Clinical Laboratory COVID-19 Response Call

August 23, 2021

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JASMINE CHAITRAM: Hello, everyone and thank you for joining the Clinical Laboratory COVID-19 Response Call; my name is Jasmine Chaitram. I am the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. I've been hosting these calls, but I wanted to let you know that there's actually a team behind all of this that helps and supports the whole production and logistics of making these calls happen. And I want to take a quick second to say thank you to all of them-- Meredith Reagan, Johanzynn Gatewood, George Zhang, and Nancy Anderson, and there have been others along the way. But those individuals have been really helpful in making these calls happen, and I just wanted to say a quick thank you to them today.

I'm also going to give you a couple of reminders and a couple of things to do during the call, or not to do during the call, and then we'll move into our agenda items. So the first thing I wanted to tell you about is the Division of Laboratory Systems, and I'm sure you've heard about this before. This is the division that has been hosting these calls since March of 2020. And we have an outward-facing responsibility for clinical and public health laboratories in four goal areas, including quality and safety, training and workforce, preparedness and response-- which is why we hosted these calls-- and laboratory informatics and biorepository and data science. And as I mentioned, we've been hosting these calls since March. And it's really to serve as a liaison between CDC Emergency Operations Center and the clinical lab community and public health laboratories.

We have stood up a Preparedness Portal to better serve all of you, and this includes all of the information at One-Stop, which our division provides or is involved in. This includes LOCS messages-- that's the Laboratory Outreach Communication System, where we send out a lot of email communications, including announcements for these calls. We have an archive of all of our Clinical Laboratory COVID-19 Response Calls-- we call them CLCR Calls. And the transcript, audio, and slides are available in this portal. We also have links to other CDC pages that may be of interest or information that you're looking for related to the COVID response.

Our next call will be on Monday, September 20, from 3:00 to 4:00 PM. We do host these calls every two weeks. The next call falls on Labor Day, so we are all going to take a break that week and take that Monday off. But we will be back in four weeks, which will put us at September 20th. We do want to hear from you, so please send your suggestions for training and workforce development to LabTrainingNeeds@cdc.gov.

Sorry. Hang on. OK. And finally, how to ask a question in the Zoom webinar system-- so this is really important, and I go over this every week. We really would like you to put your questions in the Q&A box and not in the chat. If you put it in the Q&A box, that allows us to track your questions. So after the call, if there are questions that haven't been answered, we can either find an answer by talking to an SME, or we can queue up those particular topics for a future call. It's also helpful for you to include your email address, in case we are not able to answer your question, and we need to get back to you at some other time.

I do want to remind everybody that these calls are intended for laboratory testing issues, and we don't have subject-matter experts for some of the other questions that have come through. And so please try to keep your questions focused on laboratory testing issues or testing issues in general. And we will try to get to as many questions as we can.

As I mentioned, sometimes we can't get to all of the questions, because of the number of questions coming through and not a lot of time for the calls. Or we may not have a subject matter expert available on the call to answer that particular question. But we will keep a record of these questions. We do go back to them, and it does help us identify some of the things that you're concerned about, and some of the things that we need to be thinking about communicating or coordinating internally with CDC, and other parts of CDC on.

OK. And so I think my last important message is to let you know that the slide decks may contain presentation from panelists that are not affiliated with CDC, and this is really important if you go back to our Preparedness Portal and look at our archives from speakers that are not from CDC and their slides or their information they present, it may not necessarily reflect CDC'S official position, so please keep that in mind when you review these materials. And with that, I think we are ready to go to our very first speaker for today. Today, we're actually getting our various updates from Dr. John Barnes. He is on the CDC COVID-19 Laboratory Testing Task Force. John.

JOHN BARNES: Thank you, Jasmine. Next slide. All right, so the update for this week is that Delta is continuing to increase from-- and actually increased from 94% to 99%. We have Delta broken out into three main categories right now, the B.1.617.2, the AY.3, and then you will see these AY.2 and AY.1s. Those our Delta Plus variants, and you can see the relative proportions of those are very, very low. The AY.3 is a lineage that is called by Pango, and it is in the US at about 12%. Overall, Alpha is continuing to decrease from 2.4% to 0.3% over the past week. We are updating the variant tracker proportions and are now casting weekly now, and as opposed to bi-weekly. And Gamma is decreasing from 1% to 0.2%.

