

# Clinical Laboratory COVID-19 Response Call

## July 12, 2021

### Agenda

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **SARS-CoV-2 Variants Update**
  - Jessica Chen, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **SARS-CoV-2 Testing in the Workplace**
  - Nate Wade and Mara Aspinall, Arizona State University
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

**JASMINE CHAITRAM:** Hi, everyone. And thank you for joining the Clinical Laboratory COVID-19 Response Call. I am Jasmine Chaitram And the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems here at CDC, we've been hosting these calls since March of 2020. We're so glad that you're here to join us again for another call.

We have our agenda showing today. Before we get into our speakers, I'm going to cover a few housekeeping items and also tell you a little bit about the Division of Laboratory Systems. I've done this on every call, so apologies for those of you that have heard it multiple times, but we don't know if we have new participants and would like them to know a little bit more about us as well.

So the Division of Laboratory Systems at CDC has been supporting clinical and public health laboratories long before the COVID response, and throughout, we'll continue to do so. We serve as a liaison to the Emergency Operations Center and provide communication to the clinical laboratory community. One of the ways that we do that is through these calls.

In general, the topics that the Division of Laboratory Systems is covering has previously not just for the response, but has been in the areas of training and workforce development, quality and safety, informatics, biorepository data science, and then of course, preparedness and response. And so I will now cover a few housekeeping topics, like our [Preparedness Portal](#) where you can find a lot of information, all of the things that we're supporting, including [archives of our LOCS messages](#)-- this is the [Laboratory Outreach Communication System](#). And another mechanism for us to provide critical information to use for the-- related to the COVID-19 response.

We also have here an [archive of our Clinical Laboratory COVID-19 Response Calls](#). You can find the transcript as well as slide presentations and the audio from previous calls. And we provide links to other CDC COVID web pages that may be of importance. So this is a good place to go for all information related to the COVID response and our role in preparedness and response as well.

Our next call will be on Monday, July 26 from 3:00 to 4:00 PM. We do host these calls every two weeks, and they are usually scheduled for an hour. Today's call may be a little bit shorter. We have less topics to cover as we go forward. So we will continue to schedule the calls for an hour, and if we get done early, I'm sure people won't mind.

And we continue to ask for your feedback. One topic is training and workforce development. And you can send those questions or concerns or needs to [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov), and it will help us to inform the things that we're doing in the areas of training and workforce development.

And before we have our first speaker, I want to just remind you to please use the Q&A button in the Zoom webinar system. And it's really important that you put it in the Q&A button and not in the chat. This helps us to track the questions that we're getting. We do try to answer your questions live during the call.

Sometimes we don't get to all the questions or we don't have the right subject matter experts on the call to answer your question.

So it's very helpful to have a record of the question as well as your email address so that if we don't ask your question during the call or don't answer your question during the call, we can get back to you. And that would either be by email or maybe as an agenda item on a future call. And just a quick also reminder and ask to please keep your questions related to clinical laboratory testing issues. I know we've had speakers in the past come on and talk about different things like vaccine and other topics like CMS billing, but for today's call we don't have those subject-matter experts here, so please try to make your questions focused on clinical laboratory issues.

Let's see. Last thing I want to say is a reminder that the slide decks that we post on our preparedness portal that I just showed you and the slides that we present during these calls are from panelists who are not necessarily affiliated with CDC. And so that presentation content from those panels may not necessarily reflect CDC's official position on the topic that is being covered.

And with that, I think we're going to go into our very first update, which is on the variants. We've had this topic covered before on these COVID calls. We've had various speakers today. We have Jessica Chen from the Laboratory and Testing Task Force joining us. Jessica, we're ready. And I will advance your slides, just let me know when to do that.

**JESSICA CHEN:** Excellent. Thanks for that introduction, Jasmine. And good afternoon, everyone, and Thanks for the opportunity to speak on this today. I'm Jessica Chen. And I'm from the Strain Surveillance and Emerging Variants Team within CDC's Laboratory and Testing Task Force. Today I'm going to highlight our newest data on the circulating SARS-CoV-2 variants in the United States. Next slide, please. So first I'm going to present the national weighted proportions for the two-week period ending June 19. These proportions are weighted to help correct for non-random sampling across time and states. Just last week on our webpage we've included our-- the WHO names of all the variants in addition to the Pango lineages. So that's a nice change for ease of use.

