Clinical Laboratory COVID-19 Response Call
September 20, 2021

Agenda

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- **SARS-CoV-2 Variants Update**
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JASMINE CHAITRAM: Hey, 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. We've been hosting these calls since March of 2020, and we've had quite a few. So thanks to those of you that have joined us for almost every call or every single call, which would be amazing.

Today, I'm showing our agenda. We've got three topics other than the intros that I'm going to give. And we will get our variants update from Dr. John Barnes from the CDC Laboratory Testing Task Force. And then we will have some information about flu testing guidance from Dr. Manish Patel from the CDC Influenza Division. And then Dr. Tim Stenzel from the US Food and Drug Administration, and Tim has been with us on many of these calls.

Before we do that though, I do want to cover a few items, and I want to talk a little bit about DLS, the Division of Laboratory Systems that has been hosting these calls. And our focus has been on supporting clinical and public health laboratories. This has been going on for some time, not just for the COVID-19 response.

We've been doing this in several different areas, including quality and safety, workforce and training, accessible laboratory data through informatics, and the use of that data through data science. We also manage the CDC Biorepository. And then of course, we've been supporting preparedness activities. We also, before I skip sorry, I want to just quickly mention one more thing that I've said before, but for any of those that are new to this call. Our role in the response has been to serve as a liaison to the CDC Emergency Operations Center, which is managing the response for COVID-19.

OK, so one quick announcement, we do now have a new free online training for the Clinical Laboratory Improvement Amendments of 1988. And so this is a really great training for anybody who has to adhere to CLIA requirements, and that basically applies to all of you that are testing even, if you're at a waived facility or even if you're doing waived testing. So you should check out this training if you haven't already.

The other thing that I want to bring to your attention is our CDC Preparedness Portal, which is our one stop shop for a lot of information. In addition to links to other CDC resources related to the COVID-19 response, here we have the transcripts, slides, and agendas from previous calls. So if you miss a call, you can always go here to get that information.

It does take us about a week or 10 days to get the transcript and the slides posted, so if you're looking for that information give us a little bit of time after the call to get it posted. We also have an archive of all the emails that we send out through the Laboratory Outreach Communication System, LOCS. So if you miss a message or you want to go back and review a message, it can be found here as well.

And let's see, other things, our next call will be Monday, October 4th from 3:00 to 4:00 PM. We usually have these calls every two weeks. It has been a few weeks since our last call because of the holiday, but we will be back on schedule and having these calls every two weeks. So we'll see you again on a Monday, October 4th.

And then if you do have any training or workforce development needs, please send those to labtrainingneeds@cdc.gov. We'd love to hear your feedback and suggestions for training. I want to quickly cover how to ask a question. Many of you have been on these calls and you know how to do this, but just a quick reminder to please use the Q&A button in the Zoom system and not the chat.

Sometimes folks put that question in the chat. We do see it, the problem is if we're not able to answer that question during the call we are not able to get that question and do any follow up with it. And so if you want us to get to your question, if we are not able to do it during the call, it's always helpful to have your name and email address and we will try to get back to you. Sometimes we don't have the right subject matter experts on the call to answer your question, and we would have to take it offline and answer it in another way.

We do appreciate all the questions that are submitted, because they do help us with trying to understand what information you need and how to scope out our agenda for future calls. We do ask though, that when you submit those questions that they should be related to laboratory testing. A lot of times we get asked questions about information that's not related to lab testing, and we don't have those SMEs on the call to answer those questions.

And so the intent of these calls is really to support laboratory testing and testing in general for COVID-19, so please, limit the questions to that. And if you're in the media, please send your questions to media@cdc.gov, and if you're a patient, direct your questions to your health care provider. I think that's all I want to say.

Just a reminder that when you do go check out those slides or transcripts from previous calls that the material, the speakers may not be affiliated with CDC, and so that content may not necessarily reflect CDC's official position. And with that, we will move now into our first update, which is the variant update from Dr. John Barnes from the CDC Laboratory and Testing Task Force.

JOHN BARNES: Thank you, Jasmine. So today, I'm just going to give you a little background on what is going the outlook is currently and the variant populations. And then we're going to talk about Mu, the WHO-labelled Mu variant that has come out in the news a little bit ago. So next slide.