And then new this week, B.1.427 and B.1.429 are no longer considered variants of interest, and have been reported at less than .1% nationally. Our data for this week, it actually covers from Nowcast are from all specimens collected from 8/8/2021 to 8/13/2021. And then the weighted estimates were evaluated on 26,170 specimens that were submitted. Next slide.

As you can see by the map here of our regions, pretty much Delta is the only thing going. The darker orange wedges that you can see are the proportion of AY.3, and the other orange rest of the pie chart is really be B.1.617.2, or the Delta variant itself. AY.1 and AY.2 are less than 1% for all HHS regions and nationally. Alpha, B.1.1.7, is decreasing in all regions and less than 1% in each region, and the same with Gamma. And that is really the proportions of the SARS-CoV-2 lineages that we have currently tracking in the variant portions.

Jasmine did want me to also mention I actually have worked on the diagnostic portion of this, and there is an update for the diagnostics on the CDC-held diagnostics. Both the diagnostic panel and the flu SC2 Multiplex, we have recently updated their IFUs to include new data associated with the in silico analysis, basically looking at the new variants and whether or not they affect either assay. And the long and short is, there's no discernible differences that would lead to a decrease in sensitivity.
And that's all I have. Thank you, Jasmine.

JASMINE CHAITRAM: Thank you, John. We did get a couple of questions while you were talking. The first one, is CDC tracking Lambda? I heard on the news that cases were seen in Louisiana.

JOHN BARNES: Yes, we are tracking Lambda. Overall, Lambda's proportion is very, very, very, very low. The B.1.621 question I see is also there. And the B.1.621 are currently circulating a 0.5 of circulating viruses. Region one has the highest proportion, which is around 1.5. And there's really no change in there since the last update on B.1.621.

So the relationship of B1617.2 and AY.3, that's a really good question. So the question is, can we discuss the relationship between Delta, main Delta, or 617.2 and AY.3. AY.3 is a Pango lineage. Pango has actually gone out and made up to 12 lineages of Delta. AY.3 has a mutation in the Orf 1a region, and really does not have any spike mutations that are associated with it.

We're not really sure of the significance of that, or whether it leads to any increase in transmissibility or anything at all. It looks like it is just a lineage definition done by Pango. We may be changing some of the ways that we actually do these Pango lineages, but they have expanded lineage up into AY.26, I think at this point. So it's getting a little hard to figure out what all of them are and what they are referencing. And so really, it is not something like AY.2 and AY.1 where we do have associated spike mutations that are in variants of interest. And I think that is pretty much the last two questions answered.

JASMINE CHAITRAM: Thank you very much for your update and for answering those questions. OK, we are going to move to our next agenda item. And this will be Dr. Dean Winslow from the US Department of

Health and Human Services, who is now leading the Testing and Diagnostics Work Group, that's also known as the TDWG.

This group has presented on this call before, but it's been about a year, and there have been some changes in the work that they've been doing. So we thought it would be good for them to come back and talk a little bit about how they are supporting laboratories. Dr. Winslow.

DEAN WINSLOW: Good. So first of all, Jasmine, thank you so much for inviting me to participate. We really greatly appreciate it and wanted to give just kind of a quick update today on a little bit of the structure of the group, for those that may not be familiar, and tell you a little bit about our capabilities, and then I'd like to leave time to answer questions. So anyway, if you don't mind-- I don't know if you can turn the slides for me, that'd be great.

So again, just we'll start out and give you kind of an overview of what TDWG is about. So next slide, please. So again, we do lots of different things. And again, this group, just a little bit of history-- it actually was stood up, I think, way back in February or March of 2020. It originally reported directly to OASH, the Assistant Secretary for Health under Admiral Brett Giroir. And again, it was and remains a multidisciplinary group with great representation from CDC, we've got FDA folks deployed, NIH people. And then, of course, we work really closely with DoD for acquisition and procurement.

So, again, just the four pictures here, and I won't read every word on this slide. But we try to support test development. So, again, we actually do use some of the ARP money in our budget to actually support R&D elsewhere within the federal government. Again, one of the things that we've tried to do-- and I think this is going to be really critical going forward to make sure that we're prepared better for the next pandemic-- is how do we fund, from a US government standpoint, industrial-based expansion? And again, one of the things that we really want to do from a strategic standpoint is make sure that we've got people right here on US soil that are capable and can quickly spool up manufacturing of diagnostic kits in order to meet future demands.

