Agenda
Laboratory Outreach Communication System (LOCS) Call
Monday, October 17, 2022, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems
- **Ebola Update**
  - Joel Montgomery, CDC Division of High-Consequence Pathogens and Pathology
- **Packing and Shipping for Ebola Specimens**
  - Sabrina Debose, CDC Division of Laboratory Systems
- **SARS-CoV-2 Variants Update**
  - Natalie Thornburg, CDC Division of Viral Diseases
- **Monkeypox Update**
  - Serena Carroll, CDC Monkeypox Response
- **2022 US Monkeypox Outbreak & FSAP Regulations**
  - Denise Gangadharan and Lori Bane, CDC Division of Select Agents and Toxins

JASMINE CHAITRAM: Hello everyone, I am Jasmine Chaitram. I am the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. Thank you for joining the Laboratory Outreach Communication System (LOCS) Call. I have been on these calls before, so those of you that have been with us hanging out with us for a few years now might remember me. I'm standing in for Sean Courtney today who is on a much-deserved vacation.

In front of you right now is the agenda for today. I will go ahead and apologize for one change to the agenda. We did have John Barnes talking about influenza testing for the 2023 season. And he was not able to join us today. So we will hopefully have him join the November call to give that update.

And before we go into the different topics for today, I am going to cover a few items as just background, and some housekeeping, and just a reminder about the Division of Laboratory Systems. I'm sure you all have heard this so many times, but we support clinical and public health laboratories, and we do this in a number of areas, including quality laboratory science, supporting workforce development and training, accessible and laboratory data, and that's the informatics piece, as well as safe and prepared laboratories, which was kind of the reason for these calls that we've initiated.

We also support CLIAC, and we have an upcoming meeting that will be on November 9th and 10th. And you can register in advance for that meeting using this link here on this page on this slide.

And if you have any oral or written comments that you want to send in advance, there's also an email address (CLIAC@cdc.gov) for that. And please do that by November 4th. Our topics that we will be covering include report outs from our workgroups, and public health and clinical laboratory workforce challenges, as well as some agency actions for the monkeypox response.

We recently published a new LIVD test code mapping tool. This is specific for monkeypox virus tests. And there was a LOCS message that should either be hitting your mailbox shortly, or already has announcing

this new tool. And it's been added to the current LIVD page where we had our coronavirus tests all mapped out. So it's all in one place.

And just a reminder, that the whole purpose of this tool and our web page is to support the use of harmonized LOINC and SNOMED Clinical Terms to help improve accuracy and standardization of test reporting. So please, share this with others in the lab community as well as with vendors that are helping you to stand up new test in your information systems. This specific LIVD specification is going to map monkeypox virus diagnostic tests that have received EUA from the FDA emergency use authorization. And it has been jointly developed by a number of partners, including FDA, CDC, the In-Vitro Diagnostic Industry Community, Regenstrief Institute, and the Association of Public Health Laboratories.

As a reminder - the LOCS calls, all of the information from these calls, and transcripts and audio recordings - are available on our LOCS web page. You can go there and go back and search through any of our calls. It does take us about two weeks to get this information up on our page. So please be patient. If you miss the call, just check that page, but give us a couple of weeks to get it up.

Our next call is Monday, November 21 from 3:00 to 4:00 PM Eastern Time. We do host these calls now once a month. And that will be the week of a holiday, Thanksgiving, but we will plan to host the call that week. We want to hear from you on training and workforce development needs. And you can submit that to the mailbox listed here (LabTrainingNeeds@cdc.gov) on this slide.

And then I think this is the last thing I wanted to tell you all about, which is a reminder about asking questions, please put those questions in the Q&A section of the Zoom, which is a button at the bottom of the feature there in the Zoom webinar system. Type your question there. We would appreciate it if you included your name and email address.

We may not be able to get to your question today. Or we may not have a subject matter expert on the phone to answer your question. So if you can provide your email, we can get back to you. If you put it in the chat, it's a lot harder for us to do that. Also want to remind everybody that the questions that you submit should be specific to laboratory testing issues.

And then a couple of reminders for the media and for individuals, that this is really a lab-based call. So please direct your questions elsewhere. And then finally, I think all of our speakers today are from CDC. But sometimes, we do have presentations that are done by folks outside of CDC. And those materials are not necessarily representing the CDC's official position on a particular topic. So that's also still important because if you go back to any of our archives and you see slide decks or transcripts from previous speakers that are not employees or staff of CDC, just keep this in mind when you see that information.

