

# Clinical Laboratory COVID-19 Response Call

## October 18, 2021

### Agenda

- **Welcome**
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- **Say Yes! COVID Test**
  - Rachael Fleurence & Matthew McMahon, National Institutes of Health (NIH)
- **COVID-19 Testing and Policy in Utah K–12 Schools**
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- **SARS-CoV-2 Variants Update**
  - John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response

**JASMINE CHAITRAM:** Hey, everyone. Thanks for joining the Clinical Laboratory COVID-19 response call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. And we're glad that you were here with us again for our biweekly call. We've got a full agenda today. And I've got a number of announcements.

So I'm going to quickly just remind everybody that the [Division of Laboratory Systems](#) at CDC has a specific role in helping clinical and public health laboratories in a number of areas, and those areas include quality, quality laboratory science, training and workforce, accessible lab data that can be through informatics or just using large data sets and data science. We also manage a large biorepository here at CDC. And we have a lot of activities under preparedness and safety.

And in the area of preparedness, particularly preparedness and response for the COVID-19 pandemic, we have been serving in a role as a liaison to the CDC Emergency Operation Center providing coordination and communication to all the clinical and public health laboratories out there that are involved in testing for this pandemic. So a couple of announcements that I wanted to make before we get into our agenda, some things that are available now at DLS.

We are very excited to share this with you. For Next Generation Sequencing (NGS), we have a quality initiative, and we have some new tools available. There's a [link](#) on this slide, in particular, that shows you some of the information that we currently have that can assist your laboratories with Next Generation Sequencing and ensuring quality.

Our [CLIAC meeting](#) is going to occur November 3 and 4. That's just a few weeks away. So please go ahead and register for CLIAC. The information on how to do that is on this slide as well. We've got a lot of updates from several of our agencies, including CDC, FDA, and CMS.

We also recently launched a new laboratory risk management course. It's an e-learning course. [Links](#) are shown on this web page.

We also sent out a [Laboratory Outreach Communication System](#), LOCS, email announcing this new course. So another thing that we're very excited about and very proud that we were able to get out there and accessible to all of you.

And just a reminder that we have a [CDC Preparedness Portal](#) where you can find all the information related to preparedness and response activities, especially for the COVID-19.

We have our transcripts, archived slides, for all of our [COVID-19 response calls](#). We have all of our LOCS messages archived here. We also have links to other CDC web pages that are supporting and providing information about the COVID-19 response, including links to testing guidance. So this is a one-stop shop for those of you out there. And feel free to visit this site as often as needed.

Our next clinical lab call will occur on Monday, November 1st from 3:00 to 4:00 PM. We hold these calls every two weeks. We continue to ask for your feedback on any of your training and workforce development needs. So please send those to [labtrainingneeds@cdc.gov](mailto:labtrainingneeds@cdc.gov).

And reminder on asking a question, please submit those questions using the Q&A button in the Zoom webinar system. Please do not use the chat. The Q&A allows us to track those questions. And it would really be helpful if you included your email address and name when you submit those questions. We do try to get through as many questions as we can during the call. A lot of times, though, because of the number of questions coming through and the time allotted for the call, we are not able to answer all of the questions.

And also, sometimes we don't have the appropriate subject matter expert to answer the question. And so if you can submit those through the Q&A with your name and email, we can get back to you, or we can provide an update on future calls through either a specific agenda item or have a subject matter expert participate and answer your question. So just a reminder to use that Q&A button and not the chat.

Also, questions that are submitted, we do ask that they be related to laboratory testing. That is our primary objective with these calls, is to share information around laboratory testing needs and issues. I know that sometimes folks submit questions about vaccine mandates and other things, and we really don't have the subject matter experts on this call for those types of questions.

And then, finally, also a reminder that the slide decks may contain presentation material from panelists that are not affiliated with CDC. So these may not necessarily reflect CDC's official position on that topic.

And the slides, as I said, will be posted on our preparedness portal. I do think that almost all of our speakers today have slides, except for our last item, which will be Dr. John Barnes from the CDC Laboratory and Testing Task Force. And he will just go through a demo of the CDC website with [information about variants](#).

So with that, I think we are ready for our very first speaker or speakers. We've got some partners over at the National Institutes of Health. And Rachael Fleurence and Matt McMahon will give a presentation on a program called "Say Yes! To COVID Test". And I think they also have Liz DiNenno on the phone who can also help to answer questions once they're finished going through their slides. And with that, I'll turn it over to you, Rachael.

**RACHAEL FLEURENCE:** Thank you, Jasmine. And we can move to the next slide. I just want to acknowledge my co-presenter, Matt McMahon today as well as my colleague Dr. Liz DiNenno from the CDC and then two other team members who are not on the call today, Dr. Andrew White and Dr. Krishna Juluru, both at the NIH. Thank you. So I'm going to present to you today a program called Say Yes, COVID Test, which is really a rapid test deployment program. You can move to the next slide, Jasmine.

