

Clinical Laboratory COVID-19 Response Call

May 17, 2021

Agenda

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JASMINE CHAITRAM: Hello, everyone and thank you for joining the Clinical Laboratory COVID-19 Response Call. Today is May 17th, and we are glad you're here with us. These calls have been hosted by the Division of Laboratory Systems at CDC. We've been hosting these calls since March of 2020, last year. The Division of Laboratory Systems at CDC is responsible and has prioritized work in the areas of quality and safety, training and workforce development, informatics, data and biorepository science for clinical and public health laboratories. And we've also been working on preparedness and response activities.

I'm currently the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. And I've been here with you hosting these calls for that reason. Today we have a pretty full agenda. I wanted to thank folks that have been submitting questions. It helps us to shape what we're going to put on our agenda for our future calls. And today, hopefully, some of the questions you've been submitting around biosafety guidance and laboratory supply issues will be answered.

I did want to cover a few housekeeping things before we get into our presentations. The first is a reminder that we have a CDC [Preparedness Portal](#), which is hosted by the Division of Laboratory Systems. And it is meant to be a one-stop shop for all of the information we have related to preparedness and response. That includes our [archive of our Clinical Laboratory COVID-19 Response Calls](#) that we've hosted in the past with our transcripts, our slides, and audio of the calls.

And I want to take this time to just say, again, apologies for the last time when we had a lot of technical issues with sound. Hopefully, all of you are hearing me today and we're not going to have a repeat of that issue this week.

Also on our Preparedness Portal, we have our [LOCS messages](#). That's the Laboratory Outreach Communication System. And these are emails that we send out whenever there's important updates. You should have received [one today about the updated antigen testing guidance](#), which we're going to hear more about in a minute.

But it's good to be on our emailing list so that you can get announcements in between calls. And if you miss emails or you can't find an email that you knew had an important message from LOCS, you can go to this Preparedness Portal to look through the archives of our emails. This is also a place where you can get links to CDC COVID pages. So everything you need is right here.

Our next call will be on Monday, June 14th from 3:00 to 4:00 PM. We have been hosting these calls every two weeks. The call after this one was scheduled for Monday, May 31st. And we are going to skip that call because of the Memorial Day holiday. So our next call won't be for about a month. Sorry. I know many of you are very disappointed about that. And please continue to send us your needs around training and workforce development. We are reviewing those emails. And you can send them to labtrainingneeds@cdc.gov.

And then finally, again, how to ask a question. And we prefer that you use the Q&A button in the Zoom webinar system. If you submit your question this way, it helps us to track the types of questions that we're getting. But more importantly, if for some reason we're not able to answer your question during the call because we've got so many questions coming in, this is an opportunity for you to give us your name and email address, and we can follow up with you after the call.

I think that folks like to submit questions because this is an opportunity for them to reach CDC, but I wanted to remind you all that this call is specifically around laboratory testing issues, and so we cannot answer questions about vaccines or other types of guidance that isn't laboratory testing-related. So please try to limit your questions to be specific about laboratory testing. And if you're the media, you need to send your questions to media@cdc.gov. If you submit your question in the chat box, we may not be able to answer it. So please use the Q&A button. And as I said, we will try to answer as many questions as we can during the call.

Today might be particularly challenging because we have such a full agenda. So if we don't get to your question, we will try to do it after the call. Or we will set up a future agenda item that would answer your question. And the last thing I wanted to mention is that-- just a reminder that the slide decks may contain presentation material from panelists that are not affiliated with CDC and they may not necessarily reflect CDC's official position. And as I mentioned before, if you miss something in the slides, all of them are posted after the call, usually about a week later, to our Preparedness Portal.

And I think, with that, we will go to our first topic, which I already kind of mentioned, which is the updated interim guidance for antigen testing. And Muktha Natrajan will give us an update on that. Muktha, are you ready?

MUKTHA NATRAJAN: Sure. Thank you, Jasmine, and thanks for the opportunity to speak today. Yeah, so all of us at DLS have been working hard to update this [interim guidance for antigen testing for SARS-COV-2](#). And I'll start on the next slide, Jasmine, just by doing a bit of an overview.

I know many of you are familiar with the original guidance, but the overall purpose of this guidance is to support effective clinical and public health use of antigen tests. So there are several different categories of information that are provided in the guidance.