So the Nowcast estimates, and actually estimates that we're seeing in our weighted data, is pretty much showing exactly the same thing. That Delta is the overwhelming majority of all of the specimens that we're getting, and at 99% of all sequences that we're presenting right now. So of that the B1617.2 is a major variant.

Pango has divided this up into AY1 through 25. We are collapsing AY3 through a AY25 into the B1617.2. We're holding out and looking at AY2 and AY1 individually, because they do contain spike mutations that are unique. And that well not unique, but they're unique to those two lineages in the Delta variant. And they are of some concern. These are the Delta plus lineages that you may have heard of. And so we are looking at those and monitoring those independently.

Those have been under very low circulation in the US, as you can see, 0.1% nationally and 0.2% for AY1. All of the rest of the variants of concern or variants of interest are really, circulating in a very, very low rate, including the new designated B1621 Mu variant, which the WHO designated at the end of August. Next slide, please.

Looking at the regional version Nowcast proportion, you can see that the pie charts look fairly ridiculous and that there is basically nothing but Delta. They're pretty much all 10 HHS regions are greater than 99% Delta. AY1 and AY2, those Delta plus mutations that I pointed out before, are under 1% nationally for 9 out of 10 HHS regions. The only one that is at 1% would be region nine, which is AY1 is at 0.8% and AY2 at 0.2%.

This new B1621 Mu variant is in all HHS regions, but under 0.2%. And there is no change in that from any of this variant in any region since the last update. So it has been very, very low in circulation. Next slide.

And when we looked back at after WHO made this designation, B1621 actually did have its day in the sun in the US. There were two lineages of this particular genetic variant they can be distinguished genetically from each other, the B1621 and the B1621.1. Combined, they currently represent 0.2% of the national variants that we see.

They share a few substitutions, including some of interest, R346K, the 484 mutation, the EDK mutation there, and the N5012Y mutation. They peaked nationally at about 5% in mid to late June, and they've

really been declining since that point in time. HHS one had the highest proportion of Mu at around 20% in around the end of June.

And you can see, this is pretty much a chart over here on the right, is really kind of the typical view that we see of this particular variant. That once Delta kind of came in and took over, that the proportion of this variant disappeared. So there's been a lot of interest in this designation since it was designated as a VOI by WHO at the end of August. But those really might be explained by a couple of different things.

There was a little delay in some of the data submission of this variant because of some issues with submitting to some of the public databases that has since been resolved. And really in the NS3 data, a lot of this data is actually processed and looked at before we actually submit it. It actually all is before it's submitted to databases.

And so we feel like we had actually a good tracking of this variant through the entire time. And we'll continue to track this variant to make sure that we don't see any variants, any difference in its proportions, as we go forward. But pretty much summing up, all we see is Delta right now and not really anything else going. So thanks, Jasmine. That's all I've got.

JASMINE CHAITRAM: Thanks so much, Dr. Barnes. Let me just see if we have any questions for you. One question is, "Any comments on C12?"

JOHN BARNES: We are keeping an eye on it. The C12 variant does have some unique spike mutations. It seems to be mainly in South Africa right now.

We have seen only - I think in the US - I'm not sure that we actually have a specimen that we have identified. We have a sequence, but not a specimen that we've identified with C12. But we're looking at evaluating those mutations further to make sure that we have a handle on that one. But right now, the proportion of that one is extremely low, so we're keeping an eye on it.

JASMINE CHAITRAM: All right, thank you. Let's see, "What states are Gamma, Mu, et cetera most prevalent? Also, what is your sampling population? Is there a rep from each state? Any states left out?"

JOHN BARNES: So we try to keep our sampling population as random as possible. For NS3, we're asking to get as baseline an evaluation as we possibly can through that. So we don't want things that are necessarily being only sampled through a hospital or a particular severity of illness or something like that. And so we try to keep that going that way just so that we get a good population for us to sequence.

And then let's see, what states are Gamma and Mu most prevalent? Really, all of those are pretty much not prevalent. Gamma is pretty much now - and Mu - are both circulating at very, very low intervals. And so they're out there around across the US, but they are not prevalent in any one region, per se.