The program is a partnership between the NIH, the CDC and local public health departments. And it essentially provides 1 million free rapid antigen tests-- it's the quick view that's pictured here-- to residents in the county. Participants can order the free tests in two ways. One is through an online ordering process with Amazon, which you're already familiar with. And the second one is an ability to pick up tests at local sites through community events that's coordinated by the local public health department. Next slide, please.

We do have a number of program questions as we've implemented the initiative. We want to understand demand for these tests. So are residents going to be interested in ordering or picking up these free tests? We want to understand their access and their interest in underserved and vulnerable populations. We are interested in use and behaviors around these tests. Will people-- will these residents be willing to use tests for screening purposes? So two to three times a week without symptoms. Will they be willing to report tests, results, to the public health department?

And we're also interested in larger questions around whether a large initiative deployed like this in a community can break community transmission and are we able to set up a study design that might be able to look for that. And then finally, we also have questions about scalability, which we can talk about some more. Jasmine, thank you for the next slide. And since we don't have a lot of time, I'm just going to give you a whirlwind tour of the program, the different program components.

The public health initiative itself is really led locally by the public health department. We provide 1 million rapid antigen tests to the participating community. We have developed a website and a digital assistant for people to be able to both order tests but also receive reminders, report their test results to local public, or actually the state health department. They can also access FAQs about what to do with a positive or negative result, and things like that.

And that's our partner care evolution that has developed the digital assistant. We do have an important focus on underserved and vulnerable populations, and that's done in two ways. One is through the selection of the zip codes that are open for ordering. We, in partnership with the public health department, select high SVI zip codes for this. And then the second way is done through the community events on the ground that the local public health department organizes.

I mentioned the test result reporting. We have worked with APHL and several of the participating state health departments to enable reporting using agreed upon standards and HL7 messaging, so we do have that ability to do that on the app. It is voluntary, so people choose to report their result or not.

There's a survey that's going to help us better understand the behaviors and the uses of the tests at home. We were lucky in this round of the program to have budget for incentives to see if we could incentivize people to complete the survey and to send in test results. And then finally, there's a program evaluation that's conducted by our research partners at UNC, Duke and University of Massachusetts, and that's an ecological study that looks at pre- and post-community transmission on both sides of the intervention.

Next slide, please. And so the big picture of the initiative is that we're now active in seven communities. The first three are finished. They were in Pitt County, North Carolina, Hamilton County, Tennessee, and that was in the spring, early summer. July and August, we were in Michigan in Ann Arbor and Ypsilanti. And this next round, which is our kind of third phase, we are active right now in Fulton County, Georgia, Honolulu County, Hawaii and Louisville Metro, Kentucky. And we just launched today in Marion County, Indiana, which is the area around Indianapolis. Next slide, please. And I wanted to share a few of the initial findings in these first three earlier communities in the spring that were in North Carolina, Tennessee and Michigan and let you know a little bit about what we learned.

You can go to the next slide. This slide gives you the distribution or sort of the breakdown between the online ordering and the community pick up, and you'll see that in the first two communities in North Carolina and Tennessee, the majority of the tests were distributed on the ground and not so much-- a little less on the online ordering.

But in Michigan, the numbers reversed, and we had 56% of the tests were ordered online. In North Carolina, you might notice we did have tests left over. So we were in a fairly small county. There's about 300,000 residents in Pitt County, North Carolina. We did have tests leftover, which actually allowed us then to open up to that third community in Michigan. Next slide, please.

I'm just going to run through a few. We commissioned a market survey with a company called Research America, which I want to credit for the survey. I'll just highlight a few things in the interest of time. I won't go into a lot of detail, but the learnings on this slide where we questioned people about their concerns about home testing. And remember, this was March, April when this was fairly new, and the FDA had just done their first EUA for serial screening.

So the main concern was that home testing was-- or these rapid antigen tests were less sensitive to PCR. So that's what came out there. They were concerned about whether the test would be difficult to perform, but in future questions that I'm not presenting today, they did actually find the test, actually, very easy or easy to use. And you can go to the next slide.

The next slide and then we'll go to the next slide as well. The next slide just shows we asked people if they were aware of the program, and there was quite a high awareness in North Carolina and Tennessee. We did have paid ads and paid social media advertisements there. We did not have that social media campaign or advertising campaign in Ann Arbor, Ypsilanti, so you see there's less awareness.

Only 32% of the people surveyed there were aware. If you go to the next slide, Jasmine, you'll see that actually that didn't impact the actual ordering of the test or the picking up of the test, were fairly similar. Almost 20% in each of the communities ordered or picked up tests in these three communities. And next slide.

