Transcript

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Sean Courtney
CDC Division of Laboratory Systems

SARS-CoV-2 Variants Update
Natalie Thornburg
CDC Division of Viral Diseases

Reclassification of the Brucella Genus: Public Health Impacts
Rebekah Tiller and Melissa Bell
CDC Division of High-Consequence Pathogens and Pathology

2022 U.S. Monkeypox (Mpox) Outbreak & Federal Select Agent Program Regulations Update
Shaw Gargis and Denise Gangadharan
CDC Division of Select Agents and Toxins

FDA Update
Tim Stenzel
US Food and Drug Administration

Sean Courtney: All right. We'll go ahead and get started. Thank you, everybody, for joining us on today's call. So good afternoon. My name is Sean Courtney, and I am a Health Scientist in CDC's Division of Laboratory Systems. On the screen is the agenda for today's call.

But before we get started, I wanted to cover a few announcements and some of our general housekeeping items. So as you've heard on previous calls, DLS is the CDC division that works closely with clinical and public health laboratories across the country to support laboratory emergency preparedness and response activities. And we've been hosting these calls since March of 2020. And so DLS is able to support this work across four goal areas, quality, workforce and training, preparedness and response, and informatics and data science.

As always, we'll be sharing slides from today's call along with audio and transcript. And we'll post them online hopefully as early as next week. You can also find them on CDC's Laboratory Outreach Communication Systems page at the link shown here. And as always, we would like to hear from you. So our training and workforce development branch is interested in hearing more about the education and training gaps you're currently experiencing.

And so we invite you to send your feedback here at labtrainingneeds@cdc.gov. And so as always, if you have a question, we ask that you please use the Q&A button within the Zoom features, and not using the chat functional button. Also if you have-- when submitting a question, we'd like to ask that you please include your email address, just in case we don't have time to address your question during our conversation today, that we can be able to follow it up later on after the call.

And for a disclaimer, we'd like to remind everybody that these slide decks may contain presentation material from panelists who are not affiliated with the CDC. And so presentation content from external panelists may not necessarily reflect CDC's official position on the topics covered today. And so with that, I'm going to actually stop sharing my screen and pass it over to Natalie Thornburg, with CDC's Division of Viral Diseases. She's going to provide an update on SARS-CoV-2 variants. So Natalie, give me one second to stop sharing, and I will hand it over to you. All right, you should be good to go, Natalie.

Natalie Thornburg: All right, thanks, Sean. Whoops, let me drag this out of the way. There we go. All right, so this week, for the data tracker, we have been seeing a bit of a decrease in confirmed cases over the past seven days, a decrease in deaths, and a decrease in hospitalizations nationally. Whenever we look at the case count, that's shown in these blue bars, with weekly cases on the left y-axis, and the testing weekly percent positivity on the right y-axis, we see percent positivity has also declined in the past couple of weeks since early January, indicating an overall decline in case counts nationally.

All right, and so this is what the data tracker that was updated last Friday looks like. I'm going to remind everyone that there's two different ways to look at the data tracker. One is with the actual sequences, and to see that, you click the Nowcast off. And so these are the lineages of viruses that are circulating above 1% nationally, the weighted estimates.

And so the most recent update for the weighted estimates is for the week ending December 31, 2022. And you can see that there has been an increase, a slow increase in the lineage XBB.1.5 over the past several weeks. XBB.1.5 is a BA.2 lineage Omicron virus. It is a sub-lineage of XBB.1, which is a sub-lineage of XBB. So it is called XBB because it is a recombination of two different BA.2 viruses.

The XBB.1.5 lineage has two substitutions in the spike protein, in comparison to its XBB parental lineage virus. And so for the week ending December 31, the actual percentage of proportion of XBB viruses nationally was somewhere between 10% and 27% of circulating viruses nationally. When you turn the Nowcast on, and I'm going to click that button, if it cooperates, when you turn the Nowcast on, that uses the prior 21 weeks of sequences to predict the growth rate of viruses or the rate of decline of circulating lineages.

And so the last three weeks shown on that is modeling data. And so the modeled data for the week ending January 21, 2023, XBB.1.5, it represents approximately 37% to 60% of circulating viruses nationally. BQ.1 and BQ.1.1, which are BA.5 lineage viruses, peaked in the fall and have been declining or predicted to decline over the past few weeks.