Again, we've got several people, led largely by Steve Santos from the NIH, who's been deployed with us for more than a year, that are very closely monitoring, talking to industry, and getting market signals. And then, again, some of the, I think, the really exciting stuff that we do-- which as a clinician, which I am, that is just so near and dear to my heart is we actually have two large programs, one called ICATT, or Increased Community Access To Testing, and Operation ET, or Expanded Testing, where we're actually directly working through contractors, actually doing testing, particularly, of vulnerable populations.
So, for example, through ICATT, we started out with some actually fairly small pilot programs. We've largely expanded this, and we actually have, through our pharmacy partners, are testing in just about every state, in both the continental US as well as Hawaii and in Alaska. And again, this is basically no-cost testing for, particularly, areas that have high social vulnerability indices where we're doing testing. We've also, through ICATT, have a surge testing capabilities. So as all of you know, over the last six weeks, as Delta variant cases have surged, our ICATT program has really stepped up.

And then lastly, and I'll talk about this in a little bit more detail in other slides, is the other big thing that ICATT is doing is, of course, we're testing at the southern border. And we currently are testing at four, soon-to-be five Customs and Border Protection sector stations that handle a lot of the unaccompanied children who come across the border and then surrender to the CBP stations. They're supposed to be kept there for no more than 72 hours and then are transported-- after testing, by the way, which our group does-- to an emergency intake shelter run by ACF.

And, again, actually, I had the privilege just last week of spending a better part of a day at the largest EIS shelter in El Paso at Fort Bliss, and so I can talk more about that later. And then the other thing that, again, as a fairly recent United States Air Force officer veteran who served two tours in Afghanistan, is that I think all of us on the news have just been so upset by seeing the chaos and the suffering in Kabul and in Afghanistan. And again, the ICATT has actually stood up over the weekend, and we will be providing testing for arriving Afghan immigrants as they arrive at Dulles International Airport. Next slide. So again, some of the things that we do on a regular basis is that we work with our industry partners to try to understand testing supply and demand. Again, we're trying to pull all the levers that we can to purchase, constrain testing supplies and services, make strategic investments, and also increase testing access across the country.

And then one of the big challenges, and one reason, again, why I'm just so glad that you invited me, Jasmine, to talk to your group today, is to communicate what our capabilities are, and so that we, the CDC, through the STLT program, Asper, through its regional liaison officers, that we really coordinate our US government activities around COVID-19 testing and diagnostics in a good way.

So again, it's a real iterative process, but it's just so critical. And we're really lucky. The CDC actually has deployed Carolynn Debyle, who is our state engagement person. Next slide, please. And again, just-- we talked a little bit about this, but we do, of course, pay a lot of attention to supply readiness. Next slide. And we talked a little bit about, again, our current situation. So, again, Steve Santos and his team talk literally every day to the larger manufacturers-- and smaller manufacturers as well-- to kind of get signals about where things are going. And then, of course, we try to manage our own supplies that are actually under our own control, or at least of US government control, to try to keep those up to speed.
And then also working with our manufacturers to make sure that there's adequate vendor-managed inventory. So there was like a company like an Abbott or a Becton Dickinson, that they're actually maintaining their own inventories, both for eventual distribution to the US government, as well as for direct sales or distribution commercially. And then, of course, we also have regular contact with the large commercial laboratories. So, again, that's another thing.

And as we, I think, go forward, I think many of you-- just speaking very parenthetically-- know that there's very much a high degree of concern-- I guess I should say-- about the relative shortage of point-of-care rapid tests, both antigen as well as point-of-care molecular tests. And so, again, one of the things that I think is very important is that where feasible, because of the shortage of these POC tests, that we encourage use of the commercial laboratory tests, which are not as supply-constrained right now.

Although, again you do have the disadvantage of longer turnaround times, of course, for laboratory-based tests. Next slide.

And again, the short term, I'd already spoke a little bit about this with our surge response capabilities that we have in TDWG. So, again, these are the two programs. I guess I already sort of stole my own thunder a little bit. But, again, with ICATT, no-cost testing, focused mainly on underserved high-SVI populations. Again, we largely used our pharmacy partners, and that's Walgreens, Rite Aid, CVS, and eTrueNorth, to both test out of pharmacies as well as have freestanding sites, pop-up sites in areas where cases are surging, and then also some priority surveillance locations.