An interesting question about how did they prefer to order tests. And so these results are among those who had not, when they were surveyed, had not yet ordered any tests. So they're among those who don't have tests yet. And so you'll see-- actually, I'll start with the bottom one. Some of them actually said we don't want to receive a home test kit. So there is a portion of the population that was quite high in, for example, Pitt County, 41% of that group said we have no interest in receiving a home test kit.

But we also asked those who hadn't received, if they were going to order, how would they prefer to, or if they were going to get a kit, would they prefer to order online or pick it up. And you'll see that actually across all three communities, the preferred way of receiving the kit is through online ordering, which we thought was an interesting piece of information.

Next slide. We are, as I mentioned, going to be doing a program evaluation with our academic partners at UNC, Duke and University of Massachusetts. It'll be an ecological study that will include matched controls. Some of the outcome measures will include cases of SARS-CoV-2, the measures of SARS-CoV-2 in wastewater, mobility outcomes, hospitalizations and SARS-CoV-2 ICU admissions.

And this will all be using aggregated publicly available-- or publicly collected information. And we expect to have some of these results late fall, early winter. We don't have high expectations that we will be able to see a signal in this, but we felt it was important to undertake the study and see what might come out of that. Next slide.

And then I'll just finish with a couple of slides on our current initiative, which is really in the fields right now in these four communities. You can go to the next slide, Jasmine. So Fulton County, we launched September 20th. The same time as we launched in Honolulu County in Hawaii. And we just launched last week in Louisville Metro area in Kentucky, and then today in Marion County, Indiana.

And so in Fulton County, which is about-- they're about four weeks in, just over four weeks in, about 33% of their stock is either being ordered or distributed. So sort of a healthy start, but we do after the first few weeks see a tapering off of the demand locally, and that's generally been our experience in all of the counties, except Honolulu County, which is Oahu in Hawaii, where in the first two days almost all of the stock had been ordered online. So we had to actually throttle the website and make sure that there was reserved stock for the local distribution.

And they're actually out completely now. So 100% of their tests were used up by the end of the first week. In Louisville, they just started last week. We're about 13% the way through. I actually think it's about probably about 17% now in the first week. That number's a little old. And we just launched today in Marion County.

And I think what I'll say is we think that Hawaii was really an outlier in that very, very high demand. And generally, there certainly is demand for home testing, but it does take time to get the information out, for people to be aware of it, and then to be willing or interested to order them. Next slide.

And really, this is just to say that this partnership between the CDC and NIH and the local public health departments really involves many, many players, and this is just the acknowledgments for our colleagues, both in the federal agencies, particularly in the local public health departments who do a lot of the heavy lifting, who really are on the front lines of answering questions about positive tests, negative tests, why isn't my zip code included, and things like that.

So we're really grateful to them for all of their efforts and as well as our operational logistical partners and the research and community engagement partners listed here. So with that, I'll stop the formal presentation, and we can do Q&A with my colleague Matt McMahon and Liz DiNenno from the CDC. So thank you for your attention.

**JASMINE CHAITRAM:** Thank you so much, Rachel. We did get a few questions in the Q&A box. And I saw that Matt was really good about answering some of those already. So I'll ask you a few of the other ones that are showing now. How were the locations chosen for this program?

**RACHAEL FLEURENCE:** Yeah, very good question. So the first round we partnered with a company called DataRobot who did a modeling exercise based on a number of many, many variables, including kind of the rates of transmission, the predicted vaccination rates, prediction of the community transmission rates and then the impact of the potential initiative on the community and whether we might be able to see a signal depending on the size. And they also made assumptions about uptake and things like that. So we used the modeling exercise to select North Carolina and Tennessee.

Michigan was more kind of a convenience site, although they did, you might remember, they were right on the tail end of that major surge they had in the spring, which was still, I think, an Alpha surge. And so there was a lot of interest in that community. They met our criteria. And so they were selected for that third round.

The fourth round we were, I think, with experience, we used a different kind of algorithm, and really just used SDI community transmission and the size of the county. So this time around we went for slightly larger counties that would be able to sort of modulate in terms of the demand. So if the demand was lower, a larger county was going to be more helpful for the program. So we had different ways that I think we improved upon on each round.

**JASMINE CHAITRAM:** Thank you. There's a question in the chat from a lab. They want to know how they could get involved. I know these are-- this is at home testing that you're distributing. But are there opportunities for laboratories that have COVID testing capabilities to get involved?

**RACHAEL FLEURENCE:** It depends what they might-- how they might like to be involved. So it might be interesting to hear a little bit more about what kind of role they could see themselves playing. We're always interested, certainly, in speaking with partners, but I think we'd have to understand a little bit more about the offer.

