any way that's different from what CDC has already outlined.

The ordering provider problem is reflective of the section in June 4-- the text that strongly encourages reports to be reported back to the ordering provider so that they could be included in the patient's electronic health record. And therefore, follow up forward with the patient longitudinally over time. Making that connection between the clinical data, the EHR, in other words, and the diagnostic data, as well as demographic data is very important for folks on the analytics side in better understanding both the performance of the diagnostic device as well as the potential interventions and medical interventions, the clinical interventions that might occur with the patient and how they fare clinically over time once they've had a test or multiple tests.

The other thing that I'll mention just on the reporting requirement columns. So you'll see for the required data elements, there's a yes or no. Yes, it's required or no, it's not required. Those are the data elements that are deliverable by August 1. So we are past that deadline. Folks have been concerned, obviously, given the heterogeneity of labs and their technological readiness across the US, that they're not ready to pull the trigger, flip the switch, and have everything flowing on August 1.

We do understand that and hugely appreciate the efforts, the tremendous heroic efforts that labs are going through, especially those that have not been technologically advantaged in building out their systems in the midst of this pandemic to try to capture, harmonize, and report the things that are both required and requested. So the category of required being the yes and no data elements or those that should be prioritized for reporting. And then those that are listed as requested are requested. They were not required in June 4, but they were strongly

encouraged, and they are strongly requested, because they're very important as well, in building out comprehensive data sets for action.

So focus on required then requested. And you'll see a new category or a new description of the requirement, which is optional. So one of the Ask on Order Entry (AOE) questions became optional. And then there are several if, yes, then categories that were added in the technical specifications guide. And all of the if, yes, then are listed as optional fields. We're very aware that folks did not have those built out that folks are working on those. That some people-- some labs, I should say-- will have a much easier time building those out. And some will be very challenged.

We're also talking with stakeholders in the EHR-- electronic health records, and other vendors, hospital systems, integrated health care systems, to try to work on solutions so that we're not really overburdening providers with regards to entering Ask on Order Entry data that's already contained in the clinical record, for example, or that can be obtained from the patient himself.

So we're trying to really be flexible and very creative with regards to how that data can be obtained and recorded and does not overwhelm the clinical community. And again, thanks to CDC for working hand-in-hand in communications with clinical providers there. All right. Let's move on to the next slide, please.

There were quite a few questions that came in around the category of device identifier. So this is an interesting data element that is really important with regards to devices that is to be reported. So this just outlines that there are two appropriate options that can be used knowing that there are not device identifiers for many of these IVDs.

You can use the DI or the UDI or you can use trade name/underscore company. So on this slide, you will see a couple of examples of what that might look like, either numeric or alphanumeric. And the trade name/underscore company is a fairly good stop gap measure for us for allowing us to still be able to identify what that device is in lieu of a device identifier.

There's also a description on the slide of how can a lab obtain the device identifier coming from the manufacturer. We also have support available from FDA through a harmonization and interoperability effort led by my colleague, Mike Waters, called SHIELD, which many folks are already familiar with. So you can email FDA at the email address there listed. And then lastly, the FDA has information available publicly about how a manufacturer can obtain a device identifier. Next slide, please.

This slide is just meant to show a couple different scenarios for recording and device identifiers. There are open platforms that can be mixed and matched and platforms that are self-contained. So there's different variations. Next slide, please.

And then this is a representation of how-- or I'm sorry, this is just one kind of screenshot of how that information can be represented. So behind the scenes or under the hood. And I know

there are many folks on the call who are familiar with this, the back end coding pieces that we've worked with. This is just a glimpse of the type of information and how it falls together in the reporting files. And next slide, please.

So this probably should have been earlier in the presentation, but it's just meant to convey that we are aware that there are hundreds of thousands of laboratories in the country and not all are equally prepared to implement the June 4 guidance and the technical specifications. Next, please.

