Call Date 11/13/2023

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Call Transcript

Jasmine Chaitram: Hi, everybody. Welcome to the Laboratory Outreach Communication System, LOCS, call. Glad you can join us this afternoon. I'm Jasmine Chaitram. I am the chief of the National Laboratory Response System Branch in the <u>Division of Laboratory Systems</u>. And showing on the screen today is the agenda for today's call. I will cover a few announcements before we get into the speakers having their updates.

Saying one second, OK. Just a reminder that the Division of Laboratory Systems supports clinical and public health laboratories across the country in a variety of ways. And these calls are really about emergency preparedness and response activities. And we started these calls in March 2020 as a need for the COVID pandemic.

There are four goal areas in which DLS supports clinical and public health laboratories. That's quality laboratory science, workforce development in creating a highly competent laboratory workforce, having safe and prepared laboratories, and accessible and usable data.

The LOCS Calls are all archived. So if you miss anything or you have to drop early or you want to see information that was presented one more time, we do have a <u>page</u> where everything is archived,

including transcripts and slides from the call, as well as audio recordings and the agendas. And also, you can find any LOCS emails on this page that we've sent out previously.

We always want to hear from you about any of your training and workforce development needs. So if you have any questions or you have any suggestions for education or training, please contact the laboratorytrainingneeds@cdc.gov.

We have a new training course that is available on OneLab REACH called Fundamentals of Communicating the Hazards of Laboratory Chemicals. This is a basic-level course. It is designed for public health and clinical laboratory staff, safety professionals, and others who work in the laboratories where hazardous chemicals are routinely used and stored. It introduces OSHA standards and their role in providing information to laboratory staff regarding the hazardous properties of chemicals used in the laboratory. This course offers P.A.C.E.® credit and you can take it at reach.cdc.gov or scan the QR code on the screen. And these slides will be posted, so if you need to come back later to scan that QR code, it will be there.

There will be an 18th CDC International Symposium on Biosafety during March 10th through the 14th in Atlanta. You can register to attend. And the symposium will provide a series of engaging sessions about modernizing biosafety operations and practices. Symposium topics will include Modern Lab Design, Artificial Intelligence, and Biosafety in Space. You can find registration details and the symposium agenda on the website. The link is shown there, and we will also drop it in in the chat.

And a reminder when you're asking a question, to please use the Q&A feature in the Zoom webinar system. We do not want questions to be submitted in the chat. We do track these questions. And it allows us to just have an understanding of what the questions are that the lab community has or concerns so that we can help to formulate future agendas. When you put these items in the chat, it disappears after the call so we can't keep a record of those.

In addition, if we're not able to answer your question during the call, we can get back to you if we have your email information. So when you submit your question, if you want to submit your email as well, that will allow us to follow up if needed. And for media, please contact the CDC Media Relations at the website, email address shown here. Prefer not to take media questions on these calls. These calls are not intended for the media. It's for the laboratory community.

And just also another reminder that the slide decks may contain information that doesn't necessarily represent the views of CDC or panelists or may not be affiliated with CDC. So be aware of that when you're looking at these slides or you're referencing them later.

And with that, I think we're ready to go to our first speaker, who has been a regular on our calls, Natalie Thornburg, on the SARS-COV-2 variants. And she's going to give us an update.

Natalie Thornburg: Thank you, Jasmine. I'm going to go ahead and share my screen. Thank you. All right, we should be good there. All right. Let me make sure. Can you guys-- can you confirm, Jasmine, that you can see-- actually, I don't think it is sharing.

Jasmine Chaitram: No, it is sharing. I see it.

Natalie Thornburg: It is? Oh.

Jasmine Chaitram: You're good.

Natalie Thornburg: OK. Thank you. All right, so this is our <u>EPI-situational update</u> first. Right now, so this is the weekly COVID-19 new hospitalization admissions in the blue bar. And on the right axis, the orange line is the weekly percent test positivity. And that test positivity is a pretty good indicator of community transmission of the virus.

It has not really been circulating long enough to say true seasonality, but we are beginning to see patterns of waves since 2021. We've seen late summer, early fall wave, followed by a winter holiday travel wave. So we saw that in 2021. Last year in 2022, we saw a pretty big BA.4, BA.5 wave in the late summer, early fall, with a smaller XBB wave over the holidays.