Now you may have seen a little bit of chatter in the media about CH.1.1 virus. That's a lineage of BA.2.75. And the reason there's been a little bit of chatter is because there's some data indicating it may have a more dramatic loss of neutralization in comparison to some of the other lineages that are on the data tracker. So right now, that lineage is a low proportion of viruses.

It is currently aggregated with its parental lineage, which is BA.2.75. So if you were looking for those viruses, they're there in BA.2.75. And at least as of last week, the growth, there is no predicted growth of those viruses nationally. But we are watching them very closely to see if they begin to increase. And if they do start to increase in proportion and hit that 1% threshold, it will be broken out on the data tracker. So it will be separated from its parental lineage BA.2.75.

Regionally, we're seeing quite a bit of differences in the proportion of XBB.1.5 lineage. The Northeast XBB.1.5 predominates and represents greater than 80% of circulating viruses in regions one and regions two. In the upper Midwest, in the West Coast, the proportions are lower and really represent in some regions as low as approximately 10% of circulating viruses.

Now hospitalization rates did tick up there for a bit. But it wasn't isolated to the Northeast where XBB.1.5 predominates. There was, it seemed to be an uptick in several regions where there were likely an increase of cases, and that those hospitalization rates have now started to decline, even with continued increase in proportion of XBB.1.5.

So it doesn't appear right now as if that uptick in hospitalization was being driven by XBB.1.5 but was more likely an overall increase in case counts. And those are the updates for this week. Thank you.

Sean Courtney: All right. Thank you for those updates, Natalie, really appreciate that. I do not see any questions at this time in the chat or in the Q&A box. But I know you mentioned at the beginning of your talk that we are starting to already see kind of a downward trend. Is there any modeling or predictions to suggest that that's the continued direction that we're moving, or do they think that they may see increases for later this winter and early spring?

Natalie Thornburg: I mean, the pattern that SARS-CoV-2 infections and case counts have sort of fallen into-- and I don't think we really know if we're into like a routine or regular pattern. But we have been seeing an increase in case counts with holiday travel and gatherings in December, January, sort of a little bit of a fall through the spring. And then the past couple of summers with Delta BA.5 we have seen a little bit of an increase in case counts again in the summer and early fall. So we may see something similar this year.

Sean Courtney: OK, great. Thank you. I really appreciate that. And I do not see any questions that have come in the Q&A. So I will thank you for joining us again today. And if any do come up that you could-- actually, one just popped up just now. Let me read it really quick. Are there any updates on whether home test kits can detect COVID on individuals infected with XBB? Not sure if you would know that or if maybe Tim would be more appropriate.

Natalie Thornburg: Yeah, I defer to FDA on test performance.

Sean Courtney: OK. And I'll wait for Tim. We have Tim later on in this call and maybe he can address that during his update. So thank you, Natalie, really appreciate you joining us today.

All right, so let me open back up the presentation. All right let's go to our next speaker. And so for this we have Rebecca Tiller from CDC's Division of High Consequence Pathogens and Pathology, who's going to give us an update on some renaming of species. So Rebecca, I will hand it over to you.

And if you're on, we cannot hear you. If you're—

Rebekah Tiller: I was muted.

Sean Courtney: There you go. We got you. You're good.

Rebekah Tiller: Thank you. Can we go up to the just one more slide up? It's just the first slide. Or I could start here. There you go. OK, thank you. All right, my name is Rebecca Tiller. I'm a Microbiologist in the Bacterial Special Pathogens Branch at the CDC. And I'm here talking about the public health impacts of this recent taxonomic reclassification of the *Brucella* genus.

I also have Melissa Bell on here as well that can answer some questions, if there are any, at the end of the talk. OK, let's go to the next slide.

So the *Brucella* genus traditionally has had 12 recognized species, listed here on the left. And a recent genomic analysis has determined the *Ochrobactrum* species that are listed here on the right to be genetically close enough to the *Brucella* species to rename them into that genus.

Now we've always known that the *Ochrobactrum* have been considered near neighbors of *Brucella*. But they are really very quite different. They're environmental pathogens. They're opportunistic. And they reside in the environment, whereas the classical *Brucella* species here are listed on the left. The main ones that cause the disease called brucellosis are *Brucella abortus*, [*B.*] *melitensis*, and [*B.*] *suis*, which are also registered select agents. *Brucella canis* can also cause brucellosis, but is not a select agent.