Since the last two-week period, we've seen a decrease from 60% to 44.2% of that Alpha variant or B.1.1.7. The Delta variant or B.1.617.2 variant has been on the rise and has increased from 10% to 30.4%. P1 or Gamma has decreased slightly from 11% to 9%. And the Iota variation or B.1.526 has decreased from 9.5% to 5.5%. Next slide, please.

The next chart shows the regional differences from the weighted proportions for the two-week period ending June 19. So these are broken out by HHS regions. The Delta variant is denoted by the darkest shade of orange in the pie chart. And Delta is over 30% in five different regions and is at the highest levels and Regions 7 and 8. B.1.1.7 or Alpha remains dominant variant and only three regions and this variant is denoted by the lightest shade of orange. Next slide, please.

Next we'll go over our national now-cast estimates for circulating SARS-CoV-2 lineages. Now-cast estimates are projections intended to provide more timely information while accounting for limited

sequence data availability as we collect more sequence data for this time period. The data presented covers the two-week period ending July 3, 2021.

We are predicting that during this time period, the Delta variant or B.1.617.2 will become the predominant variant nationally at 51.7%. And this is largely at the expense of Alpha, which is predicted to account for 28.7% of sequences. Also notable is that P1 or Gamma is predicted to maintain its downward trend accounting for 8.9% of sequences. Next slide, please.

And now taking a look at the regional now-cast production of SARS-CoV-2 variants, we anticipate that during the time period ending July 3. Delta variant will make up greater than 30% across all regions, and over 50% in Regions 2, 6, 7, 8, and 9. And this variant will be at its highest in Region 7 at 80.7%, followed by a 74.3% in Region 8. Alpha is predicted to be less than 50% in all regions and less than 25% in Regions 2, 7, 8, and 9.

Thanks for your attention, that concludes my presentation. And I'd be happy to take any questions that you may have on this topic.

**JASMINE CHAITRAM:** Jessica thank you so much for giving that update. And I'm actually not showing-- oh, there's one question. Take it back. So the first question that we have, is there any information on the new Lambda variant in South America?

**JESSICA CHEN:** We are tracking that variant. We have seen that variant, but it's at a pretty low level in our US sequences. And that's all I can really update at this point. Thanks for that question.

**JASMINE CHAITRAM:** OK. Hang on. So somebody put a question in the chat, but we really need in the Q&A button. But I think it's a, can you comment on the--

**JESSICA CHEN:** Yeah.

**JASMINE CHAITRAM:** --data.

**JESSICA CHEN:** So this data is right now based on the samples that we received from public health labs through the NS3 program as well as sequences from CDC-contracted laboratories.

**JASMINE CHAITRAM:** OK, thank you. I'm not-- general question, I guess, about the significance of the Delta variant. I don't know if you want to comment.

**JESSICA CHEN:** On the Delta variant, we've observed it has increased our transmissibility as compared to the Alpha variant. However, we believe that mitigation measures will continue to be effective against Delta. So vaccination, et cetera, those all maintain pretty high efficacy against Delta.

**JASMINE CHAITRAM:** And then a related question I'm not sure if you can answer, is there any data that testing sensitivity specificity of vaccinated individuals are different than testing of non-vaccinated individuals?

**JESSICA CHEN:** I don't think I can answer that question at this time and I'd be happy to get back to you.

**JASMINE CHAITRAM:** OK. Thank you. Let's see. How many labs across the US are reporting sequenced variants?

**JESSICA CHEN:** Many labs in the US are sequencing. In terms of the public health labs, I don't know the number off the top of my head, but we're working very closely with our partners at the state and local labs to both increase capacity for sequencing, but also bring new labs online.

**JASMINE CHAITRAM:** OK. And we are getting some other questions about the Delta variant, but I think they are more clinical in nature, and I'm not sure that you're the person to answer those questions.

**JESSICA CHEN:** I agree.

**JASMINE CHAITRAM:** So we will have to table those and maybe get responses offline and provide those at a later time.

**JESSICA CHEN:** Yeah, I appreciate that. Thank you.

**JASMINE CHAITRAM:** All right. Well, I think that we will move to our next topic. And thank you again, Jessica, for joining us today. Appreciate your time and for preparing the slides and the data for us. Our next topic, we've got two guest speakers from The Arizona State University. And I believe they're going to be talking about testing in the workplace, although their title is a little bit different. So I will just turn it over to Nate Wade and Mara Aspinall.