There is some information here and in our overview of testing guidance on different types of test strategies. So that would be, of course, a factor that affects what test you want to choose and potential test accuracy. So the strategies for COVID testing relating to antigen test support are diagnostic, for those that are symptomatic or have a known contact, screening testing, for those that are asymptomatic and they haven't had a contact but it's for job purposes or their living setting, and serial testing that may not always be in no-contact situations but is similar to screening, and surveillance testing at the public health level and is not on an individualized basis but rather a large data-gathering strategy for testing.

Of course, test processing also affects test accuracy and pre-test probability. So in the lab, storage and handling conditions as well as timing and batching of specimens and specimen integrity and performance conditions of the assays should always be considered while performing the test. And as far as clinical pre-test probability, the guidance also considers the clinical context of the individual being tested in determining potential for confirmatory testing or serial testing needed after. This would be related to symptoms the individual has, whether they've been vaccinated or not, and if they've had a recent SARS-COV-2 infection.

Other factors would be community factors for the individual and, again, related to COVID exposure, whether they have a known or suspected exposure, the prevalence in their community, and a big one that has changed in this part of the guidance that I'll discuss shortly is living setting. And so we've noted that there is going to be relatively different strategies depending on if someone lives in a congregate setting when there's high interaction in a closed space, as opposed to a general community setting. Next slide, please.

And so the summary of the recent changes-- after this, I'll show the algorithms where you can see these actual changes in action. But we've updated guidance based on new published studies on antigen test performance related to-- serial testing is now discussed in the guidance as well. Clarification about which nucleic acid amplification test should be used as confirmatory testing when necessary. Considerations for people who have had previous SARS-COV-2 infections and for those who have been fully vaccinated and potentially how to handle those results and confirmatory testing as well.

There's two new antigen testing algorithms-- one for congregate living settings and one for community settings. The congregate living settings one, you may recognize as being similar to the one that was published previously. And the community settings one is a little less conservative. And I'll get into the reasons for that in a moment. And then, updates to testing suggestions for fully vaccinated, asymptomatic people to align with CDC's current guidance for fully vaccinated individuals. As that evolves-- this will, of course, continue to evolve, but right now the recommendation is no antigen testing is suggested, no testing at all for those that are fully vaccinated and asymptomatic in most cases.

Next slide, please. So here I'm showing the first antigen testing algorithm for congregate setting. And so this is for congregate living facilities such as correctional and detention facilities, dormitories, homeless and other group shelters. This algorithm highlights recommendations for testing in asymptomatic and symptomatic individuals.

For asymptomatic individuals, though, you'll also notice in this, there are several technical footnotes here that are more descriptive in the actual guidance. I'm not going to go into them all today due to time, but they're explained more. And there are several factors, like I mentioned with that pre-test probability, that might change this algorithm a little bit. So for example, if someone has a high likelihood of infection and they have had a close contact, they've not been vaccinated, the prevalence in their community is high, but they're asymptomatic and antigen-negative, a clinician may still use judgment to decide that that high likelihood indicates the need for a [NAAT test](#) before that person is told they can move forward and not isolate. That's just an example.

But yeah, it's more descriptive online as well. And so you can see here, in general, the algorithm would be that if someone is asymptomatic in a congregate setting, antigen-negative, nothing further. If they are asymptomatic and positive, though, the main difference between our congregate and community is that if they're asymptomatic and antigen-positive, we would want to do further confirmatory NAAT testing. The reason for this is that in many congregate settings, people are isolated onto COVID wards or into groups of others that have COVID. And so we're putting them at a higher risk in that isolation setting than you would in the general community setting where an individual could isolate in their own home in a very individualized way. It's quite different from the congregate living setting. So it's a little more conservative here to still to suggest that antigen-positive, asymptomatic individual receive confirmatory testing.

And on the symptomatic side, generally if someone is antigen-positive and symptomatic, nothing further. But if they're symptomatic and antigen-negative, we would recommend a confirmatory NAAT test be performed to determine whether they need to isolate or whether they can move forward to either no quarantining if they've had no known exposure, or quarantining if they have a close contact. Next slide, please. And finally, this one you can see is quite similar to what we recommend for congregate settings, but in the general community setting, as I mentioned, the main difference here is that asymptomatic, antigen-positive people we do not recommend further testing in general, depending on, of course, other factors of pre-test probability. But in general, those in the community setting would be recommended to do their term of isolation after an antigen-positive result, rather than moving forward with confirmatory testing.