It's not like we're seeing any clusters of them growing or anything like that. We'll see intermittent sequences here and there. And so it's really hard to tell what the overall prevalence of those are as we're doing our estimations, because those estimations are so low at this point.

JASMINE CHAITRAM: OK, thank you. Here's another one. "If rolling everything into B16172, we're not concerned about Delta Plus?"

JOHN BARNES: So we are, Delta Plus is that a AY1 and AY2. That's why we're looking at those individually, and we are keeping track of those. We don't see those at a very high level. And so the rest of the B1617.2, we are looking for any variation that we might see in those AY designations, AY1 through AY25, that may be growing and changing. We're just not presenting that data, because a lot of it does not have mutations in spike or other things that would be of significant risk to the population.

JASMINE CHAITRAM: OK. And there's a question about specimen type, if it's only swabs or if some of the specimens are coming from saliva as well?

JOHN BARNES: In general, most of the work we're doing with NS3 is through swabs. It's mainly because saliva we have really not as good a look. In NS3 we're also looking for the ability of growing those viruses as well. So if we see a variant that we want to study further, we're putting a-- the ones that we're asking to be submitted to CDC, we're definitely asking for specimens that we're going to have good recovery rates from.

And so in general, I think we're not using as much saliva. I don't know about some of our contract laboratories if saliva as a specimen type that they use as much. I can look into that.

JASMINE CHAITRAM: Dr. Barnes, thank you so much for joining us today. I appreciate your time. We're going to move to our next speaker, Dr. Manish Patel from the CDC Influenza Group. We're ready when you are. We can't hear you, you're still on mute.

MANISH PATEL: Is that better?

JASMINE CHAITRAM: That is, thank you.

MANISH PATEL: Yes, you're welcome. My name is Manish Patel. I'm a physician here in Influenza Division, Influenza Prevention and Control Team. I'm going to walk you through some slides on testing issues for the upcoming season. Next slide, Jasmine.

There we go. So I was asked to give you a high-level overview of some of the CDC's clinical guidance on issues that could be related to testing, clinical issues really, and provide you some of the CDC resources on this. Keep in mind, here I'll focus on influenza, not SARS-COV-2, though we'll touch on that. Also, the different tests and issues related to the test, sensitivity, specificity, will not be covered here today.

As you know, influenza really has a history of unpredictability. And I don't have to tell you we had no activity during the last year in the US, and minimal globally. And this, as you know, has never really happened since we've had surveillance for influenza. And so the question we were asked and commonly get, really a million-dollar question, is what will happen this upcoming season?

And of course, time will tell. There's been so far little activity in the southern hemisphere for influenza in locations where there's really good surveillance, such as Australia. Although the season is not over yet, so they continue to monitor it. However, I think for the US we think it makes sense, which is why we're here, to make sense of what might happen this season and to prepare for a few good reasons.

And here, monitoring for both SARS-COV-2 and influenza obviously, is becoming important. Typically, we do this pre-pandemic for influenza through various surveillance networks, and there's two broad efforts typically. One is a public health surveillance effort through established networks, as you all know, through local, state, and national levels. And then we also have clinical labs, outpatients, EDs, and hospitals. Next slide.

I think my screen is stuck. OK, there it is. And so the question really of co-circulation, could that occur, and what are the implications for co-circulation of these two viruses? And I think the bottom line is, we just don't know. As I mentioned, there's been minimal activity of influenza in the past year and a half, and we haven't seen much co-circulation even in the literature. There have been a few case reports in a case series, but it's really tough to glean much from that. So I think bottom line is, we do not have any answers to the clinical implications, at least, of the co-circulation.

There are some differences between influenza and SARS-COV-2 that are highlighted here. Some of the key differences, I think for testing purposes, incubation period for influenza is quite a bit shorter than SARS-COV-2, about one to three days versus two to 14 days. The viral shedding, the period of viral RNA detection is generally shorter for influenza than what's been seen with SARS-COV-2. And of course, clinically I think loss of taste and smell has been quite common with COVID-19 and SARS-COV-2 infection than the influenza, what's been reported with influenza before.