**MARA ASPINALL:** Thank you, Jasmine. And just so you know, I can't-- you may need to help me on-- start my camera.

**JASMINE CHAITRAM:** Yeah. We'll do that. Go ahead and start.

**MARA ASPINALL:** Perfect. So good afternoon, everyone. Nate and I are here to talk about Arizona State, but not just as an individual university, but why Arizona State. There are three things. Most importantly, we have been working very closely with the Rockefeller Foundation and the World Economic Forum to put together a lot of information data specifically around clinical labs and testing, and then more broadly the way testing is being perceived in the employer community.

The second area is that ASU has the only program for biomedical diagnostics as far as I know. Not a technical program, but a business-oriented program where people get a business degree, a master's degree in biomedical diagnostics, and we thought that that would be a very good contact. So I'm bringing this together. ASU is a pretty unique response. The third area is that in a different part of ASU we've been doing aggressive testing for the state of Arizona and broader.

So if we go to the next slide. We wanted to give you a sense of what we're going to talk about today. We won't go through all of these, but as you can see on the left, the core of our COVID response in the community is [ASUCOVIDCommons.com](https://ASUCOVIDCommons.com). This work is from a grant from the Rockefeller Foundation. And we're going to talk about these things on the right. Testing Commons and Workplace Commons will be our focus. And if we have time, we'll talk about some of the other areas.

And then secondly on the left, as you can see, we have a master's degree in biomedical diagnostics that we think would be very interesting to all of you. So go to the next slide. So let's focus on these key four activities, and what you see here is a very short summary of each of them, as well as our key partners. And today, as I mentioned, will focus on the first and the third. Testing Commons is a comprehensive resource of all of the tests worldwide. Tests that are authorized clearly in the US and Europe, in Asia and Africa, in the Middle East, as well as tests in development. And then Nate will take over and talk about our Workplace Commons, which is a very large survey-- we believe the largest in the COVID era. And if we have time, we'll talk about the other two. So next slide.

So if I focus on Testing Commons, what you'll see here is it's an interactive database. This is from a couple of weeks ago, 2,402 tasks. Now there are more than-- about 20 or 30 additional tests added. In each of these areas are searchable keys. So you can take a look at-- particularly if your lab is doing research on who else is doing a particular type of test, you can look at regulatory status, target, platform, individual company, even minutes to resolve that the test would take.

And if we go to the next slide, you can see what this looks like in real-time. This is a good example. It's a little dated, but gives you the sense. Number of EUAs according to the US FDA website. We then look at, OK, of those UAs, what are the specimens collected? What is the platform? Each of these is a hotkey, so

you can then search to say, at this moment in time, there were 231 RT-PCR tests that had an FDA E-U-A. Next slide.

You can then look at far more detail to go to the diagnostic target, to look at detection technology. This is actually quite a long list, not so much on the EUAs, but for tests and development. Analysis location, where the analysis is happening from self-test to various CLIA lab certifications and then the region. And next slide.

And lastly, we've had a lot of requests to say, tell me more about an individual company's test. So this is a list of all the companies or labs worldwide. And the LDTs, while the FDA was involved in LDTs, there were about 1,000-- closer to 1,200 right now. You can look at each of these companies. This happens to be Bio-Rad. Hover over it, and you'll get all the specifications for each of their tasks, whether there be one, or for some of our larger companies, 10.

There is a review that I can send anyone who's interested or we can make it available, Jasmine, to send to you. That looks at the first 18 months of the pandemic and how many tests have been authorized in every country around the world, as well as tests in development by technology. So that gives you a quick overview of TestingCommons.com It's free, it's available, and would love feedback on how to improve that going forward. It is our intention to keep this going ad infinitum, because the key information here is absolutely critical.

The information in this is focused on what was submitted to the FDA. After Nate's presentation I'll get back to Evidence Commons, which we'll talk about peer-reviewed articles on each of these tests. So next slide.