And the other big program, which is led by Matt Humbard from the FDA who's on deployment with this, is Operation ET. And this primarily was designed or funded for testing in K through 8 schools. We've actually expanded this to K through 12 schools, just because many schools in some areas, for example, middle school might include 9th grade. In other cases, it doesn't. So we just made that easier.
And again, we did extend our funding through June of next year, so the full academic year. And, of course, with cases surging and concern of parents as well as school administrators and teachers, that this program is really rapidly enrolling as children are returning to school. And again, we actually have four testing hubs that administratively handle this. And again, the testing for Operation ET actually is mainly laboratory-based and pool testing. But, again, rapid turnaround time through these four hubs.
And then the last thing I wanted to just talk about briefly, which I think will be interesting to those of you on the call, is just what we're doing at TDWG in terms of procurement and distribution. So, again, we do actually have, through priority acquisition contracts, purchases of somewhat-constrained supply-constrained tests, such as the Abbott BinaxNOW assay, and novel tests, including Cue and Ellume, which we actually do have stockpiles of that we do control.

The other thing which I think is just so important, that everyone who's involved with the COVID response knows, is that we also have, basically, a database, and we can facilitate exchange of supplies through our state supply exchange. So again, that's definitely something-- and I can certainly, offline, be happy to give you our best internal contact or contacts at TDWG to help you access the supply exchange.

And then the third thing, which is actually listed as the second bullet on the right, is the federal supply schedule. And again, what the federal supply schedule is, is that basically, it's a large inventory of all kinds of things, including PPE, as well as diagnostic tests, that this is, again, maintained by the VA system. And this is where, basically, state and local health departments and other government agencies can actually purchase diagnostic tests, essentially, at the low-government cost. Next slide.

And again, this just kind of graphically shows a little bit about, what do these testing programs do, and the levers that we have as well. And then just the previous slide talked about our procurement distribution things again. So provision of testing supply is basically through the federal supply schedule, as well as the state supply exchange. And again, the next slide.

And again, this tells you a little bit about what we're doing. And, by the way, this slide is out of date. So we've actually stood up these programs in many other states, besides what you see here on the slide right now. But again, I think as you know, cases are really surging right now in places like Arkansas, Florida, Louisiana, Missouri, and in Nevada as well. So, again, these are places where we're all very, very heavily engaged-- and Joe Miller and his team, as well as Matt and his team, and, of course, Carolynn helping facilitate the provision of these resources to these various states and in counties that have reached out to us. Next slide.

And again, so the last thing I just wanted to real briefly talk about was the future of procurement strategies. So one of the things that we do is we have a number of sources of intel that we try to tap into. But, again, going forward, one of the things that I'm just really concerned and motivated to help do is to actually be sure that we are better prepared for the next pandemic, which, again, may be a virus or some other type of public health emergency.

So, again, these are all things that are being discussed. And one of the things that I really want to do is to actually expand, to some extent, the pandemic testing board on the strategic side to really try to focus on this, so we're not quite as reactive as we have been up to this point in the pandemic. And next slide. And so, again, these are some of the things that we're doing, in terms of these levers-- is a new term that I've learned since I joined the TDWG is, again, long-term capacity increases through industrial-based expansion. And we actually have right now about 19 really large investments that we're funding to actually buy things, such as pipette tips and swabs and viral transport media, as well as entire diagnostic kits. And, again, warm base manufacturing, we talked about this, the ability to incentivize private industry to actually be able to flex and develop other assays, but then quickly repurpose to whatever else is deeded in the short term. So, again, this is something where the US government definitely can play a very positive role. And, indeed, we've been active in this area. And then, of course, immediate inventory coverage or stockpiling. So, again, working through the strategic national stockpile, as well as the FSS or things that we're already in the process of doing or have been doing since last year. Next slide.

And, again, to just-- this is probably something, it's pretty obvious to most of you, but-- so right now, this slide, again, is only a couple of weeks old. But there clearly have been some supply-chain risks. Some of the things, including semiconductors, people know about, have impacted not just diagnostics, but things such as automobile-manufacturing. And then in the past, we've had intermittent shortages or impending shortages of things such as filtered pipette tips.

And, again, I think our group has done a good job of addressing those and procuring additional supplies. So we are in fairly good shape right now. And, again, one of the things that was really not anticipated, even as few as two months ago, was just this increased demand, particularly as the recent surge, which has been driven by the Delta SARS-CoV-2 variant. Next slide.