This year we saw again, late summer, early fall increase in cases that peaked at about 14.5% positivity that last week of August. And it has been falling since then. If this year transmission is similar to the previous two years, we could expect an increase in cases between Thanksgiving-- and the Thanksgiving and New Year's holidays. And each year, it peaked right after New Year's. So if this year looks similar to last year and the year before, we might see an increase in cases peaking around New Year's.

This is the picture of genomics circulating right now. As a reminder, the left side of the graph is called weighted estimate. These are proportions of cases. So it doesn't capture the total number of cases being caused by each lineage of virus. It's always a proportion. So when cases are low, still, the proportions are all added up to equal 100. When cases are high, all the proportions are added up to equal 100%.

The weighted estimates on the left side of the graph are the actual sequences. And those weighted estimates are used to calculate growth rates, which we use to predict into the present tense. And the reason that we do that is because it takes time to collect a specimen, identify it as SARS-2 positive, get it to a laboratory that can perform whole genome sequencing, actually perform that whole genome sequencing, which is, you know, multiple days, maybe a week, get it analyzed, and then get that data to the CDC or into a public repository. And so that lag time-- in that lag time, we utilize the actual sequences to calculate those growth rates into the present or Nowcast. So the data on the right is modeled data, modeled into the present tense.

The data bins are by weeks. We update them every other week on Fridays. This week, we were delayed one day due to a holiday. And then on Thanksgiving week, we will also delay it one day and be posted the following Monday. But typically, it is posted with all other data Friday mornings.

What you can see is that the HV.1 lineage of virus is predicted to be the most prevalent virus lineage circulating nationally, with EG.5 predicted to be the second most prevalent. But they have overlapping confidence intervals. So their approximate-- predicted to be approximately equal nationally.

It looks like there's a lot of diversity in the circulating viruses. But there is not because we use aliases now with this Pango lineage of genomics, meaning once you get a large number of numbers after the letters in the name designations, an alias will be assigned to it. And that's assigned in order, not necessarily relevant to its parental lineage. And so really, all of these lineages, with the exception of BA.2 right there and CH.1.1., everything else on this data tracker are XBB lineage viruses. And they are very, very similar to each other, often with identical spike sequences with 0, 1, 2, 3, changes in the spike protein in comparison to the current vaccine formulation. So right now, the vast majority of viruses, 95%, 99% of circulating viruses are very, very similar to the composition of currently available vaccines.

The lineages that are growing fastest include HV.1-- and that just took over-- is predicted to be the most prevalent lineage, HK.3 lineage virus and JD.1 lineage viruses. If you scroll down beneath the map on the data tracker, you can see a dendrogram. This is not a true phylogenetic tree, but just shows you the relationship of viruses. And these two are some-- their HV.1 and HK.3 are some of the faster growing lineages. They are sub-lineages of EG.5 with an additional change. And then you have JD.1, which is a sub-lineage of XBB.1.5 virus.

Oh, and I'm sorry that I just-- there we go. All right, and that ends the genomic update for me. Thank you.

Jasmine Chaitram: All right. Thank you very much, Natalie. I'm not seeing any questions for you at this time, so I think you're excused for now. But if you want to stay on and help us with any questions that might come up, we would appreciate it. Thanks for that.

OK. I'm going to go back and share my own screen. And that looks good. So we have a next speaker coming up is going to be Kim Sapsford from the Food and Drug Administration, talking about emergency use authorization for IVDs, or in vitro diagnostics. And I have seen Kim give this presentation before. I think it is super helpful, answers all your questions about EUAs. And we're very grateful that Kim could be with us today. Turn it to you, Kim.

Kim Sapsford: Thank you, Jasmine. So you want to go to the next slide. Excellent. So I'm going to talk today-- hang on. Let me get my slides up-- talk today about why EUAs are needed. I'll talk very briefly about EUA authority and the criteria for issuing an EUA.

I'll then talk briefly about EUA versus traditional marketing submissions, the EUA documentation, and then FDA's role post-issuing an emergency use authorization.