**NATE WADE:** All right. Well, we're going to talk about our Workplace Commons initiative. And is a three-phase survey. So we started in fall of 2020. So that was Survey 1. Survey 2 is Spring of 2021. And we're going to be moving into phase 3, which is summer transitioning into fall of 2021. Our survey is engaged with employers in all industries. About 70% from the US, about 24% are from the UK, and the rest are from around the world.

And our goal is to understand how to keep workers well, how are employee-- employers keeping their workers well. And we formed a community of practice where we had over 1,100 participants; employers, mainly 250-plus employees respond to our survey. Employer case studies are also there on our website, which we're going to show you at the end. And then our interactive website, our dashboard, which we'll also showcase. Next slide, please.

This is our first survey, Facing Uncertainty-- The Challenges of COVID-19 in the Workplace. It's a comprehensive report. And if you visit our ASUCOVIDCommons.com, you can download both this one and-- next slide, which is our second report. Back to the workplace, are we there yet?

And so this survey actually took-- it happened during March of 2021, and it actually is focused on what employers that were planning to do during their returning to the workplace. And for our third survey, we're going to see actually if they actually implemented those plans. Specifically around-- we've been focused on testing, but also on vaccination, and as well as returning to the workplace and how they change their remote policies. Next slide, please.

So this is an overview of our second phase of our survey. Our top 10 industries range from technology and software all the way to energy and utilities. Six continents, 24 industries, 31 countries with 95% being from the US and UK. And then 1,168 companies from 1,339 facilities. Next slide, please.

We're going to cover these in a little more depth, but for our report, we focus on our top 10 sites which have four key areas-- vaccination, employee well-being, testing, and work from home. Next slide, please. For vaccination, we found that 88% of employers will require or encourage vaccination from employees. 40% will require all employees to be vaccinated. 16% said they would require some employees with 32% encouraging but not requiring employees. We found vaccinating at 4% said they don't plan to encourage or require, so for our third phase of the survey we're really going to be focused to see, did they actually require employees or were they in the planning stages during this time? Next slide, please.

We also found that 59% plan to incentivize employees, and we're going to be focused on that in our third survey. Did they actually implement the incentives? And what were those incentives? 61% and 60% plan to change safety mitigation measures once broad vaccination is achieved, and 60% will require employees to demonstrate proof of vaccination. Next slide, please. Mara's going to talk about testing.

**MARA ASPINALL:** So clearly we thought testing was an absolute critical piece of the survey. So on our second survey, we found that 68% of companies were testing their workers. This is a huge increase from the first survey, maybe not surprisingly from the fall of 2020 where we only heard 17% were testing their survey-- were testing their employees. Some of the industries were as high as 38%, but this was broad. High-tech industries were higher, but on average it was 68%.

Of that testing, we found that almost 30% were testing daily, but the plurality, 43%, were testing weekly. The vast majority of this testing were active disease testing, not antibody testing. But we did see a solid 5% who were just testing for antibodies. We expect that that will go down over time. Next slide.

So when we looked at that, we also wanted to know why people did not want to test. And as you could see here, the two biggest reasons were a perception that it was too costly and that it was too complicated to implement. For other reasons we saw, they were worried about employee privacy. This was before some of the EEOC rulings about tests and whether a company can indeed test their employees.

Only 19% were concerned about test accuracy. This was about half of what it was in the fall when we saw a much larger percent of companies concerned about test accuracy, which was great. We heard a little bit about liability. Certainly test availability. This surprised me as high as it was at 17%. It was clearly overwhelmingly higher in the fall of 2020.

You can see some of the other areas. What we found and one of the questions you might have is, who filled out this survey? The vast majority of the surveys were filled out by head of human resources or chief operations officer. In this survey, as Nate said, there were mostly larger companies, 250 employees or more.

When we asked about the future, about a third said they don't test today and don't plan to test. So on our third survey, we will test that assumption and see how this changed with much broader vaccination. Nate, back to you.

**NATE WADE:** OK. Now we're going to focus on employee well-being, and we heard overwhelmingly that employee mental health well-being is--

**MARA ASPINALL:** Next slide.

**NATE WADE:** --very concerned-- next slide, please. 77% of employers indicate that employee mental health well-being is become a top priority for them, and if they had employee health-- mental health being services offered, 50% said that they saw an increase in use of those services. On the side you can also see that there is a significant increase of perception by employers for pre-pandemic compared to post--

during the pandemic for mental health concerns, engagement, burnout, productivity, and morale. Next slide, please.