We haven't typically worked with labs. Obviously, it's a home testing program. The thing that comes to mind might be reflex testing, but we've generally relied on the local public health department and their current partners to sort of set that up if that was something that the local public health department wanted to make sure happened.

**JASMINE CHAITRAM:** Great. Thank you. And do you partner with organizations to get more home tests out to people who may not have the resources to hear about home testing or have otherwise limited access to testing, such as homeless populations, refugees, immigrant populations, et cetera?

**RACHAEL FLEURENCE:** So yes and no. It depends on the local public health department. We do, as I mentioned, have a very strong focus on underserved and vulnerable populations, but we largely rely on the local public health department to use their existing partnerships and relationships to make that happen on the ground. We do know that in Louisville, Kentucky, for example, the three populations that you mentioned are high on their list of priority populations to reach out to for the tests.

In North Carolina and Tennessee, our academic partners at UNC worked with their community engagement network to work very closely with faith organizations, faith-based organizations, essential worker organizations in the Latinx community and things like that, but we really rely kind of locally on who the partners already in place are.

**JASMINE CHAITRAM:** And do you happen to have any preliminary data on the utilization of the test rather than just orders? So what percentage of tests ordered followed with a result within one month as an example.

**RACHAEL FLEURENCE:** Yeah. So all that is in process. We have a little bit of information from the market research surveys but remembering that not everyone in the market research survey actually

received a kit. So that was a sample in the community. We know that only 11% of folks, and that's across the first three communities, use the test for serial screening. So two to three times a week for asymptomatic and an asymptomatic situation. So actually pretty low.

Most people use the test from the survey, they use it for if they think they've had an exposure or if they're going out and they think they might be putting someone else at risk, they want to test themselves before they go out. So that's largely how it's been used. But these are excellent questions. And the survey that we're deploying in the latest four communities will hopefully give us a lot more granular information on use and behavior change post testing. I just want to see--

**JASMINE CHAITRAM:** Thank you so much.

**RACHAEL FLEURENCE:** I just want to see if my colleagues-- if Matt or Liz want to add anything to the answers I'm giving.

**MATTHEW MCMAHON:** I don't have anything to add. I've been just trying to answer as many questions as I can through the chat here. I'll keep doing that and kind of listening as well.

**ELIZABETH DINENNO:** Yeah, and I agree. No, it's great. I think there's a lot of questions about reporting of results and are the results reported. And that's what you've been trying to get at. And I think it's really important to explain that these are not-- these are tests where you can get the results in your hand.

And so you cannot require results because it's all self-contained, which is part of the beauty of these tests as well as the challenges for health departments. So just to make it clear, no, the results are not required to be reported to the health department unless the person would like to report them. So just to be clear, because I see a couple of questions about that.

**JASMINE CHAITRAM:** Thank you for that clarification on reporting. So Rachael and team, thank you so much for presenting today on this program. There was definitely a lot of interest, a lot of questions. And Matt, if you can keep on answering those questions in the Q&A box, we'd appreciate it. I would love to keep the discussion going, but in the interest of time, I do need to move to the next speaker. So thank you again for joining us today.

**RACHAEL FLEURENCE:** Thank you.

**JASMINE CHAITRAM:** So our next topic on today's agenda is COVID-19 testing and policy to sustain in-person instruction and extracurricular activities in Utah high schools. And we have William Lanier from the Utah Department of Health here to talk about that. William. Willie.

**WILLIAM LANIER:** Hi, everybody. Can you hear me OK?

**JASMINE CHAITRAM:** Yes, it's great.

**WILLIAM LANIER:** OK, super. I updated the slides, I think, maybe the last or the second to last one just a bit. Is it possible for me to share, or would that be too complicated?

**JASMINE CHAITRAM:** Unfortunately, at this point in the call, it would be a little bit difficult. So hopefully it's not too much of a change.

**WILLIAM LANIER:** No, no. It's fine. Totally fine. Well, thanks for the opportunity. I really appreciate this. And I was not aware of this call and this group beforehand. So thank you. So my name is Willie Lanier. I'm a Public Health Service Officer. I'm the state public health Veterinarian in Utah. I'm also a CDC CEFO assigned to the Utah Department of Health. And I just started that in July of this year, so it's relatively new.

Had a chance to deploy as a PHS officer to Utah to help stand up school COVID testing back about a year ago, a little bit less than a year ago, November through January of about a year ago. And I'd like to talk to you about that experience and the [MMWR](#) we wrote on it and also related policy in K-12 schools in Utah.

So next slide. Do I advance, or do I tell you next slide? Got to tell you next slide, OK. Thank you. So this is just a graph of kind of the data we were looking at when I came on the scene to help out with this. And there's a lot going on here, but I'll orient you a little bit. So this shows COVID incidence on the y-axis and on the x-axis is dates. And you'll note this is 2020. It's about August through November of 2020.