So why are legal and regulatory mechanisms needed for emergency use of medical products? So without these legal mechanisms, there's certain preparedness and response activities that would otherwise violate provisions of the Federal Food, Drug, and Cosmetic Act. These products are needed-- these EUA products are needed for a response. They may not be approved, licensed, or cleared by FDA at the time. The products needed for the response might be approved by FDA, but not for the indication that's needed for the emergency. EUAs ensure PREP Act coverage. Act protections apply. They also facilitate import, export, and distribution of the product without violating the Federal Food, Drug, and Cosmetic Act. And then it allows facilities to pre-position MCMs for emergency use upon authorization. Shall we go to go to the next slide, Jasmine?

So the EUA authority is under Section 564 of the act. And this, with an EUA, FDA can authorize unapproved medical countermeasures. And they can also approve an unapproved use of a medical countermeasure product, i.e., giving it a new indication. And this is to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a chemical, biological, radiological, or nuclear threat agent when certain criteria and prerequisites are met. OK. Next slide, please, Jasmine.

So the prerequisites for an EUA are that there needs to be a determination and a declaration. The determination can come from one of four sources, the Department of-- sorry. The Department of Defense Secretary can declare-- can make us a determination that there's a military emergency or significant potential. The Department of Homeland Security can make a similar determination and also can make a material threat determination. And then the HHS Secretary can make a determination for public health emergency or significant potential for a public health emergency.

Once that determination is made, this allows the HHS Secretary to then make a declaration that circumstances exist justifying the use of the EUA authorities. And this declaration then allows the FDA commissioner to issue EUAs until the EUA is terminated, or the-- sorry, the declaration is terminated later. So you want to go to the next slide, Jasmine?

So the EUA criteria, the main criteria, are as I described. It's a serious or life-threatening disease or condition caused by an agent. The other criteria is the totality of scientific evidence is reasonable to believe that the product may be effective and that the known potential benefits outweigh the known potential risks of that product when it's used in its intended use, and there's no adequate approved or available alternative to the EUA product. So we want to go to the next slide, Jasmine?

So as I said, one of the criteria was the scientific evidence. And so DMD looked at the typical studies that we require for an infectious disease IVD in the traditional pre-market space and tried to determine what would be the minimum scientific evidence needed to allow a product to be used under EUA. And so we identified three studies that we typically require as part of a pre-market application that are given the time crunch of an outbreak situation. These studies typically require an extended period of time to do. And those were the precision/reproducibility study, the reagent stability study, and then obviously, the clinical

evaluation, especially at the start of an emergency when access to clinical specimens can be very difficult.

And so this slide outlines the typical studies requested for a molecular-based assay. As you can see, the LOD is required for both. This is a cornerstone study. And so that's why it's very important for the EUA, as well as the regular submission. And then for inclusivity, we do require inclusivity, but that can be technology dependent and specifically for molecular assays, we can look at in silico analysis.

The same for exclusivity or cross-reactivity. Again, that is technology dependent. And we can rely, especially for molecular tests, on in silico analysis. Interference studies are obviously required for regular submissions. They can be technology specific for EUAs. A lot of the times, if we're dealing with a standard molecular test that has an extraction method, we will not require interference studies for the EUA test. But again, that's technology specific.

And then as I mentioned, the precision study is not a requirement for the EUA. We do prefer fresh specimens if possible, and you can do a fresh-frozen if they're not used in the clinical evaluation. Specimen stability, we typically don't require it as part of the initial authorization, but they do-- sorry. I'm getting through to the next one. Sorry.

Specimen stability, it depends if you're making claims for recommendations out of what's outside of what CDC would typically recommend for that specimen type. For the reagent stability, we don't require that for the initial EUA, but we do require that the study design is approved by FDA. And then that study is started as soon as the sponsor receives their emergency use authorization.

And then clinical study, as I mentioned, sometimes it can be very limited for the initial EUA. And then we may have a condition of authorization that would require clinical evaluation to be done should specimens become available later on. So if you want to go to the next slide, Jasmine. I'm sorry, the next one again.

So EUA documentation is a very important part of the EUA submission packages. We have the EUA fact sheets. And these communicate to health care providers and patients the associated benefits and risks of using the emergency use authorization test. We typically develop these templates for these fact sheets at the time of the emergency, and we share them with test kit developers so they can use them for their EUA submissions.