And finally, we focus on the future of work, and 72% intend to offer flexible or expanded work from home policies, and we're going to test that as well for our third survey to see if they actually implemented those. Next slide, please. Finally, this is our dashboard. So if you visit [ASUworkplaceCommons.com](https://asuworkplacecommons.com), you can toggle between Spring '21 and Fall '20 to see the different survey results. If you're interested in focusing on testing, you can look by continent, by industry, by number of employees. And it's very user-friendly, so we welcome you to join the site and give us your feedback. Next slide, please. Over to Mara.

**MARA ASPINALL:** And one of the things that I would add to Nate's presentation, if anyone is very interested in the survey and you've had a chance to see some of the key questions and download the report, if in the next-- really needs to be 72 hours, if you have any questions that you would like to see in the third survey, we would love to get your feedback. We have contact information as part of the presentation, but it's [Mara.Aspinal@asu.edu](mailto:Mara.Aspinal@asu.edu) and [Nate.Wade@asu.edu](mailto:Nate.Wade@asu.edu), and please get us any questions that you would like to see in the third survey. If they're already in there, no problem. Don't feel like you have to check the survey first, we really appreciate the input.

So before we open to questions, just briefly, the other thing that we thought would be interesting-- next slide-- is that we have this MS degree in biomedical diagnostics. It is an online degree, so people can continue working. There are four pillars of the degree program, the science of diagnostics, the technology, the business, and the application.

And beginning next year we'll be adding a fifth pillar on the policy areas of diagnostics. So again, be in touch with Nate and if you'd like to learn more about the program for yourselves, for your staff. And if you're interested in teaching in the program, we'd also love to hear from you. It's about six years old, so we're still growing tremendously, about 85 people in the program today. Next slide.

But back to [ASUCOVIDCommons.com](https://ASUCOVIDCommons.com), one of the key pieces that we heard from Testing Commons is it was great to have the data for these tests around the world and understand those trends. But which tests work? Which just don't work? How does it translate into real-world evidence? So what we created and we're working with the Rockefeller Foundation to hopefully get a grant in this area is what we believe is the only interactive repository focused exclusively on COVID tests and testing. And by testing, we need testing protocols.

There is an abundance of data out there, both in the US and around the world, about how these tests are working with real-world evidence. So similar to Testing Commons, we're putting it in an online database, and you get a small sense of it here. On the left it will be in table form, there'll be a short abstract. You'll be able to search on 10 different criteria to find tests. And then if you're doing research to understand this at a broader macro level, we'll have summary maps and summary tables here.

It's important to note, this is not the meta-analysis, but if you're doing a meta-analysis, this is a great place to go to find all of the articles on a particular test or testing protocol. Next slide. And as we move forward, we would love to work with you to help fill out that database. Next-- and this, again, might be relevant to many of you, we have a tool working with RADx and When 2 Test called Connect a Test. And this is working through the nonprofit [ProjectN95.org](https://ProjectN95.org).

And for small businesses or individuals or companies or anything from weddings to small businesses, can go in and buy tests, either individual tests, typically antigen tests that can be shipped to the organization

depending on what type of organization they are, or testing services where somebody comes in and does the test for that business place. Next slide.

And to round this out, and then we'll open for questions, and happy to take it. We also do a short blog on issues. We'd love your feedback. We'd love any of you to help us write some of the blogs. As you could see here, there are everything from a very serious issue-- well, they're all serious, but how to use quantitative PCR quantitatively to is COVID testing going to the dogs and the work that the canine sniffing is going. A lot of work here, we try to keep people up to date with a 750-word blog.

And lastly, we do a number of webinars. So happy to take-- and you can to the next slide for some of the webinars, but-- or just can leave it here. Happy to take any questions and feedback. You can go back to the last slide if you want.

**JASMINE CHAITRAM:** OK. Thanks, Mara. I just-- we have several questions come through, and Nick has been-- sorry, Nate has been doing a great job answering the questions that have been coming through already. So some of them are already answered, but here's one. Are you listing LDTs or only EUA tests?