And the top two lines are what I really want to show you. They kind of stand out and there's this bump in September. And you'll see the very highest incidence line, they're a couple of different shades of green. But the highest incidence line is ages 19 through 24. And the second most right under that fall bump kind of paralleling the higher one is ages 15 to 18.

And you'll see that the vertical dashed line, as indicated, is about the time that K-12 schools began in Utah. And these were in-person. Many, many schools in the country understand, started virtually only, but the governor of Utah and others really, really insisted, no, we are going to school in person. And for the most part, that happened.

Masks were mandated. Other things were in place, prevention and mitigation measures. And then you'll see that that vertical gray rectangle is the period of time where universities were beginning. So in August, roughly. And then a couple of weeks after that, we see this really concerning bump in the college and high school age kids as far as COVID incidence.

So that's what we were looking at. Next slide. And those are Utah rates. So coinciding with the start of my deployment, we got a large number of BinaxNOW, Abbott BinaxNOW rapid antigen COVID tests from the federal government. And so Utah expressed concern.

There was this commitment from the federal government of the supply of BinaxNOW. And there was a plan developed to use these tests in order to-- in both college and in high school, particularly, which is what I'll be focusing on, given the rates that we just saw-- to do three things, three goals. So decrease COVID transmission in school populations, to allow students to participate in in-person learning safely, and three, allow students to participate in extracurricular activities more safely.

And we thought that routine serial testing in a population would reduce the risk of transmission in two ways. One, a direct way, identifying positive cases for isolation. So finding the positives, pulling them out of the transmission pool. And number two, more indirectly but importantly, incentivizing preventive behaviors. If they knew that a test was coming up, then they might engage in more preventive behaviors in order to try to avoid a positive test that might be linked to loss of opportunities for going to school or participating in extracurricular activities.

And this, as I mentioned, is in the context of universal mandated masking in schools at that time in Utah. And other distancing was also a part. And hopefully, we hoped that even outside of school these testing programs would encourage preventive behaviors like masking and avoiding higher risk situations, et cetera. Next slide. So this, also coinciding with the start of my two-month deployment to Utah, the governor had a Sunday night broadcast.

We interrupt this program-- it was really something like that. The governor came on the screen and said, we are pausing extracurricular activities in schools with the exception of high school playoffs games. And so we mobilized to use these tests to test everybody involved in high school football tournament play, the students and the staff, and they needed to have a negative COVID test within 72 hours before the game.

So we rapidly mobilized our mobile testing team in the Utah Department of Health. And a whole bunch of people, including as you'll note there, contractors, local health departments, school nurses, and even hospital staff joined the team, and in two weeks' time, the remaining tournament play we tested all of these teams. So week one, 16 teams, more than 1,800 people, and we got about 4% positive. And we thought it might have been worse, actually, but at least with these rapid tests a 4% positive.

So the people that were positive we're told you have to quarantine, you can't play in the game. And then in week two, after the teams were whittled down, we tested six teams of over 800 people and about 2% were positive. We thought that was interesting that we saw 4% in the first week and then 2% in the second week.

Potentially some early indications that a serial testing regime might yield results that we liked to see. And this project, this football testing became the pilot project for what we called Test to Play, and I'll talk about that. On the picture there you can see me donning some PPE to get ready to participate in one of these football testing clinics, pre-tournament testing clinics. So that was that at one of the local high schools. And I got to actually do some-- I was an assistant swabber that day. So that was my first introduction to COVID rapid testing. Next slide.

All right, so Test to Play. If you've looked at our MMWR, you know that we talk about Test to Play and Test to Stay. So as we came up with this idea of utilizing rapid tests for extracurricular activities, we just kind of-- that name arose somehow and it caught on. So we called it Test to Play. And after what we considered a successful pilot in the football scenario, we decided to take that and apply it generally in Utah.

And this was done by public health order effective of the end of November, 2020. And so in order for people in high school to participate in athletic and other extracurricular activities, both students and adults, they needed to be tested for COVID at least every other week. So every 14 days was the language in the public health order. They also could not have symptoms and they could not be in isolation or quarantine.

Now, that frequency that every other week was something that was arrived at based on logistical concerns and just sort of the realities of what we were facing here. It was not-- in the beginning considered an ideal frequency for detecting positives. However, it seemed to work out rather well. So the state provided schools, rapid tests, PPE, training, resources, including how to obtain their own CLIA waiver and gave them a reporting system.

There were a couple of different options for reporting results to the state. And one of the things that we considered really remarkable was that school staff was the one who did, or manage, the testing under the, generally, a school district or an LEA, CLIA waivers. They had their own CLIA waivers. Essentially, we established nearly 200, at one point, independent testing clinics, school-based, school-run testing clinics.