So we have the classical *Brucella* species here listed on the left, 12 of them. And with a recent reclassification and renaming of the *Ochrobactrum* species, we now have an additional 18 of the previously known *Ochrobactrum* species added into the *Brucella* genus. So next slide, please.

So this can create some rippling impacts down the way, simply because the *Ochrobactrum* and *Brucella* species are really very different. And then to combine them into one genus can create some problems. So major differences between the two are the *Ochrobactrum* species are predominantly environmental in their habitat.

They're also found in hospital environments. Most of the infections that they cause are from catheters. And the classical *Brucella* species predominantly reside in animal reservoirs and they're zoonotic. Again, the *Ochrobactrum* species are opportunistic. They can cause nosocomial infections. The classic *Brucella*

species can cause a pretty intense insidious disease, high morbidity. They can invade various tissue types and can develop focal complications and potentially chronic syndromes.

Infection with *Ochrobactrum* species does not cause a reportable disease. However, infection with the classical *Brucella* species, *Brucella melitensis*, [*B.*] *suis*, [*B.*] *abortus*, and [*B.*] *canis*, cause brucellosis and that is a reportable disease. *Ochrobactrum* species now included in the *Brucella* genus have a very different antimicrobial regimen for treating infection with those species. They respond to imipenem, fluoroquinolones, and the aminoglycosides, whereas infection for brucellosis, the main treatment for brucellosis is a dual antibiotic regimen of doxycycline and rifampin for six weeks, so very different antibiotic treatments.

And again, in the *Ochrobactrum* species, you do see a good bit of antimicrobial resistance. And it's really very rare to find antimicrobial resistance in *Brucella melitensis*, [*B.*] *suis*, [*B.*] *abortus*, or [*B.*] *canis*. There are a couple of strains that are lab-engineered vaccine strains that do have resistance.

So I do want to make this point for the classical *Brucella* species. But apart from those, natural acquisition of antimicrobial resistance is really very rare. Next slide, please.

So *Ochrobactrum* species are pathogens. And as I mentioned before, this is a really good paper if anyone's interested in reading more about *Ochrobactrum* as a pathogen.

But it really does list out some cases caused by *Ochrobactrum* and how they got infected, and then how they were treated. And this is really very, very different from brucellosis. Most of these infections are in patients that have underlying conditions, such as cancer or kidney issues. And then their antimicrobial treatments vary depending on the patient and their underlying conditions. And then some of them actually never received antibiotic treatment, yet they resolved their infection.

So this was just an example of how *Ochrobactrum* can be a major pathogen. Next slide, please.

So what is the public health issue here with this reclassification? And it is really, there's impacts at every level of the system. At the sentinel lab level, all of the rapid ID systems have updated their libraries. So anything that was previously called *Ochrobactrum* is now called *Brucella*. And then some of the libraries have, say, parenthetically *Ochrobactrum*, and then they maintain the species name.

There are many, many rapid ID systems in the clinical sentinel lab landscape. We've communicated with bioMerieux and they have indicated that they have updated the nomenclature in all of their systems, but at different waves. So if you have a system that maybe hasn't had an updated library yet, it will occur eventually.

So for most of the bioMerieux systems, they really only have in their libraries *Ochrobactrum anthropi* and *Ochrobactrum intermedium*. Those are the two major pathogens that come through the clinical labs

causing human infection. But then some systems will just simply ID *Brucella*, and they won't be able to distinguish the species.

So what we need to do is provide some updates on the distinguishing microbiological characteristics between the *Brucella* species and the *Ochrobactrum*, the new *Ochrobactrum Brucella* species, so that we can better distinguish them in the clinical lab, offboarding from a rapid ID system. The *Brucella* LRN testing algorithm, this algorithm was designed to detect the classical bio-threat agents, so *Brucella abortus*, [*B.*] *melitensis*, [*B.*] *suis*, and [*B.*] *canis*.