**MARA ASPINALL:** We are listing-- well, we're trying to list as many LDTs as possible. And I think somebody asked for the last slide. We're trying to list as many LDTs as possible, but it's a little tricky to be able to get the information on the tasks. So if there are any LDTs that are not listed that should be listed, please contact me and happy to add there. But until the October change, all of the LDTs of the FDA was involved with are listed.

**JASMINE CHAITRAM:** OK, thank you. And I know folks are asking about these slides and if they'll be available, and as I mentioned, we do post everything to our Preparedness Portal. So it will take us a few days to get everything up because we usually post the slides, the transcript, and the audio together. So keep checking our preparedness portal for the slides. One question for you, Mara or Nate, is can labs sign up to work with you?

**MARA ASPINALL:** Well, anyone who's interested in working with us should definitely be in touch. We are taking both a technology-agnostic and a lab-agnostic perspective. This is separate from the school working relationship, the National Testing Action Program. But yeah, I'd love to talk to anyone who's interested about how to improve the site, how to improve the information, and ensure that it's accurate going forward. So please, please be in touch on that.

I'll also emphasize that we didn't have time today, but Jasmine, if it's OK with you, I'll also get you, what we're calling the pandemic review to date, which does an analysis of 18 months or 16 months of FDA EUA approvals as well as approvals around the world and tests in development so everyone can have access to that.

**NATE WADE:** There was one-- there was one question about where's the data about positive test cases being reported to. And on our Fall tab, we actually went through that question. 28% said internal databases, 8% said medical, 19% to worker's health care provider, third party was 5%, 28% said public health authorities.

**JASMINE CHAITRAM:** Thanks, Nate. And I was just going to say that if you want to-- you, Nate, or Mara drop any of the links-- web links to the Testing Commons or the surveys in the chat box, I think that's helpful to others to see it. We do have a few more questions, but one of the questions is, where is data on sensitivity and specificity on TestingCommons.com pulled from?

**MARA ASPINALL:** So two different pieces. For the ones that have an EUA in the US, EU, Africa, Asia, or otherwise, they're pulled from the submission. So the 30 or plus-- 30 or more samples that are done there. We do post it as sensitivity specificity, not PPA or PPV-- NPV, but we do post a sensitivity specificity.

For the ones that are in development, if there has been a peer-reviewed article or a preprint from any one of the three reputable preprint services, we will post that data from the preprint. But otherwise, if it's a test in development where somebody writes me an email and says, this is our sensitivity specificity, we will not include it. It has to be posted officially in some way.

**JASMINE CHAITRAM:** Great, thanks. I think there's been some requests for your contact information to also be put in the chat. So if you could do that, if you're willing to do that, I think folks would appreciate it. Another question is, are the webinars open to the public? And it looks like you're answering, but I think it would be helpful to hear.

**MARA ASPINALL:** Yes. They are all open to the public. Again, you can give us your name to put you on the mailing list. And then Nate, the recordings, all but one are posted as well?

**NATE WADE:** Correct. They're all posted, and I just put in the chat about our diagnostic commons, and that's where you can find both Mara and myself and our contact information.

**JASMINE CHAITRAM:** And I'm not sure if you asked this question or your survey about whether or not employers would be reporting results to public health and what types of tests that they were using, like if it was an antigen test.

**NATE WADE:** Yeah. I tried to answer that. For our Fall '20, that's on our tab. And so I think it was 20% said public-- they're reporting public health. So you can actually drill down our report. It doesn't focus on all the information, but if you're interested in those specific questions, you're going to drill down in our dashboard.

**MARA ASPINALL:** And there was one question, Anonymous Attendee, should corporate America shift to surveillance tests that may be more rapid and more affordable? We don't have a clear answer here, but I think the answer is going to be yes. And we will ask questions about the shift from PCR to antigen tests and the shift to surveillance testing and what that means.

And surveillance testing in both a pulled PCR antigen approach, but also wastewater, air monitoring, and otherwise. So we will get some additional data on that in our next survey. And I think Nate made this clear, but the next survey will start at the beginning of August.

**JASMINE CHAITRAM:** OK, thanks. And I think-- I'd ask you a question about labs contacting you to get involved, and I think someone has posted a question more specifically, can diagnostic lab partners with Testing Commons Initiative to provide diagnostic services.