Great. And I think those were all my slides. And, again, I'm not sure how much time I have. I don't want to step on Tim Stenzel's time. But I'd be happy to answer questions. And, again, through the Q&A function if, again, if Jasmine could feed those to me, and I'd be happy to answer by email. I also put in the chat-- and

Jasmine, it would be great if you could share-- is my CDC email. So, again, any of you on the call, please feel free to reach out to me directly. And if I don't know the answer, I'll put you in touch with the person in the TDWG who will be able to help you.

JASMINE CHAITRAM: Thank you so much, Dr. Winslow, for presenting that information about the TDWG and for being here this afternoon. We did have a couple of questions, and we do have time.

DEAN WINSLOW: Oh, great.

JASMINE CHAITRAM: So I was thinking I'd ask you a couple right now. And then I can definitely send you some by email that we don't get answered. I think, in general, there is an interest in supporting these programs that you mentioned. And so there's questions about how they can get-- the labs can get involved, be considered for inclusion in things like Operation ET or the ICATT program. Are there specific recommendations for laboratories to get involved, or what's the process?

DEAN WINSLOW: Yeah. So are you talking about state and county public health laboratories, or are you talking about commercial laboratories?

JASMINE CHAITRAM: These are probably clinical laboratories that are asking these questions right now. It's kind of hard for me to tell just from the name. But I think it's probably going to be clinical or commercial labs.

DEAN WINSLOW: Yeah. So, again, there is-- as you know, because large dollar signs involved with this-- sort of a competitive process in terms of which laboratories are used, for example, for Operation ET. Of course, for ICATT, that's mostly point-of-care testing, so that's not laboratory-based. But, again, we will, I think, be competing some of the Operation ET, which is the large laboratory-based program that we have. So again, mostly, again, we're in the business of surge testing, which is largely been driven by point-of-care, and to a lesser extent, OTC, or over-the-counter, take-home tests. But, again, I could definitely hook commercial laboratories up with Steve Santos, who is responsible for industry engagement as well.

JASMINE CHAITRAM: Thank you. And it turns out that some of the questions are also being asked from public health labs, so I think they're interested as well.

DEAN WINSLOW: Yeah. Well, absolutely, well, with public health labs, again, myself, and Carolynn Debyle would be your best points of contact. And, again, we really are making every effort to make sure that we're working closely with our CDC STLT folks, as well as the ASPRhealth department liaisons.

JASMINE CHAITRAM: Thank you. So a couple of other questions that are coming in are about the Abbott ID NOW. Have you been in touch with that manufacturer? There was a news report of them destroying a bunch of tests, and so there's concerns about the supply issues for the Abbott ID NOW.

DEAN WINSLOW: Yeah, so I think it's not the Abbott ID NOW. I believe the big concern is the Abbott BinaxNOW test, which is the rapid antigen test. And, again, I don't want to say anything on a public hall, but I think this was very disheartening for many of us to read.

And, again, what I can say, though, is that Abbott is responding-- and they're actually in the process now-- of rehiring-- it's something like 1800 people. They're apparently incentivizing employees, so they're going to be paying them even more than they were being paid before. And they'll be running apparently three shifts a day. So they actually are reopening the two factories that they shut down.

So I think that's good news. And hopefully, they'll be back up to speed in a few weeks. But, again, this was very unfortunate. And just because of this, and I think that if, particularly, the cases dramatically increase over the next few weeks, it will be really, really important for-- as much is whether it's feasible-- that we use laboratory-based testing, swab-and-send testing, which, unfortunately, it doesn't have quite as rapid a turnaround time as a rapid point-of-care test, such as the Binax assay.

JASMINE CHAITRAM: Yes, and thank you. You're correct. It was the BinaxNOW. I misspoke on that one. There was a question about what cities-- for some examples of cities or states where the Operation ET is currently going on. And I know you showed a slide. And from the slide, I saw California, Missouri, and I think Nevada. I don't know if you have anything more to add on that one.

DEAN WINSLOW: Yeah. I think that, I believe, was the ICATT. That's the surge testing. So Operation ET is helping out with some of the surge testing, but most of the surge testing is actually through the ICATT program, which, again, is largely point of care. And that's really just about all 50 states in the US. And, of course, places where we've been requested to go in as a high-priority include some of the real key states, where we're seeing 60 or 100,000 or more new cases a day.