That is a very brief overview, obviously, of this guidance. There is a lot more in there, but hopefully that provides you with some of the big updates that we've performed. And thank you for your time. I'm happy to answer questions as they come or once we're ready to do that. Thank you.

JASMINE CHAITRAM: Thank you so much, Muktha. We did get a few questions. I'm going to ask you a few of them then, since you're on the line, if you wouldn't mind going through the Q&A. And you could go ahead and type your answer in to the question as we continue the call.

But the first question I have for you is, are colleges and universities considered congregate settings, or only those living in residence hall, excluding off campus students, faculty, staff et cetera? So I think the question is, are residence halls considered congregate settings?

MUKTHA NATRAJAN: Yes. In general, we are following the CDC'S definition there. And so dormitories, where people have high levels of interaction, we would generally recommend the congregate settings. But there can, of course, be some clinical discretion there again. The reasoning I gave for the confirmatory testing in asymptomatic, antigen positive cases in congregate settings, with individual isolation being difficult, which it would be in general in a dormitory. But if the clinician doesn't feel like that is the case, I think there is some flexibility there.

JASMINE CHAITRAM: OK. And you were breaking up a little bit. So we may need to repeat some of the stuff in the Q&A. So one other question for you is-- and I don't remember seeing this. So just let me know if it's already in there. But does the antigen guidance define congregate setting? Because we got a question about listing those specific groups that would be included in a congregate setting.

MUKTHA NATRAJAN: We give examples in the antigen guidance. I'll put a link to the CDC page that has some more information on how CDC defines congregate settings as well.

JASMINE CHAITRAM: OK. Great. And do K-8 schools use the congregate setting or the community setting flowcharts?

MUKTHA NATRAJAN: We did not specifically do a separate algorithm for schools. And so in general, they would not be considered a congregate setting. So we would suggest the community settings algorithm for them. But yeah, we did not include a separate algorithm for transient populations, which you would think something like schools or work forces in high-density settings would be there.

JASMINE CHAITRAM: And I think this question, I believe, is about the community setting algorithm. It says, for asymptomatic folks that test positive, there is no need to confirm by NAAT?

MUKTHA NATRAJAN: So yes, like I mentioned, there is a Footnote Three there that you can see, and there's more details on the actual guidance. But if the person, in general, has a high pre-test probability and they're asymptomatic and antigen-positive, there's really no need to do any further testing on an asymptomatic, antigen positive case. However, if they have a low likelihood of SARS-CoV-2 infection, such as they have not had a close contact or suspected exposure to a person with COVID-19 within the last 14 days and are not fully vaccinated and have not had a SARS-CoV-2 infection in the last 3 months, then we would recommend confirmatory testing.

JASMINE CHAITRAM: OK. I think we've lost connection with Muktha. So I am going to go ahead and keep us moving forward since we have other things on our agenda. And thank you to Muktha for joining us today. She's still frozen. Our next speaker is from the Division of Laboratory Systems. And like I said, this is to answer some questions that we've gotten about the biosafety guidance. Aufra Araujo is on, and she has been on before. And Aufra tell us what's updating with the biosafety guidance, please.

AUFRA ARAUJO: OK. Now I unmute. Good afternoon, everyone. Like Jasmine said, my name is Aufra Araujo, and I'm a health scientist with the Division of Laboratory Systems at CDC. Today, I will provide a brief overview of the [CDC biosafety guidance](#) updates. I'll go through these updates section by section, starting with the general guidance section. The main update is the addition of a resource on general considerations for laboratories performing biological risk assessment. In this resource, readers will find a step-by-step overview of the risk

assessment process. Other relevant resources added to the general guidance section include EPA's resources on approved disinfectant for SARS-COV-2, EPA resource conservation and recovery regulations, and state universal waste programs in the United States for hazardous waste.

Moving on, in the anatomic pathology section, we've added information on PPE. At a minimum, all personnel, whether practicing anatomic or clinical pathology, should follow standard precautions when handling clinical specimens, including hand hygiene and the use of PPE such as laboratory coats or gowns, gloves, eye protection, or a disposable mask and face shield to help protect the skin and mucous membranes of the eyes, nose, and mouth.