So we have at the end of this now, in a couple of slides from here, some recommendations clarifying the use of the particular LRN algorithm, particularly the *Brucella* LRN PCR, to rule in or rule out whether a *Brucella* that's identified as a *Brucella* is actually a bio-threat *Brucella* or one of these previously known *Ochrobactrum* species. Biosafety, the BMBL has really nonspecific language talking about handling *Brucella* species in general. And this is now going to require some additional clarification on handling the previously known *Ochrobactrum* species. They do not need to be handled on a BSL-3.

The existing recommendations from *B. obit*, the biosafety safety recommendations for *Brucella* species, still stands, for [*B.*] *suis*, [*B.*] *canis*, [*B.*] *melitensis*, and [*B.*] *abortus*. And then as already mentioned, patient management, infection with *Brucella intermedia* or [*B.*] *anthropi* could create confusion for physicians. And I'll show you a case in point in the next slide, that demonstrates how physicians could kind of misdirect antibiotic therapy.

So there needs to be some clarification provided to the clinical community, really distinguishing between infections with previous *Ochrobactrum* species and the *Brucella* species that cause brucellosis. And this also filters up into the whole reporting. OK, next slide.

This is an actual report that one of the state labs that we redacted out of PII. But we received this from one of the state labs a few months ago, that this is a 16S gene sequencing result from a previously known *Ochrobactrum* species that was identified as *Brucella intermedia* or *Brucella anthropi* by 16S gene sequencing. And the report that went to the physician resulted *Brucella* species. So when we saw this, it really kind of rung home, like when patient management comes into play this is really kind of where there could be the biggest impact.

So I don't know specifically, in this case, how the physician treated this patient. But again, there needs to be clarification to the clinical community and to clinical labs on really understanding now *Brucella* is various. It's going to have to be reported more at a species level. So there needs to be more determination at that level to inform patient management. OK, next slide.

And this is where I just want to draw everybody's attention back to the ASM rule-out algorithm that I put here. I think the last time it was updated was in 2016. And this is just a series of-- I know you all are familiar with this. But it's the series of microbiological tests that can rule in or out the classic bio-threat

Brucella species. But what's lacking on here right now, with this current taxonomic change, is what the *Ochrobactrum* constraints would look like on this algorithm. So next slide.

Yeah, I made a table. And hopefully we can somehow incorporate this into an updated rule-out algorithm flowchart. And this is just all of the microbiological and phenotypic characteristics and tests that you would do in the flowchart, and the distinguishing features of the classical *Brucella* species and the *Ochrobactrum*. And what's highlighted in yellow are areas where they differ.

So they are able to be distinguished using the ASM rule-out, if you get a *Brucella* ID on a system that doesn't distinguish a species, intermedium or *Ochrobactrum*. But the biggest difference between these is that the *Brucella* species and *Ochrobactrum* just really morphologically look very different. Their colony morphologies and the size of their cells are just very different.

Brucella species, the [*B.*] *suis*, [*B.*] *canis*, and [*B.*] *melitensis*, have very teeny-tiny colonies, where *Ochrobactrum* are big and liquidy. And the *Ochrobactrum* species will grow on MacConkey agar, whereas the classical *Brucella* species will not. Motility is also an area where there could be some differentiation there. Most *Ochrobactrum* are motile. But some testing here is indicated, that some, it's difficult to determine if they're motile or not. OK, next slide.

So this is just a close-out. And these are general recommendations right now. And I would really appreciate any input that you all have here as an audience on additional areas where we might not be considering for recommendations. We're hoping to develop an FAQ-type document to put out in different places.

So if there's questions that you have or areas that we may have not addressed, please feel free to share them. So at the clinical laboratory, our recommendation is that if you have a bacterial isolate that's identified as *Brucella (Ochrobactrum) anthropi* or *Brucella (Ochrobactrum) intermedium*, evaluate using the ASM rule-out. And we'll hopefully provide a table that can help you have on hand the characteristics of the *Ochrobactrum* species.

If you're unable to differentiate using those particular methods, then refer to your state lab. If you are in a clinical lab and you have an isolate that's identified basically as a *Brucella* species, again, use the ASM rule-out. Look at the distinguishing characteristics between the classical *Brucella* and the *Ochrobactrum*. If you cannot rule it out at that level, then refer it up to your state.