And also some places like-- you wouldn't think too much, but Hawaii is a really interesting thing. So it was about two or three weeks ago, we were contacted by the Asper liaison. As well as the CDC STLT person assigned to Hawaii to stand up surge testing sites, actually, in Hawaii. Apparently, they also are having a fairly large number of cases. And there was a large amount of travel between Las Vegas or Clark County, Nevada, and Hawaii, which may explain some of the spread in Hawaii.

JASMINE CHAITRAM: All right, thank you. And I'm not sure if you can answer this question, but it is, why is the US testing so much less per capita than places like the UK and Canada?

DEAN WINSLOW: Yeah, I think it's just really unfortunate. And one of the things is that we have some more barriers, I think, to it. And I think just the mistrust of science and the misinformation that's out in the ether right now has certainly affected not only testing, but most importantly, uptake of vaccination, which is just so sad. But it's not, I don't think, for lack of resources that testing is lower than elsewhere in the world. It's really, I think, just a whole kind of confluence of really negative factors.

Oh, by the way, I just also wanted to point out, if you could send this out to everyone, Jasmine, is that-- I just got a message from Carolynn on the chat that TDWGInfo@hhs.gov is the sort of big inbox that people can use to contact us as well as reaching out directly to me and Carolynn.

JASMINE CHAITRAM: OK, great. And I think-- yeah, I saw that come up in the chat, so that's great. People can see that there, and we can always help with getting that email address out there. So I think that I am going to move to our next speaker. And I do want to thank you again for your time and for being here today. We appreciate all of the information that you provided.

DEAN WINSLOW: No, thank you so much, and again, really appreciate all the work everyone on this call is doing, so take care.

JASMINE CHAITRAM: OK. Before I go to the last speaker, I just wanted to comment real quick, because one of the questions was asking about forecasting testing needs for SARS-CoV-2 and flu. And I just want to go ahead and give you a heads up that we will have a speaker on the next call, September 20, talking about flu testing guidance. So please tune in for that. OK. And with that, I will go to our last agenda item for today, Dr. Tim Stenzel from the Food and Drug Administration. And I think you all know Tim has been with us for quite a few calls. Tim, whenever you're ready.

TIM STENZEL: All right, Jasmine, thanks, and really appreciated the previous two speakers and what they had to share. Monica, in the Q&A, asked about a very detailed, specific situation about test development, and I would just urge you to reach out directly to the FDA. We'll need to know more details, if anybody else was looking at your question. An interesting finding, and we'll be asking things like, which PCR test did you use? Did you try other PCR tests? But we'll need to know the details before we can give you a response. So just reach out to our Templates EUA email address (CDRH-EUA-Templates@fda.hhs.gov) and we'll work on that.

So there were a couple questions that were submitted that I'd like to go over. And one of them had to do with a test that has been notified-- and I'll go over with that is-- and hasn't yet been authorized. And the specific test is the Centaur SARS-CoV-2 antigen central lab test. And the question is, can I begin using the test while waiting for the EUA? My lab is a high-complexity testing lab. I really appreciate your input and advice.

So we initiated this policy all the way back in March of 2020, so a year and a half ago, where, in order to make access to SARS-CoV-2 tests as quick as possible, a manufacturer could simply complete their validation studies, notify the FDA. If we accept the notification, we'll post them on the website. And they were able to launch that test commercially prior to the formal EUA authorization. And we've been using that tool since the very beginning then, in order to speed access to more and more tests.

And this particular test-- and I double checked. Yeah, it is notified. It is on the FDA website. And it says that it hasn't yet been EUA authorized. And so that review is still ongoing. And so the simple question is,

yes, labs can use these tests, but they should note that they're not EUA authorized. And then note that we're still doing a review, and that should be noted.
I have a couple links-- or at least one link that I put in-- no, two links related to this, so you can look at the tests that are both on the notification list. And then the notification list, once the test is authorized, is updated to say that test is now authorized. And there's a link to that authorization. But you can also check the FDA authorized list for tests that have been authorized. And notified tests will show up on both. And so that pretty much answers that question.

And the next question asks, what we need to do to validate the EUA citrate tubes from the UK? So these are BD Vacutainer Plus Citrate Plasma Tubes that are manufactured in the UK, and they were not cleared-- they're not cleared through the FDA. However, the FDA reviewed their information about that Vacutainer tube, and determined that there would be no safety concerns, likely safety concerns, given that review. So-- and due to the shortage, has made those tubes available in the US, because there was slightly less demand outside the US for the citrate tubes than in the US. And so BD, they wanted to support the US pandemic response with regard to coagulation testing, which the blue top citrate tubes are used for.

