Agenda
Clinical Laboratory COVID-19 Response Call
Monday, January 24 2022 at 3:00 PM ET

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **COVID-19 Data Tracker for Testing**
  - Jason Hall, CDC Data, Analytics, and Visualization Task Force
- **FDA Update**
  - Tim Stenzel, US Food and Drug Administration (FDA)
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, CDC Laboratory and Testing Task Force

JASMINE CHAITRAM: Hello, everyone and thank you for joining the Clinical Laboratory COVID-19 Response call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. The Division of Laboratory Systems at CDC has been hosting these calls for the last couple of years and has also taken the lead in providing critical information to public health and clinical laboratories around the country.

I'm showing today's agenda, which changes weekly or biweekly, whenever we have these calls, but just real quickly before we get into that, just a couple of other things about the Division of Laboratory Systems. As I mentioned, we're here for clinical and public health laboratories and we focus a lot of our efforts in for specific goal areas and that is quality and laboratory science, workforce and training, preparedness and response, which is part of the reason why we host these calls, biosafety and accessible and usable laboratory data, informatics and data science fall into that category.

We have created a CDC Preparedness Portal and this web page belongs to our division but links to critical pages that the CDC has for COVID-19 Response-related information. Here we also have our transcripts and archive with slides as well as the audio from our previous calls in case you missed one of our calls or you want to just go back and hear something again. And usually takes us about a week to get this information up, so please have patience with us.

Also posted on this web page are the LOCS messages. These are emails that we send out to testing facilities nationwide and you can sign up if you're not already getting those at LOCS@cdc.gov. And like I said, all of our messages dating back from the beginning of the COVID response can all be found on this page.

One quick announcement that I want to make is an upcoming event on January 28 from 1:30 to 2:30 PM Eastern Daylight Time. Our event is going to be a OneLab Training Network opportunity on updated storage and shipping guidance for submission of samples to CDC infectious disease laboratories.

And our next announcement is our next call will be on Monday, February 7th from 3:00 to 4:00 PM and we host these calls every two weeks. And if you have any training or workforce development needs, please send those to the labtrainingneeds@cdc.gov.

And a reminder, for those of you that have been with us for a while you know how to do this, but if you're new please submit any questions you might have using the Q&A button in the Zoom webinar system. We don't want you to use the chat. It's hard for us to track anything that's put into the chat.

Sometimes we get asked questions that we can't answer on these calls because we don't have the subject-matter expertise or we run out of time. And if you want to get an answer to your question or at least help us with formulating topics for the next agenda, it's helpful to put that question in the Q&A box along with your name and email address. Those aren't required, but they are necessary for us to get back to you with an answer if we don't answer your question live. And then of course, if you're with the media, please send your questions to media@cdc.gov and patients, send your questions to your health care providers.

And then for the information that's posted on our preparedness portal as well as the information that is presented in these calls, we do have panelists that are not affiliated with CDC sometimes present on these calls. And just a reminder that they don't necessarily reflect CDC's official position.

And with that I think we're going to go into our first topic for today, which is the COVID-19 Data Tracker and the information CDC has about testing to date and Jason Hall has joined us. He's been with us before. It's been a little while. But he is from the Data Analytics and Visualization Task Force. Jason?

JASON HALL: Thanks, Jasmine. So I've been asked to give a quick update on basically lab data reporting overall for COVID. And also to go over some of what we show on our lab data tracker, our COVID Data Tracker, here at CDC. I'll go into a few other topics as well that are related, but starting off with the top line, this is what we show on COVID data tracker. It shows NAAT results nationally over the course of the pandemic we've received at CDC.

This is from all of the jurisdictions and then from all of their facilities roughly. 761 million NAAT tests as of last week. I think we're about 800 million now. And daily volume has ranged, we averaged, over a million throughout the course, but recently we've had days where over 3 million were coming through. And this is positives and negatives, of course.

And for some frame of reference, prior to the pandemic public health was receiving somewhere near 30 million for all reportable results nationally. So this is just enormous volume. Years' worth of volume, in some states, coming through in a day. So what we show is NAAT tests only and excludes antigens. It excludes serology. It excludes lineage results that come through.

This is what we used for a while. It's been consistent. It's something we can use across all states. It's also representative in a lot of the antigen data that we have that I'll go over with you in just a second. And

particularly when we use these data, like we do with other data sources around hospitalizations and capacity and emergency department use and vaccination statuses, all of these data sets go together and are used in a coordinated way.