**MARA ASPINALL:** We don't provide any diagnostic services or recommend any labs. So it's really the information that we're providing and the data and ensuring that is transparent and broad as possible. So from that perspective, there's no opportunity to partner. However--

**NATE WADE:** I was going to say that in the chat, to answer that question, I posted Connect a Test. And so under the disclaimer-- so if you want to be involved in Connect a Test, there's a process through Project N95 where you can go through that process to be involved if you have a laboratory test that meets our criteria.

**JASMINE CHAITRAM:** OK. Thank you so much, and I know that you guys had a bunch of questions there. And so I appreciate you answering them both online and on the phone here. And we will post the

slides, and there seems to be a lot of interest in this presentation, so we will, of course, get those up on our website soon. And just thank you so much for providing all this information. I myself am looking forward to checking out the TestingCommons.com site. I think it would be very helpful to see all of this information in one place.

With that, I think we're going to move to our last speaker. So thank you again, Nate and Mara, for joining us today. And our last speaker for today is Tim Stenzel with the FDA. Glad you can make it, Tim. I was getting a little worried. I didn't see you on the call earlier. But I will go ahead and turn it to you for any important updates that you might have.

**TIMOTHY STENZEL:** Hopefully you can hear me. Don't really have any updates. But while I'm here, if there are questions, I'm happy to provide them. I didn't get questions ahead of time that we were going to respond to on this call, but--

**JASMINE CHAITRAM:** Tim, I just sent them to you. I sent you a few questions right-- yeah, right before the call. I can try to pull them up.

**TIMOTHY STENZEL:** Can you read them to me? I was-- I'm sorry, everyone. Some back-to-back calls.

**JASMINE CHAITRAM:** Oh, no worries. I know this is the life these days. Hang on, let me see if I can put my hands on them. OK, so the first one is, the Abbott ID NOW testing instrument able to detect current variants, including the Delta variant? So I guess just a general comment from you on how FDA's working with manufacturers to verify or to check about tests and being able to detect variants.

**TIMOTHY STENZEL:** So yeah. So first, the FDA is working with CDC and NIH RADx to assess the impact of mutations on all sorts of tests, including molecular, antigen, and serology tests. Molecular is the easiest to assess. And the vast majority do not overlap known mutations or variants.

And even when they do, most molecular tests target multiple parts of the virus. So even if they were to have a problem with one part of the virus because they have other targets of the virus, they do just fine.

So [FDA has a website](#) for tests that may be affected by mutation.

And the good news now is how we define significant impact on performance. That would be a decrease in the sensitivity of tests due to mutations or variants of 5% or more. That would be the significance level.

We do not have any test in the United States that are authorized tests that are impacted by a mutation.

To our knowledge, that includes molecular antigen and serology tests. In particular, the question was about the ID NOW, and there are no significant impacts to the ID NOW.

**JASMINE CHAITRAM:** Thanks, Tim. And the other question I got before the call-- it was also posted in the Q&A, is the Lyra direct included in the Lyra recall?

**TIMOTHY STENZEL:** So the Lyra recall, that both tests use the same primers and probes to my knowledge. One is an extraction step up front, the other does not. The challenging thing with the Quidel Lyra assay is when the sample is extremely high-positive. The instrument settings used for the Lyra are such that it doesn't start recording until five cycles later than some of these-- well, not five cycles later.

There's a period of not recording and the beginning of the Lyra assay, which is true for a number of assays, because baseline is in the beginning can be very noisy.

But the recall has to do with instructions for how to inspect the curves having to do with the Lyra assay.

And so you can-- laboratories that have these instruments uses that, they can identify curves that hop up-- the pop up before the instrument starts recording. So these can be identified. And then they can be diluted and rerun.

The Lyra direct uses a non-extraction method. It tends to be analytically a little bit less sensitive than the one that includes an extraction step up front, so it may not be impacted by this as much. But because they use the same primers and probes in the same instrument, I would be watching both for that if you're using those assays. But again, if you use the mitigations that are explained in the recall, you will not fail to detect high-positives.

**JASMINE CHAITRAM:** Thanks, Tim. Another question, is the FDA fast-tracking tests specific for a variant detection or variant testing?