In the decentralized and point-of-care testing section, the content was deleted to streamline the biosafety guidance page, but we provided links to the specific web pages on guidance for SARS-COV-2, point-of-care and rapid testing and self-testing. In the procedures with a high likelihood of generating droplets or aerosols section, we've added information on N95 respirator and disposable mask with a face shield as examples of additional precautions to provide a barrier between the specimen and personnel.

In the environmental testing section, we've added language on avoiding cross-contamination by utilizing designated area for donning and doffing PPE. Emphasis here is on the donning and doffing areas being separated from each other.

In the virus isolation section, we've added language on animal biosafety level 2B-- practices during inoculation of animals with infectious wild-type SARS-COV-2 virus. Inoculation of animals with infectious wild-type SARS-COV-2 virus should be conducted in an animal biosafety Level 3 laboratory using ABSL-3 practices and respiratory protection.

Finally, in the laboratory waste management section, we've added the paragraph on laboratory waste generated during processing and testing of a specimen associated with COVID-19 to clarify the following. The bio-hazardous waste should be discarded as bio-hazard waste. Always disposal must comply with local, regional, state, national, and international regulations.

And the waste disposal regulations may vary at the state and local levels. Therefore, it's necessary to consult EPA'S regulations in your state waste program. We've added EPA'S resources, where detailed information can be obtained as well. And those were the quick updates I had, Jasmine. There is a question we received. I don't know if I have time to answer that question.

JASMINE CHAITRAM: Yes. Please go ahead and answer that question.

AUFRA ARAUJO: OK. So this is a question we received last week on pneumatic tubes. And the question is whether CDC plans on updating the [guidance on the use of pneumatic tubes with COVID-19 specimens?](#)

The current CDC guidance on pneumatic tube use is still relevant in summarized CDC current recommendation. However, each laboratory or facility should perform a risk assessment to determine the most appropriate biosafety measures and practices to implement. And that's the answer for that question, Jasmine. Back to you.

JASMINE CHAITRAM: Thank you so much, Aufr. I'm going to move to our next speaker because I see the time is going on, and we're going to not have enough for everybody to speak. So thank you for joining us. And we'll have you on a future call. All right.

So next, we're going to do an update on SARS-COV-2 variants. We haven't done that in a while. We've got a new face and a new and a new name doing the update today. It's Steve Oberste from the CDC Laboratory and Testing Task Force for the COVID-19 response. Steve, go ahead whenever you're ready.

STEVEN OBERSTE: Thanks, Jasmine. Next slide, please. So first, I just want to mention that everything I'm going to talk about is on our COVID data tracker and [variant pages](#). So if I skipped something, or go through it too fast, you can always look at it there. And those are updated every Tuesday night, so another one will be coming up tomorrow night.

So first, I wanted to start with the B.1.617 lineages that have been in the news lately and of particular interest.

They've been declared [variants of interest](#) by the US Government SARS-COV-2 Interagency Group.

It's actually kind of a family of lineages-- four lineages, the B.1.617 and then there's a dot-1, dot-2, and dot-3.

They're all somewhat related, although each has its own particulars in terms of spike protein mutations. They all have in common the L452R. And three of the four have the E44Q change.

These changes in the receptor binding domain all have potential for reduction in neutralization by some of the EUA monoclonal antibody treatments, which is why there's particular interest in following these and watching them.

There's only a little bit of data that's starting to come out, but we're watching the data very closely-- both what's being generated within the US at CDC, as well as others in other places abroad that are generating data.

So far, there are several different-- I guess not completely conclusive data. Some have shown that there's very little difference in neutralization from, say, vaccinee sera, whereas others have shown a slight decrease. So we'll keep watching those, and we'll reevaluate as the data determines.

Next slide, please. This shows the national prevalence for SARS-COV-2 variants as of the week ending April 24. And again, these are updated continually, so just keep an eye on the website. They'll be updated again tomorrow night.

The B.1.617 variant of concern has increased to 66%, so about 2/3 of the variance that we see in the US. The P1 variant has increased nationwide to 5%.

And those colored dots to the right of the table indicate in red the ones that have increased, and in blue the ones that have decreased. So B.1.351 [variant of concern](#) has decreased to less than 1% at 0.9%. The B.1.427, 429 has also decreased to about 3.2%. And the 526 and 526.1 variant of interest has decreased to 8.2% and 3.0% respectively. The B.1.617 variant of interest lineages were all below 1% as of the 24th of April.