Another important document is the manufacturer package insert instructions for use. Or if it's a laboratory-developed test, we normally have reviewed the standard operating procedure. And we publish an EUA summary online. And those documents describe how to perform the test and how to use the EUA product. And they also summarize the analytical and clinical performance the FDA used to assess the benefit risk of the EUA product for its intended use. So you want to go to the next slide, Jasmine?

The other key document for EUA packages is the letter of authorization. And it's this letter of authorization that authorizes the emergency use of the test and allows it to be distributed in the US. The letter includes

the criteria of issuance of authorization and the scope of authorization. And the letter includes conditions of authorization that are required to be met by the manufacturer of the test, any distributors, this includes third-party distributors, the laboratories that are using the test, and anybody else that may be using the product. So you want to go to the next slide, Jasmine?

The letter of authorization will also include things that are waived, certain requirements that may be waived for the purposes of the EUA. And one of the most common ones is waiving of good manufacturing practice because FDA appreciates that it can take some time to bring an IVD under full GMP compliance. And so a lot of the times, that will be waived initially as part of the authorization.

There are risks associated with this, as evident by the number of compliance activities the FDA dealt with during COVID. And if you want to go to the next slide, Jasmine.

The letter of authorization, another key element to this is the conditions of authorization. And these conditions relate to the distribution of the EUA product, its manufacturing and labeling, registration and listing requirements. It outlines how sponsors can make changes to the EUA product that can be requested and made, how to report test results and any adverse events.

It outlines certain content that's required to be included in any descriptive printed matter, advertising or promotional materials. And more importantly, outlines any required post-authorization studies that are required as a condition of authorization. And this can include the real-time reagent stability studies, reevaluating any analytical clinical studies, submitting the product to an independent evaluation, testing any recommended reference materials, and then any continued evaluation such as how the test responds to any mutations that may occur in the pathogen.

So it's very, very important that all parties involved in the manufacture, distribution, and use of the authorized product are familiar with the content of the letter of authorization and the associated conditions of authorization. So you go to the next slide, Jasmine.

So we post all of this information publicly on the <u>FDA website</u>. And the links are included here. And if you go to the next slide, Jasmine. In the links, we have web pages for each of the different emergency declarations that we have. So this is a screenshot from the COVID, but we have for all of the tests that we authorize, we include the letter of authorization. We include any subsequent granting, which we'll update-we'll describe any changes to the product. We post the fact sheets for health care providers and patients, and then also, the instructions for use or the EUA summary for laboratory-developed tests. And we post this information in near real time on our website.

And if you go to the next slide, Jasmine. I just wanted to describe our FDA's role once the EUA has been issued initially. So we follow up quickly with manufacturers if there's any potential issues with performance that are observed, such as false positive or false negatives. We can monitor supply and device usage. We can effectively authorize any modifications to the EUA through supplements. This can

include new specimen types or addition of new instruments, which will either trigger a reissuance of the EUA letter, or it can be granted at the division level.

We follow up on reports of misuse of the test and any fraudulent claims. And any EUAs that are revoked, either due to an action by FDA or at the request of the sponsor, these EUAs are posted on FDA's historical web page. And then we also occasionally deal with EUA declaration terminations, like we did recently with the EV-D68. If you go to the next slide, I just want to thank everybody, and here are some resources.

CDRH have their own <u>EUA page</u>, as well as the FDA-wide <u>EUA page</u>, which includes products from CDER and CBER I've also included links to the <u>COVID</u> and the <u>Mpox</u> pages, the <u>historical website</u> so you can look at EUAs that were revoked. And I've also included some links to the <u>CDRH device databases</u>, where you can look, using the product codes that I've listed at the bottom of the page, you can look to see what tests have been clear and approved for-- these are COVID examples. But hopefully, that's a useful resource for people. And that's it. Thank you.

Jasmine Chaitram: All right, Kim, thank you very much for that very informative presentation. We did get one question in the chat, which I think is-- I'm sorry, in the Q&A, not the chat. Don't put it in the chat. Put it in the Q&A.