**TIMOTHY STENZEL:** It is a priority. The challenge with this is that it's-- even looking at the updates from the CDC or any other updates on what the mutations or variants are doing in the US, and it changes rapidly over time. So if a developer spends a lot of time, say, developing a test that can detect the UK variant, and now it's really outstripped by the Delta variant, but that test may be less important and you're not detecting the Delta variant.

So we continue to recommend to the FDA that whole genome sequencing be used to identify variants and mutations. Oftentimes to actually identify a variant and call it a variant, you need to understand all the mutations that are present, because some mutations-- individual mutations could cross variants.

So it is very important. We do prioritize sequencing and variant detection. We're hoping that certain mutations and variants don't greatly impact vaccines, say, other therapeutics, but we're prepared for that to possibly happen, and we've heard test developers were able to give some development and validation recommendations for validating their assays, and we are working with various providers who can do this. And those developers who can quickly switch from one variant detection to another with their technology could be very important in responding to variants and mutations.

**JASMINE CHAITRAM:** Thank you. When would the FDA be expected to get back to usual business like reviewing premarket submissions for non-COVID tests?

**TIMOTHY STENZEL:** We no longer have any full submissions paused at the FDA. We are accepting and reviewing all at this time. And unfortunately, they will not, in all cases, be able to meet our previous commitment on turnaround times. But everybody who submits something now for a full market reauthorization, whether it's a 510(k), PMA, or De Novo, is assigned to a reviewer, and the review starts. And we endeavor to take a quick look at it and identify any potential issues and let them know as early as possible. So that's good news.

There is one area that we are not back to full steam ahead with, and that is on Q-submissions or pre-submissions for certain areas. So we are reviewing Q-submissions and pre-submissions, and it has to do with an investigational device or IDE exemption for any companion diagnostics for any COVID-related submission and for any breakthrough designation submission.

However, unless-- if it's not-- doesn't fall in that category, we do a review for those that are perhaps critically important for public health reasons. And we do review some of those, but by and large, we are letting submitters of Q-submissions and pre-submissions that fall out of those areas that we can review now, we're letting them know we can't review them now. We're directing them to look at previous decisions by the FDA to inform their best efforts at coming up with a development validation plan.

If I didn't mention, COVID-related pre-submissions and Q-submissions are also welcomed right now because we are strongly encouraging those who want to convert their EUAs to full application, we want to support that effort right now.

**JASMINE CHAITRAM:** All right. Thanks, Tim. I don't see any other questions specifically for you. There is one in the chat box. I think it's more appropriate for probably someone from CDC to respond to, but I'll ask it just in case. This is-- do you have any status or studies in the work for frequent home testing for over-the-counter public health antigen testing to assist with early identification without the need of a prescription or without the need for symptoms?

**TIMOTHY STENZEL:** Yeah. And we've authorized a number of OTC antigen and molecular tests, and home collection tests are ready. And so those pathways are open. What we don't have is the studies that show that serial testing, that the pathway that we allowed to get to OTC, if you didn't have performance information on an asymptomatic test.

But there's quite a few now that are over the counter that are for sale and you can buy them. But what we don't know is how good they really are in serial testing for detection of asymptomatic folks. And so we're awaiting certain studies that are ongoing. One of them sponsored by NIH and the community studies using the QuickVue test that is OTC in order to assess its ability to deal with this public health emergency, when you lived at home in a serial testing fashion. And then there's other studies that are ongoing. And then, of course, some OTC developers have already determined their performance in asymptomatics and they're not-- and they're not required to have serial testing performed with their tests. So they're OTC and don't need to do that serial testing. So hopefully that's a helpful response.

**JASMINE CHAITRAM:** It is. Thank you, Tim, very much for joining us today and for continuing to participate in these calls, we do appreciate your time and answers to all of the questions. And with that, I'm going to start wrapping up our call. Just a reminder that our next call will be in two weeks on Monday, July 26. A reminder that the slides, transcript, and audio from our calls will be posted.

For those of you that have put questions in the Q&A that I wasn't really sure that our speakers could answer or they were not able to get to for some reason, we will try to get answers to you after the call or we will have future topics on these calls that address some of those questions.

And thanks again for being with us, especially those of you that have been calling in for more than a year. We do appreciate all of the questions and all the comments. It's helpful to us to also know what the concerns are in the lab community, and it helps us to develop future agendas. And with that, I just want to thank you all and remind you to keep things safe. And have a good day.