The last slide is essentially a breakdown of the different inquiry categories and who's been submitting inquiries to the DLS website-- I'm sorry-- email address. The vast majority have been clinical laboratories with maybe a quarter of others, including academic, commercial, health departments, professional organizations, private sector asking questions. And of those questions, the majority have to do with reporting itself, which is related to, but not exactly what I was talking on today, which are the data elements themselves. But certainly, related, and we're working very closely across HHS and with the different lines of effort having specifically to do with reporting and reporting streams. And then there are a few other categories of questions that got a piece of the pie-- test results information, coding, et cetera.

There's one other topic I'm going to sneak in there really quickly that came in today and this was not on the slides, but we've become aware that there appears to be some confusion in the community on how to report results from pooled specimens. So this is actually really important and becoming more and more important as universities, schools, other congregate settings are looking to roll out screening and surveillance protocols. There will be more pooling.

So in anticipation of that, we specifically worked-- I mean the royal we-- worked together with other stakeholders to have a code created that should be used for reporting negative results from pooled specimens. So that code is a SNOMED CT code. And it is included in the technical specifications guide for lab reporting, one of the previous links there. And it's a code. It's a numeric code for not detected in pooled specimen.

So this was added to the HHS lab data reporting implementation specs in order to help maintain transparency for negative results associated with pooled specimens from asymptomatic patients. So this is really important in helping us to run analytics on the results, the test results, as they come in, and better understand the impact of pooling on test performance. But also, understand how many individual results are coming in as pooled, and therefore, were probably part of a screening or surveillance strategy as opposed to individual diagnostic testing strategy.

But in any event, this approach in terms of the coding for pooled specimens is consistent with the intent outlined in the package inserts, which includes some language about qualifiers and amplifies the message that negative results from cool specimens are distinct and different and should be analyzed as such, versus individual specimens that are tested. All right, so I will stop there. Sorry, that was a bit long, Jasmine. I think the last slide is just a thank you. So thank you.

**JASMINE CHAITRAM:** Thank you, Sara. So just a comment on the last couple of things you said about pooling and reminder-- this kind of ties back to two things on the CDC website. One is the [guidance on pooling](#) and one is the FAQs on testing. And so CDC also has some information about [when to report](#). So not so much about what to report, but when to report in the diagnostic screening and surveillance scenarios.

OK, so then we have a few questions for you, Sara. The first one is, what do you use for an LDT device ID? And a follow up question to that-- similar, so maybe you can think of both of them-- for an LDT ELISA, should we list device identifier as kit name manufacturer?

**SARA BRENNER:** I'm going to have to go back and talk to the Unique Device Identifier experts within FDA, but I'm going to say my initial thought is that you can go ahead and use that same coding-- it's not really coding, but it's the manufacturer name underscore that was in the slide on UDI. You can use that. Test name, underscore, lab name. But if you want to capture that question-- actually, I'm writing it down, and if there's a chance to bring that back to the group in a future clinical lab call, I'll do that.

**JASMINE CHAITRAM:** Sure. And we do record all of these questions, so I can always follow up with you later. Another one that we got, similar, is the trade name needs to be a concatenation of the analyzer and assay along with the manufacturer if the UDI is not known, question mark?

**SARA BRENNER:** Yeah, That's right.

**JASMINE CHAITRAM:** OK. For reporting the device identifier, what's the best way to identify our reagents from one vendor and run on an instrument from another vendor, especially if a bridging study was performed to run the reagents on an instrument not included in the reagent EUA?

**SARA BRENNER:** That's a great question. I'm going to come back to you on that one.

**JASMINE CHAITRAM:** OK. Here's another one. One slide listed patient occupation as a reporting requirement. This is not consistent with the June 4 guidance, which asks, employed in health care? Please clarify.

**SARA BRENNER:** OK. Sorry, the question was, they list their occupation and don't provide a response to the-- are they employed in health care?

**JASMINE CHAITRAM:** It sounds like in our guidance, we have patient occupation versus the employed in health care that was the data element that was in the June 4 guidance.