The question is pretty general about how can a laboratory get a test authorized under the EUA. Is there-I know you're showing this page with authorizations. But is there a page that has the how-to to get an EUA?

Kim Sapsford: I think that's normally-- we normally publish that sort of information in our policy guidances. So you can have a look at some of the policy guidances on the CDRH COVID page. You'll have a link to the policy guidance. And that will explain how to actually submit an EUA request to FDA. It also describes what we will review and what we won't. So you want to look at FDA priorities in that policy guidance as well. But generally, there's an email in there that you would submit your package to the email inbox, and then it would get logged in as an EUA submission if there's a declaration for that particular pathogen. If there isn't a declaration for a pathogen that you're interested in developing a test for, we can review it in the pre-EUA space. So yeah, those are the different options.

Jasmine Chaitram: Thank you very much, Kim. I'm not showing any other questions for you at this time. Really appreciate again, that you were able to come on and do this presentation for us today.

Kim Sapsford: Thank you. You're welcome.

Jasmine Chaitram: All right, we are going to move to our next topic on the agenda, which is going to be a presentation about *Brucella* - What's New: Changes and Challenges, from Kurt Jerke. And I will turn it over to you, Kurt.

Kurt Jerke: Well, thank you. And thank you to the CDC for giving me the opportunity to speak with you all today. Next slide, please.

I just do have to let everyone know the information presented here today are my own views and opinions, and they do not reflect that of the government, the United States Army, or the United States Military Academy. Thank you. Next slide.

So just a brief outline of some of the topics that we're going to cover today. Next slide. OK. So before we dive in, I just wanted to refresh everybody maybe a little bit on what is *Brucella*, or at least when we refer to select agent species of *Brucella*. So these are gram-negative coccobacilli, pretty small, about 0.4-by-0.8 microns. They are the causative agent of brucellosis. This is a zoonotic disease.

So we associate this with *Brucella melitensis*, *Brucella suis*, and *Brucella abortus*. Those are all select agents. And you can see the various organisms that are associated with those bacteria. And then also, *Brucella canis*, which is carried by dogs, but it is not classified as a select agent. Next slide, please.

OK. So brucellosis presents a couple of different ways. There's an acute disease. Generally, patients complain of fever, headache, muscle pain, joint pain. It's a fairly nondescript types of symptoms. And then there's also a chronic disease, where patients will have recurrent fever, again, kind of complaining of fatigue and some joint pain. So again, nothing really specific that screams the patient has *Brucella*.

One of the problems or challenges with *Brucella* is it's got a very low infectious dose. So literature cites anywhere from 10 to around 100 microorganisms is all that is needed to initiate the disease process. And then there are various routes of exposure where one can be exposed to these bacteria. A primary one is in the laboratory. And in fact, the CDC points out that *Brucella* is still one of the most commonly reported laboratory-associated infections due to bacteria. Certainly, we can get this from food, for example, from things like unpasteurized cheese, and then exposure to animals, either occupational or recreationally. Next slide, please.

So first thing I want to hit on as far as at least the changes go, has been a recent taxonomic change. And this relates to the genus *Ochrobactrum*, which was designated as a genus back in 1988 largely based on phenotypic data. So these were non-enteric, anaerobic gram-negative rods. They were shown to produce acid from several different carbohydrate sources, and they were motile.

These are environmental organisms. They can be found in a variety of sources to include from soil, from water, plants, and from various animals. By and large, they are opportunistic pathogens. There are about 18-- or there are 18 different named or formally named *Ochrobactrum* species out there. And of those 18, 5 of them have been named in clinical scenarios.

So some of them have the potential to be opportunistic pathogens, not all of them. And again, they generally are kind of low virulence type of infections. But then, this brings us to 2020. So it was proposed to reclassify the *Ochrobactrum* to the genus *Brucella* based on genotypic data. This is in line with the

rules under the International Code for Nomenclature of prokaryotes. And they are currently undergoing this process of being renamed.

Right now though, both names are considered valid. So whether you want to use the *Ochrobactrum* genus name or the *Brucella* name, these are both considered valid. It is important though that labs point out, and particularly in their reporting-- and we'll get into this a little bit more later-- is that if you're reporting out *Brucella*, formerly *Ochrobactrum*, these species do not cause brucellosis and they are not classified as select agents. Next slide, please.