So our first update for today is going to be on the Ebola in Uganda. And we were going to have Joel Montgomery, who is the Incident Manager of the response here that's been set up at CDC. But I think he got pulled away. And today, we're actually going to have Seymour Williams join us. And Seymour, are you on?

SEYMOUR WILLIAMS: Hi, Jasmine. Can you hear me?

JASMINE CHAITRAM: Yes, I can. Thank you.

SEYMOUR WILLIAMS: OK, thanks so much for this opportunity. I'm Seymour Williams. I'm the Deputy Incident Manager. And Joel is actually-- I think he's in a press-- is having a call with the press. But as you can imagine, this is increasing in importance, our support for the Ugandan government in dealing with this particular issue around Ebola.

And the reason why it's so particular as some of you may already know, it's Sudan Ebola virus, which is very different from Zaire Ebola virus. I don't know how many people know about this already. I'm assuming since your call is monthly, you might not have been caught up. So my apologies if I'm doing the updates and there are some repeats. But I'll give the situational overview, and then just maybe give some laboratory highlights since this is a lab call.

But four weeks ago in September 20, Uganda Ministry of Health declared an Ebola outbreak. It occurred in Mubende district, which is in Central Uganda about 107 miles outside of Kampala. As I said, it's the Sudan strain of Ebola virus (EBV). And we do not have a vaccine, and we do not have therapeutics per se. And I'll mention a little bit more about that in a minute.

This is the fifth outbreak of EBV caused by Sudan virus since 2000. And the current outbreak is in the same area as Uganda's most recent EVD outbreak, which occurred in 2012. During the 2012 outbreak, we had limited secondary transmission. And the outbreak was effectively contained. And we're really trying to do the same. There are no FDA approved medical countermeasures for Sudan Ebola virus. And there are some experimental therapies.

The geographic scope of this outbreak is affecting five districts in Uganda, Mubende, Kyegegwa, Kassanda, Kagadi, Buyangabu. So as of the 17th, we have a total of 78 cases, 58 confirmed, 20 probable. There are 41 deaths, 21 confirmed, 20 probable. There have been about 10 and 11 infections among health care workers, with about four deaths. There are 32 recoveries. Contact tracing is going very well. They're reporting a 93% follow-up rate among 514 active contacts.

Just a brief on our global efforts, we've been actively working to get deployers. As of October 16, there were 18 CDC responders in Uganda, seven epis, three lab, three ecology. We're working closely with the CDC office that's there, and with the Ministry of Health, and the WHO, and other nongovernmental partners in country.

As some of you know, CDC has been in Uganda since 1991. And we have a country office since there in 2000. And it's a good thing that we've invested in the country. And the work is very critical as we're using our relationship with Uganda and the CDC office as a staging hub for coordinating the field response efforts.

I think you might want to just hear a little bit about what we've done for domestic preparedness, as some of you may have already participated in. We sent out a Health Alert Network health advisory. And then we also had a webinar, a COCA call, where some I think, over 4,000 people attended virtually. Last week, there were updates on the guidance for Ebola viral exposure risk assessment within the US, and the Viral Special Pathogens Branch as a 24/7 consultation line. And all the Ebola viral disease guidance is being reviewed and updated on the website.

Let me cut to lab. I suspect there might be several other things you'd want to know about, but I'll leave it for the Q&A. So currently, there are no rapid diagnostic tests for detection of Sudan Ebola virus. And there are some discussions that are ongoing to determine how Sudan Ebola virus RDTs could be approved, manufactured, and made available in the future.

Some of you know this already, that back in 2010, CDC established the viral hemorrhagic fever surveillance and laboratory program in Uganda in coordination with the Uganda Virus Research Institute (UVRI) and the Ministry of Health. This program established a national surveillance system and a state-of-the-art diagnostic lab, and serves as the National Reference Lab for VHS. This is the same lab which provided confirmation of the current Sudan virus outbreak.