And so a further question is, what is required? There is really nothing required by the FDA. We've also put a link in there to the sodium citrate tube issue. And you can go there for frequently asked questions and the responses to those questions. But there's nothing that the FDA requires for you to validate on those tubes. However, there may be national, local, organizational, or accreditation requirements that are applicable.

And there's things that are good, common practice, perhaps, to do. But, at least from our review, we do not see an issue with the tube. We are tracking any potential MDR as closely that might result. But I'm not aware of any to date. And so with that, Jasmine, I think I've answered all the questions, plus one from the Q&A, the live Q&A.

JASMINE CHAITRAM: Thank you, Tim. I've got another one for you. I think you can answer this one. It's about the Ellume, which was mentioned in the last presentation. And a question about, can someone explain the disclaimer that Ellume has in regards to their false positive rates being affected by geographical prevalence?

TIM STENZEL: Yeah, so I wasn't aware of that disclaimer, so I then chatted with one of our subject matter experts. OK. I think the disclaimer is-- I'm going to read it now. False positive results may occur, particularly in individuals without COVID-19 systems and/or individuals who live in areas with low numbers of COVID-19 infections, without known exposure to COVID-19. So all this is is a general disclaimer that-- and I'm not sure how universal it is in our authorizations-- but it's clearly observed that the false positive-- so, on average, across the board, it's been my experience, looking at the false positive rate for antigen tests, that it's somewhere around 1%, maybe 2% false positive.

And so if you are testing in a very low-prevalence area, the number of false positives to true positives will go up. The ratio will go up. So it's simply a notification. There's nothing any particular about the Ellume's test. This is just-- and this is true for all tests, in fact. Even molecular tests, when we-- and the FDA has given input into some large COVID studies using molecular as quote, "truth," there is the chance when we initiated the study that even with molecular tests, you can have false positives in very low prevalence areas.

And so we had a way of reflexing those positive molecular tests to do other molecular tests, best 2 out of 3, or if 3 out of 3 agreed it was positive, then we'd, for the clinical study purposes, we'd call it a positive. So, really, for any kind of testing, if something doesn't make sense-- so if it's positive, and you don't think it should be positive, confirmatory testing, usually with a molecular test-- and if you use a molecular test first, to confirm it with a different molecular test, to be sure-- and that's true for potential false positives as well as false negatives. So hopefully, that cleared that up.

We had an issue, I think, of understanding some of how you handle positives for antigen tests when the prevalence is very low. And so that wasn't part of our effort to help those who were using those tests too. And there is, I think-- additional confirmatory testing is wise when results are suspect. Alright, Jasmine.

JASMINE CHAITRAM: Great, thank you. I did get another question through a different mechanism, that was asking about Quidel's home test, and do we know when we're going to see that one?

TIM STENZEL: Quidel's QuickVue home test is already authorized. It's OTC. And as far as commercial availability, I would direct any questions to Quidel. I mean, I've certainly seen public notices of them going through various distribution channels to get that out and into-- and I know, and I believe they are selling it. But I will say-- and Dean's very well aware of this as well-- we're seeing a huge increase in demand for the home OTC tests. And I think the demand early on, when these were authorized, was incredibly low-- surprisingly, incredibly low. But demand had been building up. And when Delta hit, then the demand went through the roof. And so there's-- at least, temporarily-- there's a relative lack of OTC in what we call the sales channel. And we certainly want to encourage the developers of authorized OTC tests to do what they can to address this situation in the short-term.

JASMINE CHAITRAM: Thank you. I think another question that you might be able to answer-- well, you should be able to answer-- is there is a question about availability of COVID-19 immunity tests. Can you just comment on that?

TIM STENZEL: Yeah. So this is a very frequent, common question today. And I've been thinking about sometime how to-- over the weekend, actually, how I can better answer this question. So we get a lot of questions about, well, if you got antibodies, doesn't that mean something? And the truth is, we don't actually know what it means enough to determine what an individual patient should do or not do. And a lot of questions we get are, well, if I had COVID before, and I'm antibody-positive, why do I need to get a vaccine? And I would say that that's what-- I believe that's what the CDC recommends, that even if you've had COVID before, to get a vaccine.