So these data with NAAT tests only are still really representative of what is going on nationally. Also forgot to mention the case data that comes through. Cases are separate from the lab tests.

So if we go to the next slide. Just something we don't show very frequently, and we don't put on our website, it's the antigen data and sequencing results. We do get millions and millions of antigen results from the states, but we don't have a really good way of knowing out of how much we receive, so what the denominator is. And we know that it's uneven by state. So some states are delivering very, very little and some are doing probably what is representative of what they actually receive.

So we've received almost 200 million antigen results over the course of the pandemic. And then for sequencing results, from states that is, we received almost 800,000. So that is after a specimen that was positive on a NAAT test was subsequently sequenced and produced a lineage and that lineage was recorded in addition to the result from the NAAT test. So that's what we've been receiving. And that really started in spring to summer of 2021.

So I was saying that the completeness varies by state and that's why we don't use it in the National Statistics. We do look at it periodically for comparisons. That's why we can see in some of the states that are more complete that the NAAT tests are representative. And we're not necessarily losing any visibility there by not being able to show that.

Also part of the reason the completeness is different is these tests are largely manually entered wherever they're used. So if you have big screening programs and other types of programs set up, not only are a lot of the tests not diagnostic and followed up with a PCR test, but also you have to keep up with all of them. So the data entry has been a big problem in a lot of these facilities. And we've heard from jurisdictions for a long time can this requirement be eased? Because it's really hard.

Sometimes the facilities they told me they have to choose between doing their regular work at a nursing home or entering the data. And so it's just not a situation that we want everyone to be in right now. But the requirement is still there. But just wanted to highlight that there's a lot of problems making sure that every last test just has the data produced, let alone have the data sent. So a variety of reasons we don't use this, but again, within the NAAT test we have I think the visibility is still there that we need. We've shown it in multiple states, and we use it with other data sets for the response.

So if you go to the next slide I've just bolded a few topics here. One of them is reporting odds, which I was kind of touching on the last slide. So we've had requests to at least rollback some of the requirements on reporting for the antigens for negative tests. So we have been working with HHS or their sister agencies, other operating divisions with people weighing in and commenting from FDA, ONC, CMS, HHS, Office of

the Director, and CDC. And we've had some back and forth and it's taken a while, but we're still working on trying to get this updated.

The updates that we've been working on would focus on a few changes. One would remove the federal requirement for reporting negative antigen tests and leave it up to states if they wanted to have an additional requirement to require those. It makes clear that sequencing is not really covered in section 18 125 of the CARES Act, although it is really encouraged that labs performance sequencing take steps to use the specification that we have in a technical guidance to send lineage results to public health products.

And also it covers self-administered testing, which again, is not reportable and it's not made reportable under the current proposed language. So we're working through trying to get this cleared and approved to post. I think you all can imagine over the last year maybe we get close and then delta happens and then we get close, and Omicron happens. Well, hopefully we're close. So we're still pushing to get an update.

So processing issues to high volumes, I don't know that labs have had any of these issues, but jurisdictions have run into during this last peak some real bottlenecks trying to make sure that they could get all of their positives through in time with their theoretical limits on their processing and then also into their systems for use for producing cases and tracking cases and also marrying them up to vaccination data for breakthrough and other sorts of metrics that they can track.

So there have been a number of states that have told us that they've had issues either processing negatives - they've had to park them - or just getting delayed and having to catch up over weekends and things if they can, on positives. So that, hopefully, will start to subside soon, but it did pop up again during Omicron.

And the last thing we'll talk about is self-administered tests. I alluded to what we currently have proposed. But there is a lot of self-administered tests that have been sent out have been purchased and I guess everybody knows that there's another billion promised at some point and you can order them now. It's still unclear exactly what they're going to be delivered, but there's a lot more coming at some point.

These aren't and haven't been moved to be made reportable. There may be a few jurisdictions out there that have stood up portals that will enable voluntary reporting. The feds still haven't done this and most states have told me they're not planning to, but it's unclear to what end yet. What is clear to us is that we have a real interest in working with the manufacturers to get data platforms and data apps in place to enable these pipelines to be built should we need those data, not that we're moving to make anything required, but getting the tracks laid so the data can move.