In the hospital setting, the timing of onset of what we call severe disease and presentation to the hospital typically happens earlier with influenza, at least most cases of severe influenza tend to come in within a few days of the infection onset. Whereas we've seen with COVID typically patients present during week two, days eight, nine, 10 or later. Next slide.

So I think suffice it to say, clinically there's lots of overlap between the two viruses, and so it'll be challenging to tell the two viruses apart. Here, I think the implications are that we'll need laboratory testing to differentiate the two,if they do co-circulate. And the testing strategies for influenza really vary by clinical setting typically in typical seasons. And so the testing strategy for the two viruses during co-circulation might also depend.

And here's sort of the general summary you see on the slide. For influenza, there's really you could break it into hospitalized patients and non-hospitalized patients. And among hospitalized patients, the general recommendation is to test for influenza because it has treatment implications with antivirals, and then possibly infection control implications also. So during co-circulation testing here could be through various approaches, but typically what we're seeing is either there is singleplex testing for influenza and for SARS-COV-2, or there might be multiplex testing for both.

In the outpatient setting this could really vary. I think here, can either test for both viruses if the capacity exists, or just SARS-COV-2. Typically for influenza pre-pandemic, testing in the outpatient setting is not as common as inpatient settings, and oftentimes clinical judgment is used and recommended in terms of treatment implications for influenza. Next slide.

I won't spend too much time on this. I think this has been covered before. But in general, the influenza tests that are recommended can also vary by setting. For outpatient settings obviously, I think you want something rapid, point of care tests. And here also molecular assays are recommended, though if they're not available the rapid influenza antigen detection tests are also considered acceptable, recognizing that sensitivity is lower.

For hospitalized patients, here the recommendation is stronger. It's either RT-PCR or other molecular assays that are recommended for influenza. For subsets of patients, such as immunocompromised patients, I think there is a recommendation for broader multiplex assays to consider other pathogens as well. I think this probably goes without saying now, but viral cultures, serology, is not typically recommended for making diagnoses of influenza. Next slide.

And so next few slides sort of cover, I won't go through in too much detail, but will point out where these resources exist. So we have several good web pages, I believe, on influenza testing guidance. We've had them pre-pandemic, and recently they have been adapted to anticipate this potential situation of co-circulation of SARS-COV-2 and influenza. And this is the general web page, which has the updated CDC guidance on both testing as well as the treatment implications, focusing more on the influenza side. Of course, there's a whole host of other web pages for SARS-COV-2.

This focus is on the co-circulation piece. On the left in general this page has three or four sections, but two I want to point out, are the ones on the left up there talk about the proposed algorithm for testing and treatment. And on the right there are some resources on the various influenza detection assays and tests that I will not cover today. Next slide.

Then I can go into a couple of these algorithms that are very high level. First is for the outpatients and emergency departments, where basically as I mentioned, influenza testing recommendations really depend on whether the patient will be hospitalized or not. And so here, this one web page sort of breaks the patients down into yes, you're hospitalized, no, they're-- sorry, not you. Yes, they are hospitalized, no, the patient's not hospitalized. And on the left, if they are hospitalized, then it walks you through some of the testing implications and some of the treatment recommendations.

The general difference, once again, is if you're hospitalized the recommendation is to test for both SARS-COV-2 and influenza. And the reason again to test is that in hospitalized patients might benefit from treatment with antivirals, and also there might be implications for infection control issues specifically related to influenza, in addition to SARS-COV-2. Next slide.

And so this is the same web page again. It just focuses a little bit more on some of these testing issues. So if you drill down here on the left you can see that there's three topics on specimen collection, testing for both viruses, and treatment. And essentially, you would collect specimens on all participants, patients in the hospital setting.

And for testing, the recommendation is to use either multiplex or separate singleplexes for influenza. Once again, rapid antigen detection assays are not recommended for inpatients for influenza due to their lower sensitivity. And I think they're falling out of favor at any rate. This is for hospitalized patients.

If you go to the right this considers outpatients and emergency department patients, which might be a little different, but they're lumped together. If they present with acute respiratory infection or illness and they do not need hospitalization, they sort of fall on the right. SARS-COV-2 testing recommendations are listed there but focusing in on the influenza.