**SARA BRENNER:** Yeah, the question should be specifically. Were employed in health care with routine access to patients or with routine patient contact. That's what we're asking.

**JASMINE CHAITRAM:** OK.

**SARA BRENNER:** I think it is stated that way on the lab implementation specifications guide released on July 31.

**JASMINE CHAITRAM:** OK.

**JASMINE CHAITRAM:** Another one what should laboratories do when told by states that the state is not ready to receive the data required by the June 4 guidance.

**SARA BRENNER:** Yeah, we're getting this a lot. This is a scenario-- I was actually on calls earlier today about this scenario. That, I work closely with other colleagues on the data reporting. You are helping to streamline transition to seller and things like that. So you could reach out to DLS inquiries. I'm not sure if you already have an answer to that on your website, Jasmine, at CDC. But if you can't find that information, send an email and we can engage with you on how we're approaching it. It's very state-specific

**JASMINE CHAITRAM:** That's correct. And I don't think we have a specific answer, but we do have a team at CDC that is helping to provide technical assistance to state health departments. So I agree with you that the best suggestion is to send an email to [DLSInquiries@cdc.gov](mailto:DLSInquiries@cdc.gov). And then we can work with your state health department and with you to do whatever is necessary for them to be able to receive that data.

One more question and I think you and I could take this in parts. It says, is the CDC still receiving data from all state departments of health? The administration changed the reporting requirement. To which agency results should be reported? Is CDC still getting that information?

And so the answer to that I'll start with is that the CDC is still encouraging laboratories to report to state health departments. The states need this information to do their case investigations and their contact tracing. We are receiving data from the state health departments. The data we receive, I think, you mentioned this, is deidentified. I think that CDC is not receiving or is not asking to receive data directly from any laboratories except for six large commercial laboratories, which were sending data initially to CDC early and the response so that we could have some idea of the testing that was going on or percent positivity. So Sara, can you clarify if there is any reporting requirements directly to HHS outside of what I just said?

**SARA BRENNER:** I don't think I have anything else to add. I mean, of course, folks here are welcome to provide data. And there's also been of a side stream on FAQs with regards to hospital labs and clinical data, coming out of clinical hospital labs. But I think the moral of the story and the take home message is the goal in the changes in reporting were to increase the efficiency of the flow of data and to increase the efficiency of exchange and sharing that data with CDC and others across the entire agency who need the data. It's challenging when you make switches like this for a number of reasons, but the overarching goal is to improve efficiency, quality, and comprehensiveness of the data for all parties who need it, including CDC.

**JASMINE CHAITRAM:** Great, thank you. And the last question is, in California, is it still the case that all results should be reported to the state and positive results should be reported locally too? And I will go ahead and answer that. And it is the CDC recommendation that you reach out to the health departments in California for their reporting requirements.

OK, thank you, Sara, so much for being on the call and presenting that information and answering those questions. We're going to move to the next speaker, which is going to be Tammy Beckham. She's also with the US Department of Health and Human Services. And she's going to give us an update on the status and the federal procurement of testing supplies. And there are no slides for Tammy, so she will just be speaking at this point.

**TAMMY BECKHAM:** Hi, good afternoon. Can you hear me?

**JASMINE CHAITRAM:** Yes, I can hear you. I think I heard a little bit of an echo there but hopefully, that will go away.

**TAMMY BECKHAM:** Great, thank you. So it's a pleasure to be with you this afternoon. What I wanted to just chat about is to give a little update on the status of testing supplies. And I will update on federal allocation. So the testing and diagnostic working group continues to work with states to help meet goals to include those for swabs and media. And we will continue to do this through December. So to give you an example, in September, we will be working with the states and providing over 18 million swabs and over 18 million vials of media. And that will be viral transport media and PBS or saline.

We also continue to work with the state through our subject matter experts to implement their testing plan and to talk to them about inventory and available platforms. We continue to work with the manufacturers as well to understand what inventory is going to be available between now and then looking all the way into next year, that helps us have a good understanding of what is available and how to guide states to full implementation of their testing plans.