So UVRI and a CDC viral special pathogens branch have completed next generation sequencing of five of the PCR positive samples from the outbreak. They have been cleared and deposited in a public repository to provide necessary information for evaluating current diagnostic activities and developing new opportunities. The VRI VHF program has tested over 400 samples submitted since September 19 as part of the outbreak response. The results are shared back to the MOH to establish and authorized systems within 24 hours of sample receipt. So teams from UVRI and CDC Viral Special Pathogens branch are ready to deploy to the field, and they provide laboratory services, including high throughput RT-PCR testing of samples and clinical chemistry.

Just a side note, but important to know the importance of laboratory testing, they were testing negative samples for Sudan Ebola virus. And they identified three cases of Crimean-Congo hemorrhagic fever. And two of those cases were fatal. Two of these samples were sent from Mubende suspected EBV cases, and one was received as a surveillance sample. I should stop now, because there might be other things you might want to know, but I'll leave it for the Q&A. But those are the updates for the outbreak for our current involvement and for laboratory. I'm willing to take questions, but maybe we should finish up the other panel speakers, and we can come back to questions you may have.

JASMINE CHAITRAM: Yes, thank you so much, Seymour. I just wanted to clear up a couple of things. So we did not have any additional slides. Things are evolving, hard to put together slides for the presentation where we're giving you up-to-date information. So no slides were presented for this one. The HAN that was mentioned, that's the Health Alert Network, we did send out a LOCS message when the HAN went out. So hopefully, you all received that.

But we also have staff here at CDC that have put the link to the HAN in the chat, so you can find it quickly. And COCA was mentioned. COCA is a call that was held with clinicians, the clinician community.

Seymour, we do have a question for you. And the question is, can you please confirm that the BioFire and Xpert Ebola assays do not detect the Sudan strain? Seems like some of the Ebola antigen RDTs, such as OraQuick, might detect Sudan perhaps with less sensitivity than Zaire. But performance needs to be directly evaluated. Is that evaluation in progress?

SEYMOUR WILLIAMS: I am not a laboratorian, so I'm not going to step outside of my lane. Please send me that question in an email, and I'll respond to that person. I am aware of the conversations about what is available for testing. And I think at least on the US side, they are making the BioFire available to do testing for Sudan Ebola virus, but I need to confirm that with my laboratory colleagues.

JASMINE CHAITRAM: That's great. Do you happen to know how many public health labs in the US will have this testing capability?

SEYMOUR WILLIAMS: I think right now, the number 11 sticks out in my mind. But it's increasing daily, because it has to do with not just the availability, but also CLIA certification.

JASMINE CHAITRAM: OK, that's great. Thank you so much, Seymour. If you want to just hang on, we'll see if any other questions come in. Our next speaker on this topic is Sabrina DeBose from the Division of Laboratory Systems. And she's going to talk about packaging and shipping, which is going to be critical for sending specimens to a public health laboratory if testing is needed. Sabrina?

SABRINA DEBOSE: Yes, thanks, Jasmine. I hope everyone can hear me OK. So I wanted to say, my name is Commander Sabrina DeBose, and I will be providing updates on the current guidance related to packing and shipping for Ebola specimens. Keep in mind, I only have one slide, but I'll just give you the guidance, and then the one slide has a reference attached.

So although the travel, the risk of travel associated Ebola cases in the United States is low, CDC recommends that clinical laboratories review information on specimen collection, and transportation, and transporting infectious substances safely for specimens suspected to contain Ebola virus. Clinical laboratories should also contact their state health department before sending specimens for testing, and follow all requirements for packing and shipping category A infectious substance, following 49 CFR 173.195, category A infectious substances.

These specimens are not considered select agents, because they have not been identified to contain Ebola virus. In the APHIS/CDC Form 2, request to transfer of select agent and toxins does not need to be completed. CDC also recommend that testing be conducted only for persons who meet the criteria for persons under investigation for Ebola virus. Ebola testing is available at select public health laboratories that are members of the Laboratory Response Network. Next slide, please.

This slide here contains the reference for the guidance that I just provided. And you definitely can use these links that are provided on the screen. Next slide, please. We would like to make you available of our OneLab training. OneLab is hosting a packing and shipping considerations for suspected specimens webinar, featuring Dr. Julie Villanueva and other CDC subject matter experts on September 27 at 1:00 PM Eastern Time.

This webinar is recommended for those in public health departments, clinical and public health laboratory professionals, and health care personnel. The information to register for the OneLab training is also provided in the chat. That concludes my presentation. Thank you, Jasmine.