And the challenge is-- and I think the best way to explain it is-- we now know that, with the Delta variant, that fully-vaccinated individuals are getting COVID, are being admitted to the hospital, and, unfortunately, some of them are dying. And yeah, there's an overabundance of folks who have immune disorders or immune dysfunction. But very clearly, your average person who, in all likelihood-- and CDC probably knows more about this-- is getting an antibody response. And yet, they're still getting Delta.
And unfortunately, those that are vaccinated, it appears, obviously, that in the literature, that they have much severe unnecessary death compared to those who are unvaccinated. But it just illustrates-- and the reason I bring it up-- it illustrates the point that just because you might have antibodies doesn't mean you know whether you're protected and that level of protection.

And so there are a lot of ongoing immunity studies, and the FDA is looking forward to seeing the results of those studies, and a correlate of protection. And the FDA has, for other vaccines, like rubella, authorized a serology test to inform about immunity. So for rubella, we know the sterilizing level of antibody in the international units against the vaccine. So clinicians can see whether or not a patient is above or below that and re-vaccinate as needed.

And so that is a fully quantitative-- those are fully quantitative tests linked to international standards, so that no matter what test manufacturer there is, they're all linked to an international standard, and you know what the units are, the international units that will give you protection. I mean, that's ideally what we'll look for in these studies if it's possible.

And that the chances may not be as great, given the mutation rate of this virus, and the variants and the mutations that are occurring, but we remain hopeful. And if the data comes through, then we can definitely inform about immunity. All right. Hope that was helpful.

JASMINE CHAITRAM: All right. Thank you, Tim. It is. And I'm going to ask you one more question. So the question is, how should clinicians and labs think about the difference between diagnostics versus screening testing for asymptomatic and nonexposed individuals? On the one hand, FDA says that tests should have a specific screening claim for this purpose. However, FDA has put out enforcement discretion guidance in late 2020 that says otherwise. So can you clarify that a little bit?

TIM STENZEL: Yes. We put out a Q&A that talked about-- because there were some few manufacturers who had come in, test developers had come in and validated for the asymptomatic population, that we said, basically, it's better to have something than nothing. And so that was a statement then. Then we worked on a new pathway that allowed much easier initial authorization for screening. And the difference between diagnostic and screening in this sense is diagnosis of somebody with symptoms or, say, has a known exposure to somebody who tested positive and is at high-risk, versus somebody who has no known high-risk situation and does not have any symptoms.

And so I forget the total number of authorizations now that we've provided for this screening claim based on their performance and symptomatic patients. But I believe it's well over 20 now have this. And any test

that is over-the-counter automatically have the screening claim along with it. And all the over-the-counter tests also are offered authorization for point of care. So the point-of-care version of those OTC tests also has-- if the manufacturer had wanted to go that route-- have the screening claim.
So that's the situation. So where possible, it would be ideal to use tests that have been authorized for screening. If they follow the screening pathway, it does involve the need to do serial testing. And that's typically two or three times a week with an antigen test or once a week with a molecular test. And if folks need any additional help or any additional guidance, you can please send the FDA an email at the Templates EUA address CDRH-EUA-Templates@fda.hhs.gov. I don't have that handy to put in the chat, but I know that it's been posted before by the CDC.

JASMINE CHAITRAM: OK, no worries. We can either find it and put it in the chat, or we can send it out in another means. We can put it in the transcript, or we could also do another LOCS message on it. Thank you so much, Tim, for joining us. And with that, I'm going to wrap up today's call. I do want to thank all of our speakers for being here today and taking time out of their schedules to talk with the clinical labs.
I do also want to thank all of you that have submitted really great questions. I'm apologizing now that we didn't get to answer all of them. Some of them were really good, and tough questions that we really need to put some more thought into providing an answer and also get some subject matter experts that can help us, and hopefully maybe even be on a future call to answer some of the questions specifically around individuals that are vaccinated, but are testing positive.

I just want to remind you all, again, that our next call is not going to be for a few more weeks. We're going to be taking that holiday. And we will see you on September 20, but you can continue to submit questions or things you'd like to see on future calls, topics you'd like to hear us discuss, to our LOCS mailbox. That's LOCS@cdc.gov. And that's it for today. So thank you for joining us, and we hope to see you again in a couple weeks-- four weeks.