Having said that, just a little discussion about where we are with inventory now, and we do know and we have taken many questions from our state partners about inventory across the different manufacturers. And what we're currently telling folks is that we know that many of the major manufacturers that have the all-in-one test, such as Roche, Hologic, and the Abbott N2000, the Cepheid and others like the Abbott ID Now will continue to be somewhat flat line between now and the year as far as their inventory goes. But we do know that there will be additional inventory on the market through vendors like PerkinElmer and Thermo Fisher. And so we're encouraging folks to diversify their platforms to meet their testing needs going into the fall.

We continue to work with the RADx program and BARDA, taking a look at new technologies that are coming through the pipeline and anticipating inventories and the ramp up time that might be available to us throughout the fall, and what inventories, and how do get those in the market with the best use cases for those tests. Obviously, we worked closely with them, so that

we have good understanding of that. And while we don't have anything that I can say today, we're hoping that some new technologies come into the market over the next month or month and a half that will add to our ability, our flexibility, and our testing platforms.

As you heard Sara say, it's really important to do the data reporting so that we understand how these tests are being utilized, and where the tests are being performed, and the available inventory that's out in the state. So that really helps us take a look at where we need to, if we need to, work with are manufacturers to help allocate specific assays.

We've been working with the state and with the craft teams that have been going out, as well. We're looking at surge areas and where needed to move in extra swabs and media to accommodate that. We've also recently worked with two commercial labs to help ramp up their capabilities that within the next six to eight weeks or so, we'll have another million tests available from the commercial labs. We've really been working with the commercial labs to reduce that turnaround time. That's been such a pain point for many of you out there, understanding that those turnaround times need to be well within 48 hours, no longer than 72 hours so that you can have actionable results off of that.

We also continue to work using our DPA authorities for industrial-based expansions, whether that's in swab production or whether that is investing in antigen production such as the antigen tests that have recently come on the market. We also continue to purchase the Abbott ID Now and send those out to states as we have been. And we will continue to do that through December. And we will continue to work with the states and manufacturers on the newer technologies, and especially, we spent quite a bit of time over the last several weeks working with manufacturers as well as different laboratories on pooling and taking a look at how you use pooling in different scenarios. And I know that FDA will probably talk a little bit about that in a few minutes.

So overall, we're continuing to reach out to states, continuing to provide that subject matter expertise and continuing to work with them on a testing plan while at the same time, really trying to stay on top of what's happening with the manufacturers, the inventory, anticipate supply chain issues. We've heard from many of you and we have heard from many people out there around the supply chain issues around consumables. So not just free agents, but acknowledging there's also issues with pipette tips, et cetera, especially in fully automated the platforms.

So we have a very robust effort underway to try to at least help alleviate a little bit of that pain and burden and really approaching that from different points of view. Working with some of the current manufacturers. And then working with them in different ways. And so we don't have anything to announce on that yet, but we are in the process of working with them to try to help alleviate some of those pressure points. So realizing that it's not just reagents, but it's also the consumables that we're looking at.

I assure you that when we hear about the shortages, we get out on top of it. We look at is there an opportunity for us to find another source, is there an opportunity for us to invest in an industrial-based expansion, is there another opportunity for us to help solve the supply chain issues. And we look at everything from the very beginning of manufacturing of, for instance, a tip or a mold, the mold that's able to do that, et cetera.

And so that is what our group has been doing. And that is what we will continue to do moving forward. And we'll continue to work with states to try to help alleviate any issues and ensure that they can fully implement their testing strategies. So that's it from me, Jasmine. Thank you.

**JASMINE CHAITRAM:** Thank you. So we do have a couple of questions and comments. I'm going to read you the comments first. The first comment-- lost it. All right, hold on.

Encouraging folks to diversify their platforms is an unreasonable expectation for laboratories that are already overwhelmed while still trying to meet quality standards. That's the first comment. I don't know if you want to respond to it.