JASMINE CHAITRAM: Thank you so much, Sabrina. There is a question in the chat. Are all LRN labs able to provide Ebola testing for Ebola Sudan strain. And this was mentioned already a couple of times, and I'm just going to reiterate, that it's not all LRN laboratories, that's the Laboratory Response Network. It will be select laboratories. And there are efforts underway to help stand up the testing in at least 11 laboratories that are members of the LRN, and probably efforts to add more as time goes on and the need continues.

And also, want to emphasize-- Sabrina mentioned that you should be calling your state health department for a consult before you ship any specimens, and they will provide you guidance on which laboratory to ship your specimens to. OK. Not seeing any other questions in the Q&A section of the Zoom. If anybody else does have questions, and Sabrina, or Seymour, you're still on, please feel free to answer them in the Q&A.

SEYMOUR WILLIAMS: Yeah, I did, Jasmine. I just spoke to Joel, and the BioFire panel does pick up five targets, including Sudan Ebola virus. They would have to unlock it to find the others, but yes, find out the specific one. But Sudan Ebola virus is included.

JASMINE CHAITRAM: OK, great. Thank you so much. The other question that just got added, is there a cost for the packing and shipping training webinar? No, those webinars are free. So please sign up and take advantage of them. We are going to move to our next speaker today, Natalie Thornburg from the Division of Viral Diseases. She's been on before, and she will be talking about Sars-CoV-2 variants, and giving us an update. What's happening there? Natalie, thanks for joining us.

NATALIE THORNBURG: Sure, thanks Jasmine. Can I share my screen, please?

JASMINE CHAITRAM: Go ahead.

NATALIE THORNBURG: All right. Got it. Thank you so much. All right, so this is the COVID genomic data tracker. This is the COVID variant data tracker that was posted as of last Friday. So it's very current. So BA.5 parental lineage viruses are still the predominant circulating Omicron lineage virus, with about 64% to 70% of circulating viruses in the US, RPA.5 viruses. They've been decreasing since about late

August. And are sitting at again, 64% to 71% of circulating viruses. The second most prevalent virus is a BA.4.6. BA.4.6 is BA.4 with one additional substitution in the spike protein. And that's at residue 346. As a reminder, BA.4 and BA.5 viruses have the same spike protein sequence. And they are different viruses just because of substitutions outside of the spike protein, the spike protein being the target of neutralizing antibodies, and the only component of vaccine. The Omicron bivalent booster doses that are available in the United States have the ancestral spike, as well as the BA.4, 5, spike sequence. So anything that's circulating that is BA.4, 5, or a lineage of that is very, very similar to the bivalent booster doses that have been authorized for adults, and now more recently, children older than five-years-old.

The BF7 sub lineage has dropped to fifth in prevalence. BF7 is a BA5 sub lineage. It's a BA.5.2 with two additional mutations in the spike protein at residue 444 and 346. And then last week, we had an update where we added three additional sub-lineages to the data tracker. And just a reminder, the reason we decide to break things out, sub-lineages out on the data tracker, we have a couple of criteria.

One, it has to reach at least 1% prevalence nationally. Two, it has to have medically relevant substitutions. So it has to have substitutions that could show a reduction in neutralization titers, have some effect on-- we haven't really seen diagnostics-- but have some effect on diagnostics or therapeutics. But what we've really seen most often is substitutions that could affect neutralization.

And then of course, we need a method for identifying those sub-lineages. So early last week, Pango, which is our software that we use to call lineages, released an update that allowed us to call BQ1 and BQ.1.1 sub-lineages of viruses, as well as BA.2.75.2. The nomenclature is getting very confusing, even for those of us who look at it every day.

And so BQ.1.1 and BQ.1 sub-lineages of viruses are now the third and the fourth most prevalent sub-lineages of viruses. And they're both sitting at around 5.7% of viruses that are circulating nationally. Both of those, like BF7, are also BA.5 sub-lineages. So they are very similar to BA.5.

BQ.1 has two additional mutations in the substitutions in the spike protein at residue 444 and 460. And BQ.1.1 has those two, as well as a substitution at residue 346. So it has three substitutions in comparison to the bivalent booster containing BA.5 spike protein. And BA.2.75 is similar to BA.2.75.2, has one additional mutation on top of the ones that are already seen in BA.2.75.