We provided them everything they needed and essentially turned them loose. And note, importantly, school staff, even if they weren't involved in extracurricular activities and, therefore, fell under the mandate, school staff, if they just wanted to know their status or maybe they had symptoms or whatever, they could also be tested by schools under the same program. Next slide.

And you'll see on the picture there is a BinaxNOW. All right, so then, once we had a few weeks of Tests to Play under our belts, we decided to move-- to utilize school-based testing in another way. And we came up with the concept of Test to Stay. And we called it that really because it rhymed with Test to Play. So if you back up to the beginning of 2020, schools were in-person and their COVID numbers in the school were monitored carefully. And once they reached a certain case threshold, they were recommended to transition to virtual learning. And so this was a policy generally followed in Utah. So once they hit that threshold, they would transition to remote learning for a period of time.

With Test to Stay, we offered them an alternative to that. So we said, you could avoid that virtual period when the schools essentially shut down with testing. So the idea is offer testing to everyone in school, once you hit the threshold. If you're negative, you can stay in in-person learning. And if you're positive, you have to isolate at home.

If you opt out of testing-- it's optional, but if you opt out, you are opting for virtual learning. So essentially, as if you tested positive, stay home, participate in virtual learning. This was successfully piloted at two Utah high schools in December, 2020. And you can see the picture to the right is from a news article from one of those pilots.

And in January, 2021, we put this in place and a school then that met that case threshold could either transition to virtual learning, as they had done, or they could host a Test to Stay event. And again, this was primarily school-run built on the capacity we had built via Test to Play. Next slide.

So now I'm going to show some things from the MMWR. And it looks like you can't see the very bottom there, but it's just a link to the MMWR and the title. And this, again, shows incidents of COVID among school age kids this time, so K-12. And on the x-axis, you'll see that this is July of 2020 through March of 2021. Yes, the dates aren't on there-- or the years, but you can see the month.

So that's 2020 and 2021. And you'll note where in-person instruction begins, roughly in the end of August, and then increases in all of the ages. And the categories are 5 to 10, 11 to 13 and 14 to 17 years of age. But again, the highest increase and incidents in the high school age.

And so there's a few things, timeline items to note here. In November, the governor paused school extracurricular activities with the exception of football, as I mentioned. And then Test to Play began the end of November, and Test to Stay became an option in early January. And next slide.

So I wanted to talk a little bit about some quick results from Test to Play and Test to Stay. We called this PTI, or Prioritized Testing Initiative. It was a name we wanted to come up with to tag results in our state surveillance system so we could differentiate these from other types of tests. And we called it Prioritized Testing Initiative, or PTI.

End of November through March 20th was the period that we included for the MMWR. And there was likely underreporting in this. We try as we might-- there's always difficulties. We're standing up 100 to 200 independent school testing clinics trying to get them to report. We think, after a while, it got pretty good. But in the beginning, it was a little bit rocky, and we weren't getting all the reports. We're sure of that. But these are the results that we have. So overall, among 59,552 students in both tests to play and Test to Stay, overall PTI, 1,886, or 3.2% were positive.

Now, these were students that were getting tested potentially multiple times, so serially, especially if they were involved in extracurricular activities. So 59,000 students. Well, that was 165,000 tests. The positivity rate is people over people, but you could look at it per test and it would be a lower percentage because the higher denominator.

Test to Play, if you break them down in Test to Play and Test to Stay, so 1,700, or 3.5% positive among 50,000 students. And Test to Stay, 90, or 0.7% positive among 13,000, almost 14,000 students. And I just put a picture there in the bottom. This is just a screenshot from my email, my personal email.

We live in Bountiful, Utah. And our son, he still goes to Bountiful High School, BHS. And this was a report from the school. And you'll see down at the bottom, their parents, COVID update, we concluded this week no confirmed cases of COVID. We currently have 60% of our parents who have signed the COVID Test to Stay. So they have this system where parents could go on and provide their consent for their student in the event that the school were to trigger the threshold, cross that threshold. So next slide.

**JASMINE CHAITRAM:** And great presentation so far. I just want to let you know that we're running a little bit short on time.

**WILLIAM LANIER:** OK. Well, I'm almost done. So these are a couple of graphs from the MMWR. So the figure above, you can see after an initial blip, the positivity and Test to Play just really declined. Now, so did overall COVID incidence, but we were pleased to see the positivity decline.

You can see the various Test to Stay events in the bottom panel there, with the exception of a small number of tests, kind of higher positive blip for school K, they were generally quite low positivity, around 1% or less. Next slide. So there were a number of policy updates, and I'll just fly through these.