And we worked with a number of manufacturers already to get some things flowing. It's whatever they get, right? I mean if there's a million tests that are sold, it doesn't mean that all of them were performed. And for the ones that were performed, we won't know how many. Some proportion of those somebody will

voluntarily, and that's what will be in there. It's also what would be in the new website at this point because there aren't any reporting requirements.

But I wanted to touch on that. Just it's not necessarily talked about, other than maybe people point out in the Press that there's these data being collected. We're losing track of the pandemic. Well, I mean even if these data were flowing, under case definition from the Council of State and Territorial Epidemiologists, these are only suspect cases.

They may be considered probable by some. So they would need either more data to meet the criteria for a probable case or subsequent testing, some of them with PCR to actually have a confirmed case. So it's not necessarily causing us to lose visibility, but there's definitely a lot of testing going on in this space that isn't being accounted for and we are working to try to lay pipelines to help get this, at least the possibility of these data before.

So Jasmine, I believe that's all you wanted me to cover. If there's anything else, let me know. And if anybody has questions.

JASMINE CHAITRAM: Thanks so much, Jason. I do appreciate that. I don't think we have any questions for you. There is one question that maybe you and I could tag team and answer to. It says the governors of some states such as Florida are telling people not to get tested. Is that affecting the numbers being received and the statistics generated from those data?

And I guess my response to this would be if people aren't getting tested, then we are maybe not understanding the breadth of cases and disease spread in certain areas. However, I also understand that there are supply limitations and that the governors may be encouraging people not to get tested if unless it's absolutely necessary because of those supply chain issues. But Jason, I don't know if you have any other thoughts. I know you just covered a bunch of stuff about case reporting, but if they're not doing testing then the data is not being reported.

JASON HALL: Right. I mean, if we weren't getting tests from them that's one thing, but we're getting millions of tests. So I mean there are situations in places where people are going to emergency departments just to get a test because they don't want to wait for three hours in a line. At least they were toward the peak. Or that tests have run out in a lot of places. You can't go to Walgreens and get a test right now. You can't get appointments.

So trying to dissuade people from that you may need to get tested because you had a certain encounter or something or you're mildly symptomatic to maybe hold off I think that's what that is. There is plenty of testing going on in Florida and we're getting plenty of data from them. And if we miss some tests, again, we have a lot of visibility with the huge volumes that we're getting across all the counties in every state.

So you know, I'm not being flippant. I want to be clear. But there's an analogy that somebody told me the other day that it resonated with me. You don't have to count every raindrop to know it's raining. So we

have very good visibility into the levels of transmission in all of the areas that we're tracking through the lab data we're getting, which is voluminous, plus the other data sources.

JASMINE CHAITRAM: Thanks, Jason. Any estimate of how much the impact of PCR testing drop is due to the increased use of at-home testing? I don't think we can tell that.

JASON HALL: I would love to be able to answer that, but we don't know how much is actually being executed out there. We have some insight that there could be a lot of people that when they get positives at least that they do go get a PCR afterwards. But I wish we could answer that.

We're still seeing record volumes, so I mean it's probably not offset it that much so far. Will it as we start to go down? We'll see.

JASMINE CHAITRAM: OK. Thank you, Jason. And I do see some other comments in the Q&A box about clarification about what is coming out of the governor's office in Florida regarding testing, so thanks for that comment, whoever posted that. I think, Jason, there aren't any other questions for you specifically, but if you can hang on the line in case something comes up I'd appreciate it.

I am going to try to answer a couple of questions before our next speaker just because we probably have some extra time today. There's one question. Is there a reason that they are requiring real-time PCR for testing and not accepting NAAT for flights? And this one is a little confusing and surprising to me, so what I'd ask is if there's a specific web page where you're getting this information if you could send that to the mailbox locs@cdc.gov, I will look into that and provide you an answer. I may have to reach out to the travel task force for some more info.

The next question is, are COVID tests labeled as emergency use authorization accepted for point of care if the clinician has a CLIA waiver? So I'm sure Tim can talk about this, but all tests that are approved or authorized by the FDA have emergency use authorization and they are authorized to be used in specific settings. A CLIA waiver does allow a physician to use a test in a point of care setting if that's how it's been authorized and Tim can elaborate on that because he's going to go next.

TIM STENZEL: And if I just continue that thought and finish it. So you're absolutely correct. And then any test that's moderate or high complexity, it needs to be performed in that environment and isn't authorized to be performed at a point of care.