**TAMMY BECKHAM:** We understand the issues associated with that and I clearly understand-- I work in a lab. And so I hear what you're saying to us. What I can tell you right now is that we're doing everything we can with inventory. We have used the DPA as much as we can. We have invested in industrial-based expansions. And what I can tell you is where there is available inventory and what I can tell you is where there is not available inventory. And so that's what I can do to try to help. I understand what you're saying and that's what I can say.

**JASMINE CHAITRAM:** Thanks. The next comment. Iowa is not sharing these supplies with the hospitals. It is being used for surveillance testing only. It would be more helpful to us if the government would ease off on what they're sequestering. We are running out of reagents on a weekly basis.

**TAMMY BECKHAM:** So the government doesn't sequester the reagents, we are absolutely not doing that. So we do not have a stockpile somewhere. We are not asking manufacturers to hold on to reagents. Absolutely not. If that's the statement, that is not correct.

Everything these manufacturers are producing is going out the door on a weekly basis. We get a good idea of what their shipping is. And we are absolutely not sequestering the reagents. We are working with the manufacturers when we need to when there is an emergent hotspot, but we are absolutely not sequestering reagents.

**JASMINE CHAITRAM:** Thanks. Roche and Cepheid are still on allocation for reagents, and both vendors have told me they will not be able to increase production and increase allocations until the end of the third quarter or fourth quarter of this year. Have they communicated to the federal government a different timeline when they will be able to produce more to meet the demand?

**TAMMY BECKHAM:** No, that's the communicated timeline.

**JASMINE CHAITRAM:** All right. Let's see, I saw one more. Hold on.

**TAMMY BECKHAM:** Just a point there. We really work with both of those companies. They're absolutely doing everything they can. As you know, to bring up a new manufacturing line takes time. We have worked with the companies who are interested in industrial-based expansion help from us. There are a couple of companies who have taken it on themselves to do their own industrial-based expansions. And there was nothing that we would have done that would enhance their timelines around doing that, given the manufacturing requirements. But that is the timeline they're talking to us about.

**JASMINE CHAITRAM:** All right, thank you so much, Tammy. I think in the interest of time, I'm going to move to our last speaker to give FDA enough time to answer some important questions, as well. I do appreciate your time today.

**TAMMY BECKHAM:** Thank you very much for having me.

**TIM STENZEL:** OK, this is Tim Stenzel with the FDA. I have a number of questions. I'll try to get through most of them in the remaining time. The first question has to do with the Abbott ID Now test. The FDA-mandated studies should be done by now, shouldn't it? Are we stuck with all negatives having to be repeated due to questionable specificity that may be sensitivity? What is the latest update on Abbott ID Now? We have had some information that it should only be used for symptomatic patients and have heard that others are using it for presurgical screening.

So there has been no recent change to the assay. And at this time, the intended use statements still say negative results should be treated as presumptive. And if inconsistent with clinical signs and symptoms, are necessary for patient management, should be tested with a different authorized or cleared molecular test.

So it doesn't require negatives to be tested with some other method. It does ask for clinical judgment in that situation. The intended use can be changed if new data becomes available. And we'll always work with developers to do that. And then also, we have issued a safety communication, so I'd refer users of that test to that safety communication.

Next question is, why are we not insisting on providing CT or cycled threshold values? Wouldn't we learn a lot more about SARS-CoV-2 and COVID-19 if we went beyond simple positive and negative? So I'll answer that from the FDA's perspective. I also will note that the CAP recently published an article covering this topic, and would urge listeners who are interested to go to that publication.

There is nothing that prevents the lab from reporting cycle thresholds from authorized tests. Right now, we already use that data in research around the meaning of CTs and helping us

understanding the disease. Many molecular tests do provide a CT result, but some do not, because their isothermal. And so in those situations, it would be challenging, because many of them go to the highest value by the time it's measured.