And I'll mention, I'm going to show in just a moment some nowcasting data. And I'll just say, though, that the weighted estimates for that last period from the 11th to the 24th of April actually fall within our nowcast prediction intervals.

Next slide, please. This shows the regional prevalence of the various variants. You can see the color-coding and the pie charts there. B.1.1.7 increased or is at over 50% in all regions. And that's what we had predicted from our nowcast estimates.

It's greater than 70% in Regions 4 through 7. The P.1 variant of concern also increased as predicted. It's over 3% in all the regions except region three. And it's over 7% in Regions 5 and 7.

The B.1.351 is at least 1% in Regions 4 and 7 through 10, but it remains stable, as we expected. And again, the 427, 429 variants of constant decreased in Regions 8 through 10 to 10.5% and to 18%. 526 and 526.1 variants of interest remained stable as we expected. And the 617.1 and 617.3 lineages ranged from 0%-- that is with rounding, so very few examples-- to 0.3%. B.1.617.2 variant of interest ranged from 0 to 2.5% at the regional level. It's over 1% in Regions 8 and 9, so kind of out in the West.

Next slide, please. This shows the nowcasting data as of the week ending May 8th. And this is developed by taking not just the previous week's data but modeling all of the data up to that point and extrapolating from the last weighted estimates of the 24th of April to what was, at the time, the current day. So those will be updated again here coming up.

The B.1.1.7 variant of concern is predicted to increase to 72.4%. You can see in the table there's a prediction interval of 67.4% to 77.1%, so a relatively tight interval around that number. Of course, as the lineages that are at a lower prevalence with fewer observations could tend to have wider intervals.

The P.1 variant of concern is predicted to increase to 6.2%. And the remaining ones-- 351, 427, 429, 526, 526.1 are predicted to decrease. I'm sorry. 526.1 is predicted to stay the same. The others are predicted to decrease. However, the 617.2 variant of interest is expected to increase to 3.3%. So that clearly bears some watching. And we'll be looking at that very closely. The 617.1 and 617.3 variants of interest are expected to remain at less than 1%.

Next slide, please. And this just shows the same regional estimates, but they're the nowcast estimates just as I showed a moment ago. And what you can see is that B.1.1.7 is expected to increase to over 60% in Regions 3 through 10.

In a number of those regions that's probably over 75%. P.1 is expected to increase, too, in all regions and to be over 10% in Region 1. And the 351 expected to increase in Regions 3 and 10. The 427, 429 will be highest in Regions 9 and 10. And of course those are the variants that emerged out on the West Coast so they will remain highest there as compared to other places, whereas the 526 and 526.1 variants of interest will be the highest in Regions 1 through 3. And again, those emerged in the greater New York metropolitan area. 617.2 variant of interest is expected to increase in Regions 2 and 7 through 9. And I believe that's my last slide. Thank you.

JASMINE CHAITRAM: Thank you so much. There are a few questions that came through. Let's see. Are you able to give a breakdown of which variants are breaking through in vaccinated individuals? Do you have that information?

STEVE OBERSTE: There are some preliminary data. And so far, what we're seeing is that the variants that are being observed in breakthrough cases seem to be whatever is circulating widely at the time. There doesn't seem to be any single variant that's popping up at a higher frequency. But clearly, we're watching that very closely. And it's somewhat early days of sequencing the viruses that are coming from these breakthrough cases. So we'll be watching that closely.

JASMINE CHAITRAM: OK. Thank you. And can the labs use the data in the CDC regional prevalence of SARS-COV-2 variants in presentations, acknowledging the CDC source without advance specific approval from the CDC representative? And I think this is about our data that's publicly available on our website, which, I'm going to say the answer is probably yes, right?

STEVE OBERSTE: Yeah. Yeah. I think that's right. The public data are that. They're public. And so yeah, we always appreciate an acknowledgment. But yes, those can be used by our partners.

JASMINE CHAITRAM: Thanks. Do the current NAAT testing platforms detect these variants?

STEVE OBERSTE: There are a few-- I'm aware of a few companies that are developing variant-specific tests. But if the question is whether all of these variants are detected by the current EUA assays, I believe the answer is yes. Most of those assays target multiple genome regions. And so even if you have the spike gene target failure that we saw with several of the lineages, they're still detected because the other targets will light up. So far as I know-- and maybe, actually, Tim might know a little more-- there doesn't seem to be any loss of detectability for these variants.