JASMINE CHAITRAM: Thank you, Tim. And I'm going to go ahead and turn it over to you right now to go ahead and answer some of the other questions we got during the last call.

TIM STENZEL: OK. Yeah, I do have a number of questions that have been piling up. OK, the first question is, the FDA has indicated interest in giving EUA status to high throughput SARS-CoV-2 variant determination panels. Is this still the case? When will this happen? Most important, any of these tests will

need to be updated when new and important variants emerge? What type of process will be in place to rapidly review such updates to variant panels already granted EUA status when the program goes live? Well for a while now the FDA has been open to receiving a variant and genotyping assays, and I've stated this personally on a number of occasions on our biweekly CDRH Wednesday 12:15 PM Eastern calls to developers. There are two authorized whole-genome sequencing assays at this time. However, there's no other authorized genotype or variant assay. It is a current priority to review these submissions.

Now the challenge, as indicated by this person, is in updating the assays when a new variant comes along. The FDA recommends developers submit in their original submission or in subsequent submission a change protocol for authorization. This protocol would say how would you make a change to your assay? How would you validate it and what are the expected performance? What are the expected sensitivity and specificity for the changes?

And if the FDA reviews that, if they agree to all of that they can authorize the change protocol. The developer then, in the face of a new variant or mutation, can alter their assay, develop it according to their pre-authorized plan, validate it according to that plan, and if it meets the endpoints as agreed to on the plan, that developer can simply notify the FDA and submit their data and begin testing with the updated method while the FDA reviews that later. So hopefully that is pretty clear.

Our next question is, does FDA have any guidance for rapid tests regarding storage temperatures outside the package insert? For example, if antigen tests are handed out in extreme cold or extreme hot temperatures for a few hours, what kind of impact will that have on tests? Is there any information we can supply to callers about this?

I did post the link already in the chat for today's meeting on a website that went up at the FDA on this past Saturday about this issue. It goes into some detail. Bottom line is test developers do validate their test for shipping conditions, which is different than storage conditions. So shipping conditions can be outside of the normal storage conditions, which is going to be usually room temperature, and the tests should be performed at room temperature. See the package insert for those storage and use.

We know that at the current time, especially these 500 million to a billion tests that are being distributed to homes are arriving in mailboxes in areas that are below freezing. And so as far as we know, there's unlikely to be an impact. We do make recommendations in the web page that says basically bring the chest into your home. Bring it to room temperature at least two hours and then perform the test as described. And as long as the lines appear as indicated in the test instructions and the controls all work as indicated in the instructions, then we believe you can trust the results.

Next question is, FDA wanted a self-collected into your nasal swab for EUA rapid tests and most PCR tests are also authorized for nasal. Given that data coming from the overseas shows that high viral load may be more prominent in the throat, I think they mean for Omicron because it's not been true necessarily for other variants, does FDA intend to allow test developers to update EUAs for throat and nasal swab?

NHS has updated their guidance for all rapid tests to use combination of throat and nasal. There is a video on their website about how to collect combined sample time.

So first thing is the FDA welcomed the nasal swabs rather than nasopharyngeal swabs, which was the standard of care prior to the pandemic given how many times people would need to be tested and we wouldn't get good compliance on serial testing if everybody always had to have an NP swab.
Anterior nasal swab was thought to be the next best alternative and lots of developers went that way. It's very easy to use relative to other methods, even an oropharyngeal swab is more complicated to obtain, frequently results in gagging or throwing up, and would be very dangerous, perhaps, and difficult to properly collect in a self-collected manner.

The FDA has reached out to our international partners on this topic and had discussions. The FDA is open to submissions for the use of oropharyngeal swabs, oral swabs, and/or saliva. We have authorized a number of saliva-based tests. There are some molecular tests that have oropharyngeal swab authorizations.

There is a recent study that I put into the chat as well, a link, with some data. Some pretty good data showing the impact of either an oral swab or an oropharyngeal swab on the antigen test they used in that study. Their conclusions were that they did not recommend the use of a throat swab or a combined swab. In the oropharyngeal swab alone performed way below the nasal swab alone and the combined sensitivity increased less than 5%.