At the state lab, if you receive one of these isolates or as for *Brucella* ID and it's negative on the *Brucella* LRN PCR, you can report no *Brucella* DNA detected. And then there's no further testing really required in your lab. The LRN PCR can rule out that it's not a bio-threat *Brucella*, and we may be able to add or change language for the reporting to say no bio-threat *Brucella* DNA detected. Potentially we could do that.

If you do want additional testing, you can submit the isolate to our special bacteriology reference lab. Melissa Bell is on here from that lab because they're the ones who do the *Ochrobactrum* identification. For the clinical community, if a patient is infected with a *Brucella Ochrobactrum* species, treat for *Ochrobactrum* infection. Don't treat for brucellosis.

And again for the state epidemiologists, if a patient is infected with a *Brucella Ochrobactrum* species, it's not brucellosis, so do not report it as brucellosis. I think that that's everything on this slide. So next slide,

Sean? I'm thinking that's it. Yep, that's it. So I'll take any questions. I don't know, is Melissa able? Is she on as a panelist?

Sean Courtney: I believe Melissa was added, yes.

Rebekah Tiller: OK, all right, so you can answer some questions if you have any.

Sean Courtney: OK, great, well, thank you for that discussion today. I really appreciate the update. There is one question. It is directed, as whether APHL should also look at updating the ASM rule-out SOP to include the table that you described, and that APHL job can work with ASM on updating that SOP, if that would be useful.

Rebekah Tiller: Yes, I think that that would be useful.

[LAUGHTER]

Sean Courtney: Great. And I do not see any other questions at this time. But if you could just hang out during the rest of our call.

Rebekah Tiller: Sure.

Sean Courtney: And if any questions kind of pop up in the Q&A, it would be great if you could just address them within the Q&A. And that'd be really helpful. So but again, thank you for the talk today and for joining us on the call. And we really appreciate that. So thank you.

Rebekah Tiller: You're welcome. Thank you.

Sean Courtney: All right, so moving to our next one, we have Shaw Gargis from CDC's Division of Select Agents and Toxins who's going to talk to us about the Mpox outbreak and the Federal Select Agent Program regulations. So Shaw, I will hand it over to you. Sorry.

Shaw Gargis: That's OK.

Sean Courtney: Sorry about that. There we are. There we go.

Shaw Gargis: OK, great. Good afternoon, everybody. So I did just want to talk a little bit about the US Mpox outbreak and the Federal Select Agent Program (FSAP) regulations and just give a little bit of an update. This is very similar to a presentation that was given last fall. And there haven't been any major changes in regulatory stance since that point. But there is a little bit of an update about reporting. So next slide, please.

So the Federal Select Agent Program and HHS in particular regulates a select agent called monkeypox, now being renamed Mpox. And HHS select agents and toxins that meet the following criteria are excluded from the regulations of this part. So we have the select agent which is monkeypox virus, and then the West African clade which is clade 2, is excluded from the select agent regulations. So if you are in possession or identify the excluded strain, as I'll get to in a second, it is not a select agent. So next slide, please.

So currently there are two clades of Mpox virus, the Congo Basin clade, which is now known as clade 1, and the West African clade which includes clades 2a and 2b. Up to this point in the 2022 and now going into 2023 US Mpox outbreak, laboratory testing has indicated that the current outbreak is associated with clade 2b of monkeypox virus.

Mpox is regulated as an HHS only select agent. And entities that possess, use, or transfer this agent must comply with the select agent regulations, unless there is an applicable exemption or exclusion. And there's a couple of those. So such as next slide, please.

As I mentioned, the clade 2, which is the West African clade, 2a or 2b, those strains are excluded from the select agent regulations provided that any West African clade of Mpox virus-- provided that the entity or individual can identify that the agent is within the exclusion category. So this exclusion would apply to material that has been identified as being or containing West African clade or clade 2 Mpox virus. Next slide, please.

There's also a diagnostic specimen exemption. So the regulations provide that clinical or diagnostic laboratories or other entities that possess, use, or transfer an HHS select agent or toxin contained in a specimen presented for diagnosis or verification will be exempt from the requirements of the regulations, provided that they report that identification of a select agent to the Federal Select Agent Program and other authorities as required by law.