JASMINE CHAITRAM: Right. I was going to suggest that maybe Tim from FDA can talk a little bit more about the guidance that they're giving to test manufacturers right now about this. OK. One more. So are there concerns or guidance about the mutations T2051 and D399N regarding antigen tests?

STEVE OBERSTE: Good question. I would have to--

JASMINE CHAITRAM: Maybe that's another one for Tim.

STEVE OBERSTE: Sorry, what?

JASMINE CHAITRAM: I'm saying maybe that's another question for FDA, but go ahead.

STEVE OBERSTE: Yeah. No, I was going to say, I think that's right. Yeah.

JASMINE CHAITRAM: All right. So we'll hold on to that, and when Tim comes on, we can ask him. And if you're still able to stay on the call for a little bit and you want to go through the Q&A and see if there's any other questions that you can answer live by typing an answer that others can see, I'd appreciate it. And thank you so much for joining us today. We are grateful for your time.

STEVE OBERSTE: Great. Thanks. Yeah, I'll take a look at the questions.

JASMINE CHAITRAM: All right. So we're going to move to our next speaker. And hopefully, things will go well because I wasn't able to do a sound check with Steve Santos from the HHS Testing and Diagnostics Workgroup. That's the Health and Human Services Testing and Diagnostics work group.

And he's going to talk about how the federal government is addressing laboratory supply issues. And I think Matthew Hubbard may be joining him. Steve, are you on?

STEVEN SANTOS: I'm on. Do you hear me?

JASMINE CHAITRAM: Yes. I can hear you great. Thank you.

STEVEN SANTOS: Perfect. All right. Next slide. So I'll talk about how the US government is addressing lab supply challenges and issues. I lead an industry team here at the Testing and Diagnostics Workgroup. So the US

government has invested in expanding manufacturing capacity and addressing supply challenges in real time. You can see here on the left that we've been making industrial base expansion investments in essential lab equipment, such as domestic tip production, glove production, and swab production.

We are also currently monitoring the supply chain on a daily and weekly basis with industry partners as well as our inter-agency partners to monitor the supply chain and help in challenges and bottlenecks when we can, whether that be by some rating action, by investment, or other communication. We have done some solutions, most recently through a memo to help public labs secure tips for newborn screening as well as rating test manufacturers when needed for present supply. Next slide.

That's not everything that we're doing. There was also an announcement that was made back in February where \$815 million was directed towards a supply chain area of interest. This is a solicitation that's currently ongoing. And we are using it to expand industrial base on materials that can expand test assembly and performance, including diagnostic reagents and components for lab-based COVID test equipment to expand their capacity and increase testing, including liquid-handling robots, manufacturing of test processing consumables, which include tips as well as sample collection and testing consumables including plastics. Unfortunately, I can't give too much detail beyond this, because it's an ongoing contracting action, but these negotiations and awards are currently ongoing. And that's the quick update of what we are currently doing to address lab supply issues.

JASMINE CHAITRAM: OK. Thank you so much, Steve. There's a comment question in the Q&A box. It says, NAAT reagent shortages remain a major issue. Can you address what is the cause for this continuing shortage?

STEVEN SANTOS: We are aware of-- I see both of these issues. The GCCT as well as the blood collection tubes. We are tracking both of these issues and coming down to the root of the shortage. But it is on our radar and how to address, yes, both of those issues. And I see a bunch of questions coming up.

JASMINE CHAITRAM: Yeah. Go ahead. To the next one says, will investment include COVID antigen testing reagents?

STEVEN SANTOS: Yes. So the supply chain AOI-- I put on the slide the big key components. But that area of interest is actually very wide-encompassing. And so we have-- anything that can be used to build into a test, that's what the solicitation went out. So pretty much any raw material or component can be possibly awarded, yes.

JASMINE CHAITRAM: All right. And then is there a plan to address the shortage of sodium citrate Vacutainers used for coagulation testing that's been-- oh, sorry. It moved on me.

STEVEN SANTOS: Yes, more and more questions come up. But yes, sodium citrate, I think that was on the same thing as blood coagulation. Yes, we are tracking that and seeing what we can do.

JASMINE CHAITRAM: Great. I think that's it for questions about laboratory supplies. But if you have time to stay on the call with us-- I know you're super busy also. If any other questions pop up and you can answer them, we'd appreciate it.

STEVEN SANTOS: Yes. Will do. Thank you, Jasmine.