On number two over there, testing is recommended only if it changes the clinical management for the patient, such as need for antivirals or infection control. For example, if the patient is a resident of a nursing home or a long-term care facility, there might be some implications. Specific subgroups of patients might benefit from outpatient or ED treatment with antivirals early on, and so those patients could get tested. A preference for outpatients again is nucleic acid detection assays, though antigen assays might also be considered if the nucleic acid assays are not available. Next slide.

And so not to belabor the point, but the other web page relates to hospitalization. And so there's a similar web page like this for hospitalizations also, going into drilling into some of the details of the testing and specifically the treatment. Next slide.

And then the last, so there's three or four different web pages there. The last page specifically focuses on CDC guidance on testing and management considerations for nursing home residents who have a respiratory infection or illness symptoms when both viruses are co-circulating. And so listed on this page are series of pretty good information beyond just testing. They talk about some of the infection control guidance, and then the rationale for testing. And the recommendation here is to test symptomatic patients for both viruses in these specific populations.

For influenza here, the preferred assay is rapid influenza nucleic acid detection assays. But again, similar to the outpatient settings, rapid antigen detection assays are also allowed if the former is not available. I think the rationale here really again, is similar to the hospitalized patients, there's a lot more implications than outpatients and ED patients and general population. This specific patient population, you know

there's issues related to infection control measures and spreading of the epidemic pretty fast and treatment measures that can be put into place. So I think testing is recommended here. Next slide.

I think that sort of brings me to the end. I hope this was helpful. There's a fair amount of resources I've pointed out. They should be listed through the web links on each one of those pages, and I'm happy to take any questions. Over.

JASMINE CHAITRAM: Thank you very much, Dr. Patel. That was a lot of information and very useful. There were a couple of questions that came through while you're speaking, but they came through very early and I feel like you've answered them in the information that you presented. But I will go ahead and read them out loud, just in case you have anything else you want to add.

So the first one is, "Can you comment on testing differences between SARS testing and flu? It doesn't seem when a patient is getting a negative SARS test that they are being reflexed to a flu test." And I know you just talked about a lot of different scenarios and reasons for that. But I didn't know if you want to say anything more?

MANISH PATEL: Yeah, maybe I don't understand the question, but I think some of it might vary if it's inpatient versus outpatient. I think a lot of the influenza testing really relates to treatment less so than the testing implications have been during the pandemic for SARS-COV-2 related to isolation and quarantine. But I think the inpatient setting yes, if one is positive it is my clinical experience that oftentimes that combined with the clinical presentation does give them a diagnosis, and they might not test for other pathogens.

I think it might also depend on the availability of assays and so forth. I think our recommendation is to test for both when they start to co-circulate, if they do start, for implications related to the circulation of the two viruses possibly in individual patient. So that's a long answer. Hopefully it's helpful.

JASMINE CHAITRAM: Thank you. Another question is, "Can you comment on what happened in the southern hemisphere this past current flu season?"

MANISH PATEL: Absolutely. Yeah, the answer is nothing so far. For those who are interested, you can probably type in “WHO surveillance”, “influenza”, and/or “Australia influenza surveillance” and it takes you to some good surveillance indicators from the world, as well as Australia, for example, which has excellent surveillance. And it's been pretty much a flat line so far. It does vary by country.

There are some sporadic detections. But again, the season's not over yet. However, it is sort of reaching typical peak based on past seasons.

JASMINE CHAITRAM: All right. OK, another one is, "Some molecular tests do not differentiate between influenza A and influenza B. So what is your opinion about having a test result that basically groups A and B together?"

MANISH PATEL: So for clinical purposes, it is not as relevant. But for surveillance purposes, it is quite useful. The treatment is still the same for A and B, and antiviral effectiveness is equal against both.

JASMINE CHAITRAM: Great. "When would you recommend starting to test for influenza? Should labs be stocking up on multiplex assays now?" This one lab says, "They only have rapid testing for influenza and they have limited supply."

MANISH PATEL: Jasmine, maybe we could respond back to that question later through the laboratory task force. Typically, I will say surveillance activity varies by season. It can begin as early as October, which it did a couple of years ago, which is unusual. November, December it does increase quite a bit.