And given all the risks and challenges of also obtaining an oropharyngeal swab, the authors concluded that it was not worth the risks. And there are no antigen tests currently that have an oropharyngeal swab claim, but the FDA is open to the submission. We do recommend, though currently, that all antigen test be used as authorized.

So there was an additional question that was related. Are there any tests, either rapid, antigen, or PCR, that have been approved for throat collections? And I did put the website link for the EUA authorization so that you can go and find a test if you want that either use the saliva or oropharyngeal swabs.

Next question is sensitivity for Omicron of a waived point of care. NAAT, like Abbott ID Now, would also be good to know. So in prior CDC calls and other lab calls and developer calls, I have stated what the FDA has been doing. We started work on Omicron on Thanksgiving Day and have pretty much worked on Omicron every day since.

And we initially identified three molecular tests that could not detect Omicron and we recommended they not be used. One of those tests subsequently altered their test and was updated to be able to include to detect Omicron and after FDA review was reauthorized and it was removed from that Do Not Use list. And all that work from the developer and the FDA happened in a little over two weeks. So that was pretty intense.

And then there are no other tests, including antigen tests, that are not recommended for Omicron on the FDA website at this time. And we do continue our work in investigating Omicron on the website. The FDA still says that as far as the testing has gone, all EUA authorized antigen tests are able to detect Omicron, but it may be at a reduced sensitivity.

That sensitivity loss was seen in some laboratory experiments on actual live patient samples, but not in the sense of the way the tests are used. That is there was not a study that showed any clinical loss of sensitivity. We do have longitudinal studies underway with NIH RADx and as soon as results are available, we hope to post those or NIH will post those results.

Our next question, has FDA started reviewing EUAs again? We are still waiting and while we are fully CLIA certified. We need EUA reviewed for the NIH sponsored research samples as opposed to our patient samples. So the FDA posted a guidance update on November 15, 2021. This coincided with the Secretary of HHS also making a statement on LDTs You can go to the FDA website. I put the link for the guidance update in the chat.

You know, and I would say that, depending on the circumstances, the FDA has been reviewing LDTs, for example for home collection LDTs all along, for which EUAs continued to be required. If the FDA has received a more recent submission or there was a submission that was submitted prior to the FDA and you wanted us to review that according to the new guidance update, we are in the process of doing that.

But all the developed tests, LDT tests, that were covered under that guidance update, those that had been validated prior to November 15, 2021, as long as they met the guidance stipulations with which for LDT developers had up to 160 days, depending on the category following November 15, 2021 to submit their test validations to the FDA or to direct us to a prior submission that they want us to review. That deadline was January 14, 2022. So we have started the process of looking at these LDTs.

While we look at these that fell under the guidance update, the tests can continue to be used. The FDA did not say that these tests couldn't be used while the FDA reviews these tests. So we didn't want to disturb the LDT tests that had been on the market already when the new guidance was posted. And we're continuing to follow that policy.

If there is an urgent need for review, and if maybe a specific case, you can always email the FDA at cdrh-eua-templates@fda.hhs.gov, That email I put in the chat already, and you can reach out about your specific application and let us know why it needs to be reviewed in short order and we'll do our very best. And if you want it to come to my attention, then when you email to that address just say that you wanted to come to Tim Stenzel's attention as well and I will be in the loop.

Let's see, the last question is, can we continue to perform PCR testing in our lab using an LDT with ThermoFisher QuantStudio? So I would just summarize that if you're following the latest guidance update of November 15, 2021, and you adhere to the notification policies, then the policy of letting us know that

you want to continue using that test and you submitted data, then you're fine. If otherwise, you can reach out to our email address to inquire.

And with that, I turn it back over to you, Jasmine.

JASMINE CHAITRAM: Thanks so much, Tim. We did get a couple of questions as you were speaking. The first one is related to just the general sensitivity of tests with the Omicron variant and I think a little bit of a focus on self-testing or even point of care testing that there's lots of reports of people that have symptoms but they're getting negative test results and then showing up positive days later. There's this perception that the tests are not working well on the new variant. Can you comment on that?

TIM STENZEL: Yeah, so we're aware of a lot of anecdotal reports and been in communication with some groups such as Adamson et al., who published a preprint on this issue on 30 patients that they were tracking very closely. We were aware of those findings from the Adamson group prior to the FDA posting of the concern that although antigen tests may detect Omicron, it may be at reduced sensitivity.