JASMINE CHAITRAM: Thank you for joining us today. Thank you. OK. Our final speaker for today is Tim Stenzel from the Food and Drug Administration. And he's been on all of our calls. He's a regular. Tim.

TIM STENZEL: I'm an honorary member of the CDC. [LAUGHING]

JASMINE CHAITRAM: Yes, you're like a co-host. [LAUGHING]

TIM STENZEL: Well I know it's been helpful for me or one of my FDA colleagues to be on. And we look forward to answering some questions today. I've prepared answers to three questions. I am going to send something in chat that will help with the first question. So hopefully that goes through as I do this.

All right. The question is, can we sell extra tests we have? I have way more, in particular, Abbott antigen cards than I will ever use. So the answer is multi-factorial here.

No. For those with extra COVID tests, HHS has set up a COVID supply exchange. And that's what I'm putting in the chat because there's a link and instructions. So this exchange is useful for those who want to donate-- but not sell-- tests. Again, donate but not sell tests.

The goal of the supply exchange is to provide an easy way for organizations to either ask for additional supplies, including tests, or also surplus items not needed for themselves for others. There's a link to the form. And then they will help you out. Also other organizations can enter their preference but they will be matched to other organizations if available, introduced using the contact information they provide.

Organizations will be responsible for shipping and logistics related to the exchange. If the tests were received as a gift from your state or HHS, they should not be sold for profit. We are awaiting further guidance from HHS Office of General Counsel regarding the registration of tests from gift programs without compensation. So stay tuned.

And if this pathway that I talked about is not a choice for you, perhaps because you want to get your money back, we do recommend that you contact the manufacturer and try to make arrangements. Perhaps they have a customer who wants them. But we do recommend going through the manufacturer of the product.

OK. Onto the next question. Is the Ellume home test considered a surveillance test or a screening test? The Ellume test is authorized for individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. So it can diagnose as well as screen asymptomatic persons. It is authorized for over-the-counter use as well without a prescription. Surveillance tests are generally not those that return individual results. So Ellume and any other similar tests would not be considered a test used for surveillance.

And next question is, how is the FDA planning to move forward beyond the Emergency Use Authorizations in deciding which test platforms are in fact accurate, with regard to COVID PCR, antibody, and antigen testing? So the FDA has already authorized one test-- that's the BioFire, it's a panel-- beyond the public health emergency. They went through the De Novo pathway. It's a molecular test. And so essentially, all future molecular tests that fall under that original authorization of BioFire and special controls that come along with it, can therefore use the 510(k) pathway to get full authorization-- they call 510(k) a clearance-- for use beyond the public health emergency. We have not done a similar authorization through the De Novo pathway for serology or antigen tests yet. And we look forward to doing so. And once the first test of each type is authorized, then the subsequent tests can go down the 510(k) pathway.

The CDRH at FDA has also announced that they are working on a transition guidance to help with the transition away from EUA and enforcement policies in place during the public health emergency. We do not yet know the timeline for when that guidance will be released and do not anticipate that this transition will happen any time

soon. But we do encourage developers to come in with their full authorization commissions when they have data ready.

But I would urge test developers to pay close attention to the availability of samples, particularly of, obviously, SARS-positive samples, rates of positivity, and numbers of positive individuals in the United States are falling rapidly. And hopefully, it stays low. That does make it more challenging to test developers who do need more samples to perform the recommended validations for full authorization.

Early on, we were recommending banking. And it's probably a good thing to do now if you're not quite ready to do those studies. And with that, Jasmine, those are the ones that I had prepared. But sounded like you might want me to address another question or others.

JASMINE CHAITRAM: Yeah. That'd be great, Tim. So we have two kind of related questions. The first one was about NAAT test and the ability for them to detect variants. And if you could just talk a little bit about what guidance FDA has provided to test manufacturers, specifically for NAAT, to make sure that their tests are still performing when it comes to detection of specimens that may contain variants. And also, another question was if there was any specific concerns or guidance with the mutations T2051 and D339N specifically with antigen test. Those two questions there.

TIM STENZEL: Yeah. So the FDA, earlier this year, much earlier, issued a [safety communication around variants](#). At that time, we made public three tests that could potentially be impacted. We didn't think that there was any significant impact on overall determination of being positive or negative.