So I'll just point out one thing. We had a mask on mask no quarantine policy, and in January that went into effect. So in other words, if both the person that had COVID and the person that was exposed in school, they both had masks on, then that person that was exposed did not have to quarantine. That, we feel, further incentivized mask wearing.

Also, we engaged with the high school activities association, and they had policies that promoted mask wearing as well. Next slide. This year, unfortunately, in my opinion, based on some legislation, the policies have changed quite a bit. There are no masks mandates. In fact, it is now illegal in Utah for a school to mandate mask wearing.

So that's really interesting. However, also interesting and a little bit ironic is that some of that same legislation, last year Test to Stay was optional. Well, one of the pieces of legislation actually made Test to Stay mandatory, changed the threshold. But so far you'll see that in that bottom right cell there were eight tests to stay events so far, just over 3% positivity overall.

Next slide. So some takeaways. So the one thing I put in the updated slides was that the feasibility. We demonstrated that this was feasible to do mass large scale school-based testing by school staff, and that was really what made this possible. Another thing that made this whole thing possible is timing.

So there was a mix of risk perception and political will so that the COVID risk perception was high enough and there was enough political will behind it, and this ties in that motivation. So the governor, like I said, he paused extracurricular activities. There was always this threat of losing in-person instruction. If you have enough motivation for those activities, people care a lot about these things for their kids, it turns out-

- I mean, this was a heavy lift for schools, but basically they did it. They stepped forward and people will do almost anything for their kids to have these opportunities.

And I'm still amazed that this actually happened. But the power of partnerships to bring those together. And now we're seeing of politics both last year to bring these things about and to alter policies such that in this year we feel a bit hampered to battle COVID-19 in schools. And lastly, just kudos to everybody who made this possible. All the school partners, local health departments, other partners, including the lab staff.

I remember just the staff that needed to process all of these CLIA waiver applications in short order. That was amazing. Just a little example. So next slide. And I'll end on this, just a thank you. Just a little historical perspective. This is from the flu pandemic of about a century ago. If you look closely, pretty much everybody's wearing a mask. So something to think about historically. And in an extracurricular activity, as applied to a high school, anyway. All right, thank you very much. I'll stop there.

**JASMINE CHAITRAM:** Thank you so much, Willie. Very, very interesting data and presentation. I'm sorry we didn't have more time for you to answer questions, but there are some in the Q&A box if you want to go ahead and provide a response live so others can see your response to these questions. And we do appreciate your time in putting these few slides together for today's call.

I'm going to move to our next speaker from the Centers for Medicare and Medicaid Services. And CMS was here last week. We had a bunch of questions, so we thought we'd bring them back to give a second update on the same topic pretty much. And Felicidad (Faye) Valcarcel from CMS will be here to give that presentation. I don't think we're going to have time for questions. But, again, if you want to continue to put them in the chat box-- I'm sorry, not the chat box, don't do that-- the Q&A box, we will try to have somebody respond to those, or we will capture those and use them at a future time. Thanks.

**FAYE VALCARCEL:** Good afternoon. My name is Faye Valcarcel. And thank you, again, for the opportunity to speak this afternoon. So during the last call on October 4, CMS received several questions where we didn't get a chance to provide a response. So this afternoon we would like to take the opportunity to answer those questions.

Next slide, please, Jasmine. So most of the questions we've received during the last call covered the topics on this slide. CMS is working on the best way to provide additional information for clarity on these topics, and we hope to get that out to you sooner rather than later. So now let me go ahead and start answering the questions that we have already received.

So the first one, what state governs reporting if using over the counter test kit but perform as a point of care tests in another state? So the manufacturer's instructions for all tests that have an emergency use authorization for SARS-CoV-2 testing must be followed to include any specific instructions for test reporting. The CLIA-certified laboratory is responsible for reporting the results regardless of where the

point of care test site is located. Compliance with the secretary's June 4th guidance and CDC guidance on reporting does not fall under CLIA oversight.

CLIA is only assessing if a laboratory has reported or attempted to report the test results. In order to be in compliance with the CLIA reporting requirements, a laboratory will need to have documentation that it reported SARS-CoV-2 results or at least attempted to report the results. The next question was, due to low sensitivity and specificity of home test kits, what would the protocol be for follow-up? Such as, would PCR tests still be required?

So again, the manufacturer's instructions for all tests that have an EUA for SARS-CoV-2 testing must be followed to include any specific instructions for follow-up testing. If the manufacturer's instructions say that a PCR test must be performed to confirm a negative result on a home test and the home test is being performed in a CLIA certified laboratory, a PCR follow-up test is required. The next question.