Something that's a little bit hard to appreciate whenever looking at this is we're starting to see convergent evolution, and the same substitutions pop up in multiple lineages of viruses. So for example, the substitution R346T, which is medically relevant, it is a binding site for one of the monoclonal antibodies that's contained in Evusheld. There is a substitution of R346T that is present in BA.4 viruses, BF.7 viruses, BA.2.75.2, and BQ.1.1 viruses. And so we have a combination of sub-lineages where about 20% to 25% of circulating are viruses of multiple different lineages contain a substitution at that residue 346 in the spike protein.

Regionally speaking, whenever we look at these sort of newer named sub-lineages of viruses, the BQ.1.1 sub-lineage is most prevalent in regions two and three with 7% to 8% of circulating viruses are BQ.1.1. And BQ.1 is also most prevalent in region two, but is also taken hold a little bit in region six in Texas and surrounding areas. And that is all for my updates today.

JASMINE CHAITRAM: Natalie, thank you so much. We did have a couple of questions. Two are related to the vaccine, and whether or not they cover the top two variants on your graph, including BA.4.6.

NATALIE THORNBURG: So the vaccine, the bivalent vaccine has the ancestral spike protein, and then it has a BA-- the Omicron's formulation in the US is BA.4, 5, so 4 and 5 have the same spike sequence. So BA.5 is what's in the formulation. BA.4.6 is the same, but with one extra substitution in the spike protein. And these other newly named sub-lineages, BQ.1.1, BQ.1, and BF7 are all BA.5 viruses with one to three changes in the spike.

So what we're looking at is really all but about 3% of circulating viruses are very, very similar to the formulation, the bivalent formulation, with maybe one to three changes. And that's a much less dramatic-- like when Omicron emerged, there were 37 to 45 substitutions across the spike protein, with 15 really concentrated in the receptor binding domain. So we're really seeing much more subtle differences right now than say, whenever we saw an Omicron emerge.

JASMINE CHAITRAM: Great. Thank you. Are you able to say anything about clinical implications for BA.1 and BA.1.1?

NATALIE THORNBURG: So the numbers are too small. It's really only emerged over the past couple of weeks. We have not seen any increase in hospitalizations or deaths. And we haven't seen an increase in case counts, including in the regions where they're higher, prevalence region two, region three, region six, they're kind of hovering, they're kind of plateaued in those regions. And we're not seeing increases in cases, increases in hospitalizations or deaths.

JASMINE CHAITRAM: OK, great. And are any of these variants also an XBB?

NATALIE THORNBURG: No, XBB is a chimera. And I think there have been a couple of sequences identified in the United States, but it's way, way, way below that 1% threshold. I mean, it's really like a handful of sequences identified in the United States.

JASMINE CHAITRAM: OK. And when you get a chance, Natalie, if you could drop the link in the chat for the page that you were showing, that would be helpful. And then there was one other question about medical countermeasures, and whether or not the variants are expected to respond Bebtelovimab.

NATALIE THORNBURG: Oh, Bebtelovimab, yes, Bebtelovimab. I do think that there are a couple of substitutions in some of these variants that have been shown to-- in laboratory neutralization assays that have been-- a reduction in neutralization titers have been demonstrated. BARDA and the FDA are really

tracking the efficacy of monoclonal therapeutics, and antibody prophylaxis products. So they are monitoring that. And then we share our mutations of concern report with them directly so that they know exactly the percentage of viruses that might have specific mutations that could reduce the potency of any of these therapeutics.

JASMINE CHAITRAM: Natalie, thank you so much for joining us. There are a few more questions and comments in the Q&A section there if you want to go in and respond, I'd appreciate it. I'm going to move on to our next topic just to make sure we have time. Our next speaker is Serena Carroll. She's currently the Lab Task Force Lead for the CDC Monkeypox Response. And I do not think we have slides for Serena.

SERENA CARROLL: No, there are no slides today. And this will be a really quick update because I'm sure there will be lots of interest in the next topic. So as of October 14, we have a total of 27,317 confirmed monkeypox virus, or orthopoxvirus cases in the US. This represents a continued decline in cases. So we saw the peak in the July, August time frame, and cases have continued to decline since that time.

We have a total of 117,195 specimens that have been tested as of October 13. And our cumulative positivity rate also continues to decline, and it's currently sitting just below 28%. We have more than 97% of our existing testing capacity that remains available. So overall, I think things are moving in a positive direction for monkeypox in general. Obviously, we still have a lot of work to do, but things seem to be trending in the right direction.