JASMINE CHAITRAM: OK, great. And just I think the last question I'll ask you is about RSV. "RSV is now in the population and seems to be causing significant illness. Is there anything to mention about RSV testing?"

MANISH PATEL: I'm sorry, Jasmine, I cannot comment on that. Once again, we can get back with the comments from Division of Viral Diseases. But yes, the person is correct. There has been a fair amount of RSV activity.

JASMINE CHAITRAM: OK, great. Thank you so much, Dr. Patel. A lot of the other questions we're getting are very specific to a type of test, and I don't think you'll be able to respond to those either. So we will work with other SMEs at CDC to try to provide answers. But we do thank you so much for your time today. I appreciate all the information that you shared.

MANISH PATEL: You're welcome. Thank you.

JASMINE CHAITRAM: So one of the questions that we got in the Q&A box is about slides, and I did mention just a reminder, I did mention that the transcript and the slides for these calls are posted on our preparedness portal, and those will be up in about 7 to 10 days from now. So you can look for those there if you want to review any of the information that was presented.

And we are going to move to our last agenda item today, our closer of the call. Dr. Tim Stenzel from FDA, who's been on many of these calls has joined us again. And Tim, I'll turn it over to you.

TIM STENZEL: All right, thanks, Jasmine. It's good to join you again today. I had two questions submitted ahead of time. I wanted to go through those and then open it up for any questions that might come in. So I'll read the first question. "Given that over 50% of the US population is vaccinated and there is a high rate of breakthrough infections in vaccinated individuals," in parentheses, "alarmingly underreported by HHS and the CDC," end parentheses, "For a serial OTC indication, should we include vaccinated individuals in our clinical studies since they may have slightly lower viral loads? If so, would we need to

include the same demographic populations that are required for traditional EUA? What study design would be acceptable or does vaccination status not impact study design?"

So we just have not seen a lot of data differentiating vaccinated from non-vaccinated individuals in our submission. I'll just give you the quick answer, and then I'll go through the more detailed answer. But yeah, submit it, you can include both vaccinated and unvaccinated.

We would just like you to note that whether or not they're vaccinated. And we may do a subset analysis. And then we would gain information about relative test sensitivity for detection of COVID in those different patient populations.

So these data should then be included in the clinical line data, in an additional column that spells out whether they're vaccinated or not. Also, include the date of vaccination, if you can, specify the vaccine administered, and the number of doses with dates, if Moderna or Pfizer. Or if it's the J&J, when they were first vaccinated.

So there are lots of people who may only got a one mRNA vaccine, one or the other. There may be different levels of protection with the different vaccines and whether you had full dose or less than a full dose. So it is acceptable to include those subjects, however, granted you're not pooling both retrospective samples and prospective samples. So we like to look at those categories differently.

And then, of course, depending on the type of submission you're making, if you're including asymptomatic patients in your submission. Particularly if you're going for a screening claim that doesn't require serial testing, and do specify whether the patient is asymptomatic or symptomatic, and the dates between symptoms and when you tested. So lots of detail there. Hopefully the transcript will get this all, and happy to answer any follow up questions.

Then the next question is, "What is the FDA doing to help create primers that inform about variants and allow us to use them under an EUA?" So first of all, variant primer design, test design, taking into account mutations and variants is very important in and of itself. And we have a policy that's on the FDA website with our current recommendations about this.

And of course, we expect test developers to take into account limitations and variants that are already in circulation and develop a plan, have well-performing test already, and then a plan for what are you going to do with new mutations and new variants, and assess the impact. However, I think the question is really getting at is the FDA accepting the EUA test submissions for the reporting of variants or mutations? And yes, we are.

We're in dialogue with a number of developers that are interested in that. We have generated a set of recommendations that can be requested for the validation of these kinds of tests. And I would just add though also that full genome sequencing still remains the gold standard for this, because you get to see

the whole panoply of mutations. And if you have only a subset of mutations, sometimes distinguishing one variant from another may not be as easy for some variants as others.

So those are the pre-submitted questions, Jasmine. And I'm happy to respond to any questions that may have come in.