OK. So for reporting, so again, both nomenclature are still considered to be valid. I do want to remind everyone though that CAP does have as a requirement under MIC.11375 that it does require laboratories to update their nomenclature under certain types of conditions, one of these being for purposes of antimicrobial susceptibility breakpoints and for antimicrobial susceptibility reporting.

The other thing is it's really important to communicate with the clinical staff. And again, just want to reiterate that if you are using the new nomenclature and ASM is recommending reporting these as *Brucella* with *Ochrobactrum* in parentheses, that this is not an agent that causes brucellosis. And again, this is not a select agent. But it's still important that the lab state, you know, hey, we have ruled out this as being a select agent Brucella species. Next slide, please.

So as far as antimicrobial susceptibility testing, if you are unable to rule out that it is a select agent Brucella species, then this needs to be referred to a LRN reference lab for further confirmation, in the case of *Brucella*, formerly *Ochrobactrum*. So if your lab is using CLSI standards, then you're going to apply the "Non-Enterobacterales" methods and interpretations for reporting.

For biosafety requirements, select agent *Brucella* species need to be handled in a BSL-3 environment or in a BSL-2 environment with BSL-3 precautions. In the case of *Brucella*, formerly *Ochrobactrum*, these can be handled safely using standard BSL-2 laboratory procedures. But again, this is in a case after you have ruled out that it is a select agent Brucella species. Next slide, please.

OK. So there's in the process right now, ASM and APHL of updating the sentinel-level guidelines. And I'd like to thank both organizations for the work that they've put in getting these updated. But some things that I want to point out, particularly in the context of this change with *Ochrobactrum* is there's a few things that we can look at to quickly and easily distinguish these select agent *Brucella* species from *Brucella* (*Ochrobactrum*).

One of these, most obviously looking at the picture on the right, is growth at around 48 hours. So if you look at the blood agar and chocolate agar for *Brucella*, which is shown on the top, again, you're just seeing this very small growth, still kind of pinpoint colonies. And then there's no growth on the MacConkey agar.

Comparing this to the two species of *Brucella*, formerly *Ochrobactrum*, shown below, so *Brucella anthropi*, *Brucella intermedia*, these have very prolific growth at 48 hours. And these organisms will also grow on MacConkey agar, again, unlike the select agent Brucella species. Next slide, please.

So then this brings us to our challenges with *Brucella*. So typically, we think of *Brucella* as being a gramnegative organism, which it is. But there have been a series of reports relatively recently, dating back to 2017, of *Brucella* staining as a gram positive organism. And I've listed the reports, or the major ones that I was able to find in the literature. And you can see, this is really it's across the United States with reports coming out of Washington, as well as New York, and internationally as well, with one case that was reported in a case study from Saudi Arabia.

But in-- pardon me-- in all of these cases, these were specimens that were taken from blood cultures. They had a very slow time to positivity. So blood culture bottles did not turn positive typically, from 24 to 96 hours when they performed the gram stain from the bottle, they reported out as either gram positive rods or cocci. But then when they subcultured these, then the organisms appeared as either gramvariable or gram-negative coccobacilli. Next slide, please.

So the image here shows our-- what we typically think of *Brucella*, select agent *Brucella* looking like under the microscope. So if you look to the left there, there's that big clump of gram negative cells. Again, these are very small coccobacilli. They can be hard to resolve. Sometimes looking under the microscope, just kind of have this big, pink, aggregated mass. Again, they're gram negative and often aggregate together. Next slide, please.

So these are some *Brucella*, select agent *Brucella* species with the atypical staining morphology. So again, they are gram positive. They appear more coccobacilli to rod shaped, rather than these large aggregations like we see with the more traditional *Brucella*. These are appearing as singles, pairs, or chains. But again, not seeing these large aggregations. Next slide, please.