You secure the select agent after identification and then transfer or destroy that material within the appropriate time frames, which for this agent is seven days. This exemption would apply to material that has been identified as being or containing Mpox virus, but the clade has not been determined or the clade has been determined to be Congo Basin clade or clade 1, which we have not seen as part of this current outbreak. But it's that part that deals with the clade undetermined that there is a bit of an issue, as I'll get to. Next slide, please.

So an entity may retain this material if registered with the Federal Select Agent Program and approved to possess Mpox virus. So with that material being any material, from clade undetermined or if it was clade 1, which is the Central African or Congo Basin clade.

FSAP regulates material that has been identified as being or containing a select agent or toxin. Therefore, confirmed identifications of orthopoxviruses that are presumptive identifications of Mpox virus are not considered select agents by the Federal Select Agent Program until the Mpox virus or another select agent has been identified in the sample. And I'll get to a little more detail on that in a second. Next slide, please.

So this table hopefully clarifies some of the regulatory status and the reporting requirements of the different stages of testing. So I think one of the more common assays out there is the non-variola orthopoxvirus. Since that has not been identified to be Mpox, it is just at the orthopoxvirus level, it is not subject to the select agent requirements. And there's no reporting requirement to the Federal Select Agent Program.

However, if there is Mpox virus clade undetermined, so if it is identified as the actual species Mpox virus, but it is unknown what clade it is, then that is reportable to the Federal Select Agent Program and is subject to the select agent requirements, such as the transfer and destruction. If it's been identified as Mpox virus clade 1, also used to be known as the Congo Basin clade, that is the select agent clade and it is subject to the select agent requirements.

That, like I want to reiterate, it is according to the CDC Mpox response, that has not been identified as part of this outbreak up to this point. Mpox virus clade 2, previously known as the West African clade, that is our excluded clade. And it is not subject to the select agent requirements, and no reporting is required. So next slide, please.

Now I want to go into some specifics about select agent reporting, and some relaxation of the reporting requirements during the current outbreak. Next slide.

So when a select agent is identified, the identifying lab has to submit within seven days, usually, an APHIS/CDC Form 4 to report the identification of a select agent or toxin to the Federal Select Agent Program. Mpox virus is a select agent. So if it is a clade undetermined Mpox virus, then that is required to be reported to the Federal Select Agent Program.

I will say that, however, DSAT has authorized less stringent reporting requirements for the identification of Mpox virus due to this current outbreak. When there is a need, like the reporting could get in the way of a response, we have the ability to relax the reporting requirements. Next slide, please.

So until the conclusion of the Mpox virus outbreak as determined by the CDC, clinical and diagnostic laboratories and other entities that possess HHS select agents and toxins may submit on one consolidated report using the ASPHIS/CDC Form 4 to report the identifications of monkeypox virus for a

180-day period. So you can aggregate all of your identifications of clade undetermined monkeypox, or those that have been determined to be clade 1, which we haven't seen as part of this response, all on one report, starting from 180 days from the first identified sample on that.

And so all Mpox virus positive samples not characterized to the clade level or identified as clade 1, as I've said, can be submitted on a single sheet, as long as you list the different sample providers when providing that one form 4. And it has to be within 180 days of the earliest sample identification date. So we are putting together, and it just released today, a new what's called SA gram, which is a notification to the federal select agent program registered entities. But it's also a public SA gram that I'll be sharing that information with Sean, so it can be sent out to this community, information about how, even if the emergency declaration for the Mpox virus outbreak ends coming up soon, we're still allowing this 180-day less stringent reporting requirements.

And we will provide ample time, if that does end, to let you know when that 180 days allowance is coming to an end. And remember this is 180 days from the earliest sample identification. It's not like 180 days from when we publish this SA gram. So say you get one, you identify a Mpox clade undetermined today, you'll have 180 days to report that to our program. And you can aggregate and put others on that same form 4. So it's kind of a rolling basis from whenever you identify new samples that meet the requirements of the regulations and reporting requirements. Next slide, please.

So please note that clade 2, West African clade Mpox virus, is excluded from the select agent regulations, as I've said, and therefore you do not have to report that to our program.

It's really those identification of monkeypox virus or Mpox virus clade undetermined, or if it would happen to be clade 1 Congo Basin, then you need to report that to our program. And you can, but you can do that on a consolidated form 4, if you are, your laboratory is hindered due to the number of samples you're testing or but there's no requirement for you to do that.