JASMINE CHAITRAM: Thank you so much. There is one for you. And I'm not sure I understand it, so maybe you will. But it said, "Can Dr. Stenzel address the announcement of the addition of RDRP to the Cepheid assay? Is the end to the current problem target?"

TIM STENZEL: Hmm, that's a detailed question. I'm trying to find it written down. Can you read that again?

JASMINE CHAITRAM: It's the one from Vicki at 3:34 PM in the Q&A box. And it says, "Can Dr. Stenzel address the announcement of the addition of RDRP to the Cepheid assay? Is the end to the current problem target?"

TIM STENZEL: So there were reports with the Cepheid assay with a couple of Cepheid assays that a single nucleotide variant could knock out the signal to a specific channel. And so there were obviously concerns that if you then develop mutations and other channels with that, would that yield an overall false negative? Even though the loss of one signal in the Cepheid assay would not result in and of itself of a false negative result.

And so the developer, I don't know the details of this and I don't know what's confidential and what's not, but I know that the developers in this position would look to make a design change to an assay so that they wouldn't get single drop out for no mutation. So let's hope that that's the case here. But maybe I can get that question for the next time I get invited, and I can provide some more details once I know what's public and therefore what I can share.

JASMINE CHAITRAM: OK, sounds good. "Has FDA approved the extension of the Abbott ID NOW COVID rapid test kits that expired in July and August?" The kits have expired earlier in this month. Have they been extended?"

TIM STENZEL: I know that we extended dating to at least nine months. I don't know if we've been able to extend dating longer than that. And again, that's something that we can check on, and whatever the easiest way to get back.

We work closely with all of the developers for data extension. And we have seen some issues when some developers have gone beyond some of the dating. So it is important to pay attention to, but the developers themselves know what the FDA has authorized.

Sometimes it's not evident in the authorization what the dating is. We do that behind the scenes with each developer, looking at their dating data and give authorization through written correspondence, and then they can update their labeling on their kit. And it's less paperwork for us to update all of our authorization information on the website.

JASMINE CHAITRAM: OK, Tim, do you know if there are any multiplex tests for flu and SARS-COV-2 for saliva that have been authorized yet?

TIM STENZEL: No, we haven't authorized a flu detection in saliva yet. And that's an interesting open question, and we certainly have gotten a lot of questions about could developers do that. And we said yes, we just want to make sure it works.

JASMINE CHAITRAM: OK. Here's one more. "Would it be acceptable for a CLIA lab to internally validate a SARS-COV-2 mutation analysis assay that is currently research use only, or would the FDA guide to submit this review to the FDA for EUA?" I think it's is the guidance from FDA that this needs to be submitted for an EUA? So it's an internally validated SARS-COV-2 mutation analysis assay, and do they need to submit it to the FDA for EUA?

TIM STENZEL: Yeah, so this gets into the LDT oversight question, which the FDA is still in discussion with HHS on. Any commercial manufacturer that wishes to sell a test for clinical reporting, a kit that can detect variants, should come into the FDA for authorization of that kit. That's the best I can do.

JASMINE CHAITRAM: OK, thank you very much. That was a bunch of questions that came in. I appreciate you answering all of those, and I will get back to you with the other questions so we can dive into that one a little bit more and see if there's more information to provide. But thank you for being with us again today. As always, we appreciate your time.

TIM STENZEL: Thank you, Jasmine.

JASMINE CHAITRAM: And with that, I think I'm going to wrap up this call a few minutes early. I'm sure everybody will appreciate that. We do appreciate all of our speakers for joining us today, and all of you for being here too on the call, for submitting great questions. And we appreciate those, and please continue to send those in.

You can also send them in to our mailbox before the call so that we can have our speakers ready to answer them or try to find an SME to participate in the call. So don't wait until the call to ask the question. You can always send them in at any time. The email that to do that would be locs@cdc.gov.

And if you're not signed up to receive emails from us from LOCS, you can also request to be added to our distribution list by sending a request to the same email. But that's it for today, so thank you again.

Monday, October 4th will be our next call, and we hope to continue to support you guys in the best way that we can with as much information as necessary or that we can provide during these calls. So have a good day, and we'll talk again in a couple of weeks. Bye, everyone.