Is telehealth is performed, which state governs it? Where it is performed or where the telehealth provider is located? So again, we reiterate that the manufacturer's instructions for use for all tests that have received EUA must be followed. If there are specific instructions that allow using telemedicine or telehealth, then those instructions must be followed. For CLIA purposes, the laboratory is responsible for all testing performed under the CLIA certificate.

However, you will need to check with the particular state to see if there are any state requirements for this model. Next slide, please, Jasmine. So this slide shows you the link to the state agency contacts and the AO contacts or accreditation organization contacts if you need to reach out to them.

The next question was, is CMS concerned about the relatively short shelf life of rapid antigen tests, example, BinaxNOW, because this may become an issue quickly with a resource-intensive approach for testing? So during the COVID-19 public health emergency, in order to address the concern over COVID-19 reagent supply problems, CMS will allow laboratories to use expired test kits and reagents if they pass quality control tests with each assay run.

There is a language in our interpretive guidelines that states when, indeed, reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available. Under no circumstances, however, should a laboratory adopt policies that would allow for the regular use of expired reagents. Laboratories need to put policies and procedures in place to ensure the reagents are performing as expected.

Next slide, please. So if you would like to access the CLIA interpretive guidelines for laboratories and laboratory services, here is the link. Next question. What is the rationale for the requirement for a CLIA certificate when an over-the-counter test is being done and interpreted by other than the individual?

So generally, a test that has been authorized or cleared specifically for over-the-counter home use by the FDA is not regulated under CLIA when the test is self-administered. If the test is either performed by

someone other than the individual that is another staff or an employee health personnel and/or the results are interpreted and reported by someone other than the individual, then a CLIA certificate would be required. This model meets the definition of a laboratory in the CLIA statute and regulations, or CLIA statute and regulations. I'm sorry.

The next question. Since all COVID results are reported to the local state agency, why do we need to still notify CLIA for adding the COVID test? The short answer is that it is required in the regulations. However, laboratories with a current certificate of waiver are not required to notify CMS when adding an additional waived test. You should also contact your state as some states may have additional state requirements that are more stringent than CLIA.

If the laboratory has a certificate of compliance and would like to add a non-waived COVID test, the laboratory needs to notify the appropriate state agency. If the laboratory has a certificate of accreditation, they would need to notify their accreditation organization. The next question. If a rapid antigen test being performed is not on the FDA EUA list, can it still be used if the laboratory validates it? Yes, it can be used.

However, it would automatically default to a high complexity test, and a Certificate of Compliance or Certificate of Accreditation would be required. I think we have a couple more questions. How long can a lab do testing with a CLIA certificate of registration rather than a certificate of compliance? So our registration certificate is valid for a period of no more than two years or until such time has an inspection to determine program compliance can be conducted, whichever is shorter.

And the next question. Can temporary testing locations receive their own testing supplies directly from the manufacturer and store them at the temporary location or must supplies come from the home base lab on a daily basis? So during the PHE, CMS allows flexibility to temporarily keep the supplies at each testing site, but each testing site or facility must adhere to the storage requirements of the equipment, the supplies and reagents as specified in the instructions for use.

And then the next question. Who is legally allowed to administer a COVID-19 nasopharyngeal swab test? Staff performing COVID-19 testing need to meet the CLIA personnel requirements applicable to the assay they are performing and as designated in the EUA and by the manufacturer.

Non-waived testing, that is moderate and high complexity testing personnel, requirements can be found in subpart M of the CLIA regulations. Waived testing does not have any personnel requirements. You will just need to follow the manufacturer's instructions. You will also need to check with the state in which the laboratory is located to see if there are any state personal requirements.

Next slide, please. And here's the link to the CLIA regulations if you would like to access it. And I think our last question is, can our facility use the emergency tests found at Walgreens that give results in 15 minutes? As long as it is verified to be negative by a nurse. In order to do COVID-19 testing, a facility must be a CLIA-certified laboratory that meets applicable regulatory requirements appropriate for the complexity designation of the test.

To apply for a CLIA certificate, please contact the state agency in the state where the facility is located. Since, in this case, the facility is in California, you must contact the California state agency. They can answer your questions and will process your application. And the next slide, please.

So we are also providing on this slide the link to the memorandum that CMS issued to laboratory surveyors to provide important guidance to surveyors and laboratories during the COVID-19 public health emergency, and also the link to the FAQs. And we hope that the information you find on these documents would be helpful. And I think that's all I have. Jasmine? Sorry.

**JASMINE CHAITRAM:** All right, thank you. Thank you, Faye. And apologies to John Barnes that we were not able to get to his update today. See, it's 4 o'clock. I do want to thank all of our speakers for being here with us and for the great presentations. We will have a variant update on the next call. So sorry about that for those of you that were hanging on for that particular item. Our next call will be Monday, November 1st at 3 o'clock. So we hope to see you there. Until then, stay safe. Bye, everyone.