And the serial testing studies that I mentioned that NIH RADx is carrying out, will hopefully help confirm or not confirm the results of Adamson and all these anecdotal reports. Our labeling for antigen tests is very clear. The results that are negative are presumed negative. They're not to be trusted the same way that a negative PCR is trusted.

Antigen tests are significantly less sensitive than PCR tests. So if somebody has been exposed and they think they may have COVID Omicron, perhaps, or they have symptoms and they test negative with an antigen test, they should take appropriate precautions. And our instructions for use say that you should consider taking another test and many recommend that it be a molecular test.

JASMINE CHAITRAM: OK, thank you. Let me see. There's another question for you, to address some of the questions in the Q&A, it seems that people are testing positive three days after symptoms-- so this is very similar to the one that you just said. And this one just references a study out of Japan, showing viral loads peaking at three to six days after symptom onset. Is this consistent with what you've been seeing in your data, I guess, for tests that are being submitted?

TIM STENZEL: So in my discussions with a number of groups and, in particular, with the Adamson group, when they were serial testing and they were looking at CT results both for saliva and nasal swab, they saw that in their study that saliva peaked later. That saliva peaked before our nasal CT peaked, and when I say peaked I mean the CT went down and then viral loads went up.

And some other groups are noting that they may be seeing infectivity at higher CTs for Omicron. So we're trying to put all this information together. We're trying to understand it well enough to provide specific guidance. But again, we continue to recommend that antigen tests be used as labeled where appropriate especially with the labeling, but also if you're going to maximally use antigen test, it should be done in a serial testing manner, basically every other day, two to three times a week, that sort of time period.

JASMINE CHAITRAM: OK, great. Thank you, Tim. And I've got another question about LDTs, lab developed tests, after we file for the EUA prior to market, can the COVID-19 test be offered to clients before the EUA is actually granted or do they need to wait to get the authorization before the test can be offered?

TIM STENZEL: So any LDT test that wasn't validated by November 15, 2021 needs to come in through the normal EUA authorization route. And so it needs to be EUA authorized before offered. There are now, we believe cataloging it now, lots of tests that fell under the guidance update and over 400 tests overall authorized so there should be plenty of choices for labs to use in the interim

JASMINE CHAITRAM: Great. And then the question about why are most tests approved or authorized for ages 2 and above? And they feel that this is a gap for the population, especially for daycares.

TIM STENZEL: So there are certain limitations in carrying out IRB authorized studies. I will take that comment back, though. There is some concern about home testing of children below that age, you know, especially from some of the validations that are done in the home. But we'll take a look at that and look at seeing if we can't post a Frequently Asked Questions on this topic. So it might be good to circle back on that question for the next CDC call. Hopefully I'll have an answer well before then.

JASMINE CHAITRAM: OK. I appreciate you answering so many questions today, Tim. I think we're going to go ahead and move to our next topic so that way if there's any questions for Natalie she can cover those as well. So thank you, Tim, and next we'll move to Natalie Thornburg from the CDC Laboratory and Testing Task Force to give us an update on the variants. And Natalie, are you going to share your screen?

NATALIE THORNBURG: Yes, please.

JASMINE CHAITRAM: OK. Hold on.

NATALIE THORNBURG: Thanks. All right, I think we're good. All right, so this is the update for the COVID Data Tracker that was posted last week. The data that was posted last week has weighted estimates as of January 1st, 2022 and predictive estimates as of January 15, 2022. So the weighted estimate of Omicron as of 01/01/2022 was about 90% with a confidence interval of 86% to 91.7%. And it's been predicted to continue increasing with an estimate of 99.5% for the week ending 01/15, with a predictive interval of 99.3% to 99.7%. And that's the national data.

New data will be posted tomorrow. On Tuesday we expect the trends to continue for Omicron to be increasing in prevalence even more with subsequent decrease in delta prevalence. When we look at regional data, you can see all of the HHS regions have Omicron as the dominant circulating variant ranging from about 99.2% to as low as, I think region 7 is the lowest at 97.8%. So really all of the HHS regions have strong dominance of Omicron circulation.

Again, new data will be posted tomorrow. We expect the trends to continue with increasing Omicron and decreasing delta, so it's starting to become a bit routine, much like whenever delta took over in circulation. So with that, if anyone has any specific questions about sequences or anything else I can handle I will go ahead and take them.

JASMINE CHAITRAM: OK, we do have one question for you. What about BA.2 sublineages of Omicron?