You still can submit individual form 4's if you would like. It's just an allowance during this outbreak. If you have any questions, please let us know. You can email CDCForm4@cdc.gov if you have any questions about whether reporting is required. And the entity should also update the identification of the recipient of the sample material, if previously transferred.

And also if you make further determinations that it is an excluded strain, you can let us know and we can update our systems, if, say, it was undetermined, and then you go back and make sure and do further testing and show it's clade 2 or something like that. So next slide, please. I think that is it. I'll be glad to answer any questions.

Sean Courtney: All right. Thank you for that, Shaw. I really appreciate that. So I don't see any questions in the chat currently. But if any pop up and you're able to hang out, if you could-- I'm sorry, in the Q&A function. If you could go in there and just answer them if you have the time, that'd be really appreciated. If

not, we'll try to get them to you at a later time. So but thank you for joining us today. Really appreciate that update from you guys in the DSAT program.

Shaw Gargis: All right. Thank you.

Sean Courtney: All right. And with that we're going to move over to our FDA update from Dr. Tim Stenzel. Tim?

Tim Stenzel: All right. Thank you, Sean. So I had already responded to the XBB question in the Q&A. So hopefully I addressed that question adequately. I was asked to update this group on Mpox since the public health emergency will end, I think, at the end of this month, don't know the exact date. What is the impact on IVD EUAs, and test EUAs.

So I don't know of any impact to test EUAs. Everything that is received an EUA will remain able to be sold for Mpox. And we are, in fact, still reviewing submissions for Mpox and expect to have some more Mpox IVD test authorizations.

So the public health emergency declaration is not directly connected to the IVD EUA authority that the FDA has. The public health emergency declaration is time-limited and needs to be renewed if an extension is desired. And however, the authorities for EUAs does not have a time limit. It can end upon removal of that authority by the Secretary. But it does take action to end that.

So that ensures that tests that have been submitted and authorized under EUA authorities can continue to be used by labs. And so that's a good thing. So Ebola, the current outbreak in Africa, has come to an end, it appears. Ebola is still covered under active EUA authorities, which is a good thing because we did use those to help manage the current outbreak, even though, fortunately, we did not get any in the US. But we do actively use them in the US and outside of the US.

So that's sort of an update that I was asked to give. I did see that probably a question popped up in the Q&A. I'm not sure if it applies to me. Oh, who’s responsible for the EUA? So in both the public health emergency and the EUA authorities are in the hands of the Secretary.

Sean Courtney: All right, I actually do not see any other questions right now either, Tim. Do we have one? Oh, I'm sorry. One just came in. I apologize. So it says when the Mpox public health emergency ends, will that end the FDA EUA over monkeypox virus tests end as well? So if so, will clinical laboratories, can they start performing LDTs without the EUA?

Tim Stenzel: OK, for Mpox the FDA just required notification from LDT labs. And so labs who notified the FDA under those provisions of the guidance for Mpox can continue to test. But, again, the EUA authorities will remain in place for Mpox, and not sure at this point when and if that will end.

Sean Courtney: All right, thank you. Next question was, is there a standing FDA enforcement discretion letters for LRN assays that do not have EUA or 510K clearance?

Tim Stenzel: That would be test-specific for Mpox, and for other analytes the FDA has provided enforcement discretion letters to the CDC for their use. Anything related to Mpox and Ebola will remain in effect.

Sean Courtney: OK, great. Thank you. All right, I do not see any other questions at this time. So I just want to say thank you, Tim. Thank you for joining our call, as always. Really appreciate your updates from the FDA. And I'd just like to thank all of our participants that were able to join the call today for giving some great updates on some of the topics that we needed to have covered.

And so with that, I just want to remind everybody that our next scheduled call is on Monday, February 27th, actually. So this is a week later due to, I believe, Presidents' Day holiday that's on February 20th. So our next call is Monday, February 27th at 3:00 PM [ET]. And also if you have any suggestions for topics for future calls if you could please just forward those to us. We're always interested in making sure that we can give you the most up-to-date information for these calls and for your testing community needs.

And with that, I'll go ahead and end our call today. And again, just thank you, everybody, for joining in. And thank you for our participants. So have a great one. Thanks, guys.