The CT value is sometimes roughly used to estimate the relative viral load of a patient, though the accuracy of these estimates have not been established. And the CAP article gets at that, I believe, in a great manner. Furthermore, CT value is only a relative estimate and comparing CT values between tests is difficult without a common reference material or international standard. The FDA has developed reference material and is making that available to many, if not most developers now, and will finish sending those out hopefully, in the not too distant future. And we are starting to get data back and starting to review it and trying to make sense of it.

Ultimately, once an international standard is available, we will anchor the FDA reference panel to the international standard and be able to convert all of the test data over to international standard units. We hope that this reference material will be useful and support comparison between test performance and investigations into patient viral load.

Next question is, has the FDA posted new FAQs on antigen testing? We are working on an update as it relates to testing of asymptomatic patients. So as noted by many, the intended use statement is a little bit different than some of the others, but in general the FDA-- and is reflected in our FAQs that were most recently updated on this topic in general regarding asymptomatic testing on Friday-- is that if there is a valid clinical order and the lab feels comfortable, we would urge that the tests be done and the results reported even on asymptomatic patients.

Next question is, are sensitivities and specificities known for tests on the market when done in asymptomatic individuals? Well, to date, only one assay, the LabCorp assay, has been authorized for claims around asymptomatic testing. And their performance is listed on the FDA IVD EUA website in their summary report. So you can go there and look at the performance of that particular test.

Next question is the data on two antigen tests that FDA website shows, [EUA](#) does not include sensitivity and specificity. One thing we do use instead of sensitivity specificity-- we do use positive percent agreement and negative percent agreement instead of sensitivity and specificity has to do with ways-- the comparator test or situation. And these values are in all of the IFUs or summary reports. So just go to the [FDA IVD website](#), and it's all posted there.

Our next question is, are there any serological tests for COVID-19 approved for CLIA-waived labs? Not as yet, but we're eagerly anticipating being able to and will certainly authorize one as soon as we can.

The next question is, is an EUA required for each lab that wants to perform testing collected in the home or school or just for the kit itself? So yes, we expect if a lab is not using a kit that

already has a home collection or school collection, we now refer to it generically as a non-lab collection situation. If they're already using a test that's been authorized for that, that's fine. But if labs want to add a home, school, non-lab collection, non-observed collection to their test in their lab, then yes, that does require EUA prior to testing. And with that, that's the end of the questions I had.

**JASMINE CHAITRAM:** OK. Looking to see if we have any additional questions since we've got about two minutes. Let's see. One question, can you tell me how the Abbott ID Now compares to high throughput testing platforms on specificity and sensitivity?

**TIM STENZEL:** OK, the reported issue that we've been looking into has to do with sensitivity-- other numerous published reports that are portraying the assay as less sensitive than other molecular tests. And so we did update their intended use to state that the negatives are now presumed negatives and we did require a post-market study that Abbott is still performing. And as soon as all the testing is wrapped up, it's been publicly assured that we'll make that data available once we've had a chance to review that. And as I've previously stated, the IFU will be updated with that new information, as well.

As far as specificity goes, that is the number of false positives. We do track reports-- [MDR reports](#). And we have not noted that to date that there's any significant issue with that test. We have obviously, made public some tests that have had false positives and will endeavor to make that kind of information well known for any test that it may occur. And we believe the data suggests that there are indeed, more than expected false positives.

**JASMINE CHAITRAM:** OK Tim. Thank you so much. We're right at the top of the hour, so I'm going to wrap it up with just some final statements about our next call, which will be on Monday, August 31. We hope that you can join us. These calls are now happening every other week.

As a reminder, the transcript and the slides for these calls are posted on [Safe Labs](#). That's CDC.gov website under Tools and Resources. And if you want to receive messages from CDC, sign up for emails at [LOCS@cdc.gov](mailto:LOCS@cdc.gov). That's [LOCS@cdc.gov](mailto:LOCS@cdc.gov). And thank you again for joining us this afternoon and hope everybody's staying safe.