We then more recently updated that with a [similar notification regarding a fourth test](#) and have now put up a [website at the FDA](#) where we post all that information in detail. And we also are going to post anything else that comes up. I don't have anything today to announce regarding the impact of mutations or variants that in any way significantly impact results of tests on the market.

The significance of impact currently, we have a cut point at 5%. So if any one mutation is prevalent-- and commonly, in the recent circulated variants in the United States above 5% or any sum of different mutations sum up to at least 5%, we would take a deeper dive with the developer of that test and try to understand if performance is impacted or not at a drop in the sensitivity of a 5% or more. That's what we considered significant.

There are going to be rare cases where an individual assay will not be able to detect a variant or mutation because of the variability of the virus right now. It's basically every high nucleotide in the viral genome is able to be mutated. And most, if not all, do show evidence of mutation.

So it's why we recommend that the molecular test in particular target more than one part of the virus, because if you lose a signal from one, you still have signal from the other. That, in large part, is why the tests that we put up on the FDA website so far are still performing well in our mind. And we also came out with [guidance for developers of molecular serology and antigen tests](#) and we urge you to take a look at that.

We want them to monitor mutations and variants and assess the impact on their tests. And we also have all the proprietary primers and probes for the molecular assays. And for the serology tests, we have the antigen sequences that are used in those assays. And for the vast majority of antigen tests, we have the epitope mapping information. We're still working with some developers to get that.

So with all that sort of information, we at the FDA also track the potential impact of variants of mutations. And when there's a potential variant or mutation that might impact performance significantly, we reach out to the developers and engage with them, which is something that we, frankly, do all the time. And those that pan out as far as having a significant impact go on our website.

Regarding the question about recent publication or report about-- let's see. The 399 mutation and 205 mutation? Not on the list right now that I'm finding. Yes, we're familiar with that. We've been in communication with some potential antigen test developers that could be impacted.

The good thing about the T205I and the D399N is that particularly the D399N is in very low prevalence in US sequences right now. The report had that the 399N did cause loss of signal for the Quidel Sofia SARS assays but not the Binax. We are following up on that report.

But given that the frequency is well below 1% in the US population right now, even if this pans out, which it looks very likely to pan out as being the first report of loss of signal of an antigen test due to a mutation, it still does not have a significant impact on the overall performance of the test because of the low prevalence of that mutation. Are there other questions or time? Or turn it back over to you, Jasmine?

JASMINE CHAITRAM: Thanks, Tim. Can you just remind everybody what the name of that test was that has the 510(K)?

TIM STENZEL: That's the BioFire. There are multiple BioFire tests. I'm forgetting which one is the one that received the De Novo. I'm not sure if I can quickly grab that. Are there other questions while I try to quickly grab--

JASMINE CHAITRAM: I think other questions are also asking for you to maybe put in the chat the link for the four testing platforms that mentioned were impacted by the variants and the paper that was just mentioned about the mutations and the antigen test. If you can put links in the chat, I think folks would appreciate that.

TIM STENZEL: Not probably going to be able to do that. I'll try to do it before the end of the hour. But if I send it to you, can you make that available?

JASMINE CHAITRAM: Yeah, we can get it out. Yes, yes, we can do that. And then I think this is the last question for you, Tim. When does the FDA anticipate granting an EUA test kit for use with the post-vaccine antibody testing?

TIM STENZEL: So the US government is funding a number of studies that is addressing how to define immunity. It probably will be a truly quantitative serology sort of assessment-- if you have this level of antibody, that you're likely to be protected. So as soon as the results of those studies show the ability to address immunity, whether it's a post-viral immunity or post-vaccine immunity, we will utilize that information and any sponsors that want to make that claim for their test and have the appropriate test to be able to assess the specific measurement that would be needed to make that assessment. So it's certainly something the FDA has authorized for other vaccines and we're hopeful and look forward to doing the same for SARS-COV-2.

JASMINE CHAITRAM: All right. Thanks, Tim. I think we're going to wrap it up here because something just happened with my laptop and I've lost control. So with that, I think that's a sign for us to go ahead and end the call a few minutes early so that people can have some time between meetings. I want to thank you all again for joining us this afternoon. As I mentioned earlier, our next call's not going to be until June 14th. So that's about a month

away. And continue to submit those questions or suggestions for agenda topics for us as we plan future calls. We really do appreciate the feedback. And I hope you all have a good Memorial Day weekend, and stay safe. Thanks for joining.