JASMINE CHAITRAM: Thank you so much for some good news today.

SERENA CARROLL: We try.

JASMINE CHAITRAM: All right. We are going to move to our next and final speakers. There's two for today. And we've gotten a lot of questions. And so we thought it would be great to have this topic on one of our calls. We're going to talk about select agent regulations. And I'm going to actually ask Denise to introduce herself, so I don't butcher her last name. And the other speaker will also be joining us is Lori Bane. and thank you both for coming on the call today.

DENISE GANGADHARAN: OK. Thank you good afternoon, everybody. My name is Denise Gangadharan I'm the Associate Director for Science for the Division of Select Agents and Toxins. And along with my colleague, Lori Bane, we're going to discuss the 2022-- next slide, please. OK. It's saying my internet connection is unstable. So hopefully, this goes OK.

JASMINE CHAITRAM: Yeah, you froze for a second. I might suggest you just go off video, and that might—

DENISE GANGADHARAN: I'm going to do that.

JASMINE CHAITRAM: Thank you.

DENISE GANGADHARAN: OK. So this slide, I wanted to put it up here to just have everyone see what our monkeypox regulatory language is. So this has been our regulatory language the past 10 years. And we regulate monkeypox virus. It's listed as monkeypox virus.

And our regulations do provide for an exclusion for any West African clade of monkeypox virus, provided that the individual or entity can identify that the agent is within the exclusion category. So that basically means you can't assume that you have West African clade. You'd have to test it and identify it. Next slide, please.

So we, back in September, sent out what we call as an SA Gram. It's just a way of us communicating with our regulated community. And the SA Gram was attempting to clarify the regulatory status of materials. So I'm going to just go over the information that was in that SA Gram.

So currently, there are two clades of monkeypox virus, Congo Basin clade, or clade I, and the West African clade, or clade II. And up until this point in the 2022 US monkeypox outbreak, laboratory testing has indicated that the current outbreak is associated with the clade IIb, the monkeypox virus. And as I mentioned previously, a monkeypox virus is regulated as an HHS-only select agent.

So any entity that wishes to possess, use, or transfer this agent must comply with our regulations. However, we do have applicable exemptions or exclusions to our regulations. And the next slides will go over that information. So next slide, please.

OK. So as I previously mentioned, we have an exclusion for the West African clade of monkeypox virus, or clade II. And this is the exact regulatory language that any West African clade, a monkeypox virus is excluded from the requirements provided that the individual or entity can identify that the agent is within the exclusion category. And that's the regulatory citation there. And this exclusion would apply to any material that's been identified as being or containing West African clade, or clade II of monkeypox virus. Next slide, please.

So I mentioned we also have an exemption. So I believe this may apply to many of you that are on the call today. It's called our diagnostic specimen exemption. And our regulations provide that clinical or diagnostic labs, or any other entities that possess user transfer and HHS select agent-- so in this situation, that would be monkeypox virus-- that's contained in a specimen presented for diagnosis or verification will be exempt from the requirements of our regulation for such agent if you follow certain requirements. And the requirements are listed here.

The first is to report the identification of the agent to the Federal Select Agent Program, and any other authorities as required by law. And my colleague, Lori, will go over more in depth what is required in terms of reporting. The second requirement is to secure the agent after you've identified it. And the third is

to transfer or destroy the material in accordance with our regulations. And that's the citation that specifies the requirements for transferring or destroying.

Briefly, I'll just mention that for transfers, we have a process-- it's called a Form 2-- that you'd have to complete in order to transfer an identified select agent. If you chose to destroy the material, there are certain requirements, such as if you are an unregistered lab with our program, you would have to use a recognized sterilization, or an activation method to destroy the material. And if you're a registered lab, there are further requirements for in-house validation.

So in the chat, you'll see specific links that will take you to more of the details when it comes to either transferring or destroying the material. And this exemption does apply to material that's been identified as being or containing monkeypox virus. But the clade has not been determined, or the clade has been determined to be Congo Basin clade, or clade I. Next slide, please.

Any entity that wants to retain the material that they have identified, if they're registered with the Federal Select Agent Program and approved to possess monkeypox virus, they can keep this material. And just again, we regulate material that's been identified as being or containing a select agent or toxin, so in this situation, monkeypox virus. So if you've confirmed identification of orthopox virus, and you're using that as a presumptive identification of monkeypox virus, that is not considered a select agent by our program until you've identified the monkeypox virus, or other select agent in your sample. All right, next slide, please.