NATALIE THORNBURG: Yeah, BA.2 is the sublineage that's really becoming quite dominant in Denmark and India. We are tracking it. We haven't started breaking down the sublineages in our COVID data tracker just yet. I expect we will start doing that in the coming weeks or months.

That's still under the umbrella of Omicron, but that is not a dominant sublineage in the United States. We really only have a few specimens nationally. They're sporadic. There's at least one cluster from a small outbreak in Arizona, but it's really like a couple of dozen of specimens and not a lot of specimens and, at least thus far, it doesn't seem to be taking over the Omicron sublineage. But we are watching that sublineage.

JASMINE CHAITRAM: OK. Another question. Do you have any information about the variant types being seen in hospitalized patients given the lag between infection and hospitalization?

NATALIE THORNBURG: We don't. Because our sequencing is surveillance sequencing, it's not always linked to patient information. We have seen some data with hospitalization rates just in other countries and also domestically and it really does seem like Omicron results in slightly lower hospitalization rates than Delta did.

Of course the data is always confounding with prior history of either infection or vaccination, so the more people are infected and have some level of immunity, we would expect hospitalizations to decrease over time in general. So that information is confounded by the very high prevalence of either vaccination or from individuals with prior infection.

JASMINE CHAITRAM: Thank you so much. Let me see. Any update on the Deltacron from Europe?

NATALIE THORNBURG: Yeah, so it seems to be that that was not a true recombination event. That was likely an artifact of data analysis. So there's no good indication that there have been any real recombination events between Delta and Omicron.

JASMINE CHAITRAM: OK. Thanks, Natalie. I'm not sure if you can answer some of these questions. I'm going to ask them. If you need to defer them, that's fine. The next question is, do you have the current stats for virulence or mortality for each variant compared to the flu, as well as broken down to vaccinated versus non-vaccinated vaccinated versus boosted? What is the status I guess of hospitalization of delta versus Omicron? What is the stat?

NATALIE THORNBURG: Yeah, I don't have those stats at the moment. I expect those stats will be able to be finalized and posted as we've now really shifted heavily from Delta to Omicron, but of course, any sort of data would be confounded by prior vaccination and/or infection.

JASMINE CHAITRAM: Thank you so much, Natalie. Not seeing any other questions that I can ask you specifically at this time. I'm going to go back to Tim, though, and see if I can get Tim to answer a few more if he's still on. The question is--

TIM STENZEL: I'm on.

JASMINE CHAITRAM: Hey, Tim. If we file an EUA now can we provide the test to the public during the EUA application review period? We anticipate that it will take the FDA a while with all of the incoming EUA applications.

TIM STENZEL: So I already responded to that question on the call, which said that didn't fall under the November 15, 2021 guidance, then the lab would need to wait on the response. There's a number of kits that their labs can use and we're not aware of all kids that are authorized being in short supply. And the other thing is that if I put an email on the chat, again email that to our COVID email address and ask for me to be included, take a look at it, and see what kind of priority we can put on that test.

JASMINE CHAITRAM: Thanks, Tim. And I wasn't sure if there was any difference between LDTs or other tests being submitted for EUA.

TIM STENZEL: Oh, yeah. I should clarify all of my responses around test submissions have been around LDTs because always manufactured kits need to submit. There's never been a question about kits. They are always needed to be submitted to the FDA.

JASMINE CHAITRAM: OK. Thank you for that clarification. The next question says, if my state, Washington, was granted EUA authorizing capability, do we still submit our data to the FDA?

TIM STENZEL: Check with your state.

JASMINE CHAITRAM: OK.

TIM STENZEL: There were seven or eight states and territories that are on the updated guidance through a link that continue to have that right, but it's up to the states. So check with your state.

JASMINE CHAITRAM: Thanks. I'm just scanning to see if there's anything else I need to ask you.

OK. I think that it would be, because of the types of questions that we're getting, it's probably better for us to hold these and review them internally and provide a response through agenda topics on our next call. I

do want to thank everybody for joining us today and for our speakers and for individuals that submitted questions. It is helpful to see what your concerns are and we will work to address these in some way, shape, or form.

And I'm sure that you would appreciate it if I gave you just a few minutes back today. So with that, I'm going to go ahead and adjourn today's call and thank you all and we will see you on February 7. Have a good day.