So keeping this in mind, just a few things I think it's worthwhile for labs to think about. So one is, this really highlights the importance of communication between the laboratory and clinicians. If clinicians have this high on their differential or they are suspecting brucellosis, that this is being relayed to the lab can help make sense when you get maybe something that's not gram staining the way that it should. Of course, education and training for the laboratory staff-- I think now that the labs are becoming more aware that this is a potential problem, they can begin to think about how to counteract it, think about steps or places in their laboratory processes where they may be able to put some steps in to mitigate this as a potential risk.

And then reconsidering some of their laboratory processes-- one of these may be as laboratorians, we need to think about not just worrying about slowly growing gram-negative rods or coccobacilli, but having elevated concern for really, all slow-growing organisms, particularly those taken from blood cultures and working all of these organisms up in a biological safety cabinet. Next slide, please.

So this concludes my presentation. Are there any questions?

Jasmine Chaitram: Thank you so much, Kurt, that was great. There is one question. It's, what caused the false gram-positive staining for *Brucella* species from the literature?

Kurt Jerke: So what causes them to stain gram positive?

Jasmine Chaitram: Yes.

Kurt Jerke: We wish we knew. I don't think there's been nothing that I've come across in the literature that explains either something with the biochemistry or the genetics of the organism, or something that was done in the way that they were handled that caused them to stain gram positive. In a couple of the reports, they made a point of mentioning these things were restained. This was done by experienced technicians. You know, so it wasn't a laboratory error. It was a legitimate result from that organism.

Jasmine Chaitram: All right. Great. Thank you so much. I'm not seeing any other questions at this time. If you can stay on though to the end of the call in case one pops up in the Q&A and you can go ahead and answer it for us that would be much appreciated.

Kurt Jerke: Happy to.

Jasmine Chaitram: Awesome. Thank you. And thank you again for joining us today. And I know we've been wanting to hear this *Brucella* update for quite some time. So really appreciate you speaking. Our next presentation is from the Division of Laboratory Systems. Our communication team has done a lot of work to improve the LOCS website that I talked about in the beginning, our archive, to make it easier to search and filter, especially for emails. And I think that for those of you that do go back there to try to find something like I do from a couple of years ago, you're going to find these updates very helpful. James, take it to you.

James Bratton: Thank you, Jasmine. My name is James Bratton. And I'm a Health Communications Specialist in our Division of Laboratory Systems Office of Communication. Jasmine, I'm going to just go right to sharing my screen to show the <u>web page for LOCS</u>.

Well-- so just quickly, earlier this autumn, we added search, sort, and filter functions to our website. So these functions, as Jasmine said, make it easier for us, or for any of you to search through the more than 300 LOCS messages archived on our website. So you can scroll down a little bit on your screen. You'll find latest news from LOCS. The top three messages will be there, how to engage with LOCS, and then we have our search, sort, and filter function.

So among the 300 messages, we have those that date back to the website's inception in 2017. And filters include topics like message type, federal partner mentioned, professional organization. So you can click on a dropdown menu to find a variety of selections. And then it'll show you the results, how many we have

in our database of past messages. And then you can click on the messages to find particular content of interest to you.

So after professional organizations mentioned, we have the year published. We have disease mentioned, laboratory topic mentioned, and pathogen. So earlier today in this call, we heard about EUAs. So you can select on that and find an assortment of messages.

So we're hoping that this is an improvement for folks who are interested in looking at what's been published in the past. If you want to contact us about the website, please email us at locs@cdc.gov with the subject line "LOCS website." Thanks, Jasmine, that concludes my presentation.

Jasmine Chaitram: All right. Thank you very much, James. I don't have any questions for you. Hopefully when-- and is the new page live now?

James Bratton: Yep. It sure is.

Jasmine Chaitram: All right. Great. So hopefully, folks will check it out and see if they have any questions for us, which they can submit through the LOCS email, locs@cdc.gov. Thank you, James. And thanks for all the work on this. Appreciate it.

James Bratton: You're welcome.

Jasmine Chaitram: All right. Well, that kind of wraps us up for the day. Our next call will be on Monday, December 18 at the same time, 3:00 PM. And that will be our last call for the year. We do need your help though with topics for that call, so please send us your ideas for things we should be discussing that would be useful to your lab community.

And I'm also just showing quickly some of our CDC social media sites that you can go to visit things that are happening. And just finally, thank you all for your time today, and we will see you in a month. Have a good day, everyone.