So this is a simplified chart. I was trying to make everything I just said more easy to understand. So this is the regulatory status of material. The left column lists what your test result is. And the right column will say whether or not our select agent requirements apply.

So if your test results in non-variola orthopox, the select agent requirements do not apply, because that's not a select agent. If your test results in monkeypox virus played undetermined, the select agent regulations do apply. If your test results in monkeypox virus clade I, or the Congo Basin clade, yes, the select agent requirements apply.

If your test results in monkeypox virus clade II, or the West African clade, remember, this is an excluded clade provided that you can prove that that's what you have. Then the select agent requirements do not apply. All right, next slide, please. So the rest of the presentation will focus primarily on selecting the reporting. And I'll turn that over to Lori Bane.

LORI BANE: Denise, are you going to drive?

DENISE GANGADHARAN: No, I think Jasmine's doing it.

LORI BANE: Oh, this is awesome. I get to boss Jasmine around for a little bit. Sorry. So we just wanted to provide some further information on reporting the identification of a select agent. And in this particular case, it's regarding monkeypox. And so one of the things that we have recognized is that, yes, we're

dealing with a current outbreak, and we do have some flexibility in the regulations to authorize less stringent reporting. And so next slide.

So basically, what we've done-- and it should have been probably provided as a link in the chat-- one of the things that we have recognized is for those samples that have been identified with the monkeypox virus, either clade I, or if it's undetermined, what we have done is we are allowing entities to basically batch report those identifications. And we're also allowing that the identifications can be reported for basically, every six months. And so what we're recommending that you do is that, again, it's for clade I, or monkeypox virus that has been not determined the clade. And so you can submit one single Form 4, and then you can submit a spreadsheet that will list information on the different sample providers. Jasmine, next slide.

And again, it's just reiterating the fact that it's only for those that have been identified as undetermined. But what happens if you now have reported to the Select Agent Program that you've either identified and undetermined, and now you've done some type of classification, and you now have identified the clade II? All we're asking that you do is report that information back to the program.

If you have not submitted your report yet, you can actually remove those off of the spreadsheet that you're using. And so again, in the case where you already reported the information to the Select Agent Program, you would just notify us. And we've provided the email. It's kind of easy, CDCForm4@cdc.gov. But if you have not, then all you would do is remove that information off the report that you're sending us to. Next slide.

And now, we're just going to go over some different scenarios with you just to kind of hopefully, answer some of the questions. So we've got laboratory A. That is basically just the sample provider. And they've tested it positive for orthopox. And then they want to send it to laboratory B for further clarification.

So laboratory B identifies it as monkeypox virus, but they have not determined the clade. So who is responsible for reporting that to the Select Agent Program? Well, so each entity that has identified the agent would submit the Form 4. But what we need is there's an A and B part of the form, and so that would be for the reference laboratory that identified it. And then there's a C and D that we would need to be completed from the entity A that basically would tell us if they're still in possession of it, or were there any potential exposures while the facility was working on it.

And then again, the next question is, again, stating that laboratory A has the original sample. We would again want to know again, if they're still in possession of it, and then if there were any potential exposures while they were working on the agent. Again, these are only for the ones that are identified as undetermined, or clade I. Next slide. I think I'm hitting that home, huh, Denise?

And then what are the requirements for waste from those patients that have been diagnosed? And so we do have an exclusion in the Select Agent Regulations that states that any waste that is basically from the patient during the patient care is considered excluded from the regulations as long as it's decontaminated,

or transferred to another site. But they have to comply with both the state and federal regulations for destruction.

And I know a lot of the hospital labs use a company that they use to send the materials out for destruction. And this would be after seven days of the conclusion of patient care. And so most of the time, after the patient has been discharged from the hospital. Next slide.

All right, we'll open up the chat for any questions or comments that you have. And Denise and I will tag team these. So to clarify, if a laboratory uses an assay detecting non-variola-- oh, do I read these, Jasmine? Or do you read them for me?

JASMINE CHAITRAM: You can read them.

LORI BANE: Oh, darn it.

JASMINE CHAITRAM: That's totally fine with me.

LORI BANE: OK. You just want to make me try to say hard words, don't ya? To clarify, if a laboratory uses an assay detecting non variola orthopoxvirus only, without secondary confirmation of monkeypox, am I correct that such specimens are not considered to be potentially contain a select agent, and thus, results would not need to be submitted via Form 4? And so, David, great long question. Denise or Jasmine, can you go back to that table?

JASMINE CHAITRAM: Yeah, hold on.

LORI BANE: And David, you'll be able to tell that I was a previous teacher. So bear with me. Now, for your question, I'm going to make you answer it. So you've identified not monkeypox, but you've identified non-variola orthopox virus. So what would you think? Is it a yes or a no?

JASMINE CHAITRAM: And all of our participants are muted, so he--

LORI BANE: Oh, darn it.

JASMINE CHAITRAM: Answer you in the chat.

LORI BANE: Oh, well you wish you could mute me sometimes, don't you, Jasmine? So David, you are correct. Yes, it's a no.

JASMINE CHAITRAM: All right. I do have some other questions for you, Lori.

LORI BANE: OK.

JASMINE CHAITRAM: And I think you covered this, but if you could just do it one more time so that folks are really clear, first question is, if a non-select agent facility has a monkeypox sample, positive by generic monkeypox test, but not confirmed to be clade II, and it's not for diagnostic purposes, what is the time frame within which they must ship or destroy the samples?

LORI BANE: So they've identified it as a-- it was identified as monkeypox through diagnosis.

JASMINE CHAITRAM: It was generic a monkeypox test, but apparently, it's not a diagnostic test. So maybe it's like surveillance, or research, or something.

LORI BANE: So it's still considered identification. So it's monkeypox virus, clade undetermined. So yes, it's subject to the regulations. And so based on the regulations, they have seven days to transfer it to a registered facility. And in those cases, if there are concerns that they cannot transfer it within those seven days, if they will contact us again, at that CDC email address (CDCForm4@cdc.gov), we can work with them and provide them special permission if they cannot get it transferred within those seven days.

JASMINE CHAITRAM: Great. Thank you for that. Another question is, if lab A simply refers the specimen to another lab, lab B, and lab B performs all the testing and identification, does lab A have any reporting requirements?

LORI BANE: Now, that one's a great question. And unfortunately, yes, they would, because again, regardless if they send it, one of the things that the reference laboratory is going to do is, they are going to complete that A and B part. And one of the things that we want, we we're really interested in knowing is depending on how the reference laboratory completes it, if they sent the entire sample to the reference laboratory, then no, there's no reporting requirements. But we may follow back up with them one, to confirm if they're still in possession of the sample. And in this particular case, there was no work. So there was no occupational exposure.

And that's really kind of what the Form 4 is. We just want to make sure that we ensure compliance. And so as part of compliance, and making sure that those samples aren't readily available, and got missed, or the possibility of an exposure, and that we need to make sure that there's some type of medical countermeasures going on.

JASMINE CHAITRAM: OK, great. And another question opportunity for you to kind of reiterate, it's the same sort of thing, where a sample is being submitted. It's not up to the provider. There's nothing that the provider needs to do that submitted the specimen. Is that correct?

LORI BANE: Correct.

JASMINE CHAITRAM: OK. And let's see, this one, I haven't had a chance to proofread it first. But it says, if a lab has a test identifying generic monkeypox, and it's been validated for a clinical diagnostic use, and then performs typing identifying all cases as clade II, does the lab need to report?

LORI BANE: No, that was one of the FAQs is, so they've identified it. And then they've gone to that further step and determined that it's an excluded strain of a select agent. And so that would be excluded. So therefore, there are no reporting requirements.

JASMINE CHAITRAM: Excellent. Thank you so much, Lori and Denise, for being on with us today. I think it was really helpful for the labs to hear it from you guys. And appreciate your time, as well as all of our other speakers for joining. We're almost out of time. I did want to mention there was a couple of questions in the chat about non-Ebola routine diagnostic testing and guidance for those specimens from an individual that might be a suspect case.

CDC is putting together some information, and will hopefully be able to host a webinar in a couple of weeks. So keep an eye out for that notification when we get that together and can provide that to you again, through the OneLab Network. And just thank you all again, for your time today, speakers especially, for spending time with us, and answering questions, and putting together great presentations, and excellent updates. And we will see you again in a month. So take care everyone.