Transcript

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Welcome
Sean Courtney
CDC Division of Laboratory Systems

Avian Influenza Update
Carrie Reed and John Barnes, CDC Influenza Division

Marburg Virus Disease Update
Christine Kosmos, CDC Marburg Domestic Response

Aircraft Wastewater Surveillance for Early Detection of SARS-CoV-2 Variants
Cindy Friedman, CDC Division of Global Migration and Quarantine

CLIA Post-PHE Guidance
Sarah Bennett, Centers for Medicare and Medicaid Services

FDA Update
Timothy Stenzel, U.S. Food and Drug Administration

Sean Courtney: All right. We'll go ahead and get started today. Thanks, everybody, for joining our call. My name is Sean Courtney, and I'm a Health Scientist in the Division of Laboratory Systems here at the CDC. On the screen is our agenda for today's call. Sorry I'm moving things around. But before we get started, I just want to cover a few of our announcements as well as some housekeeping items.

All right. 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 DLS supports this work across four goal areas. So 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 the audio transcript and the slides, and we'll post them online by the end of next week. You can find them on CDC's Laboratory Outreach Communication System page shown at the link here.

And so we want to hear from you. Our Training and Workforce Development branch is interested in hearing more about the education and training gaps that you're currently experiencing, and we invite you to send feedback to labtrainingneeds@cdc.gov.

I'd like to ask you if you have a question today to please use the Q&A function in Zoom, not the Chat feature so that we can address it during the call. Also, please include your email so that we can follow up if we're not able to address your question during the call. And if you're from the media, we'd like to ask that you-- and if you have any questions about the presentation or want to follow up, we'd like to ask you to please reach out to CDC Media Relations at media@cdc.gov. And of course, if you're a patient, please direct any of those questions to your health care provider.

And CDC's OneLab TEST is now live. We invite you to join the newest OneLab element by visiting the link shown here, as well as-- I'm sorry, excuse me. As a OneLab test member, you can engage with a diverse community of testers, network with peers and experts, and access free online courses, resources, and job aids.

And so look for more details on OneLab test kickoff event in June. And as always, I'd like to remind everybody that these slide decks may contain presentation material from panelists who are not affiliated with CDC, and presentation content from external panelists may not necessarily reflect CDC's official position on the topics covered.

And with that, I'd like to introduce our first speaker today. We have Drs. Carrie Reed and John Barnes from CDC's Influenza Division. And they'll be providing us with an avian influenza update. Carrie?

Carrie Reed: Hi, there. Thanks, Sean. Hi. This is Carrie Reed. I'm the Branch Chief for Epidemiology and Prevention Branch in the Influenza Division at CDC. And John Barnes is on with me today as well.

Now as you're aware, I think John has presented on this call before, along with others, that CDC and our partners continue to monitor and respond to outbreaks of highly pathogenic avian influenza, H5N1, in wild birds and poultry. And while we continue to assess that the overall risk to human health is low, we know that influenza viruses are unpredictable. Outbreaks are ongoing in wild birds, poultry, and mammals, which necessitates diligence on our part and on the part of our partners as well.

We've been working for a while now with STLT partners to monitor people with known exposure to H5N1 viruses to quickly detect any cases that occur. Usually, this is people that have been involved in poultry depopulation efforts. But given the severity of illness of the recent human cases, CDC has also been discussing with partners the feasibility of increasing surveillance efforts among severely ill persons in the ICU during the summer months when seasonal influenza activity is otherwise low.

So this would help us detect any rare human cases of H5N1. Would also help identify other potential cases of variant influenza viruses, which we often see associated with agricultural fairs and other agricultural events during the summer and late summer.

And so one of the challenges is that while clinically available influenza tests will detect H5N1 and other novel influenza A virus infections, most clinical testing doesn't include subtyping. So while they would

result as an influenza A-positive, you wouldn't necessarily know that a patient has an infection with something other than a usual H3N2 or H1N1 virus without further testing.

And so to enhance detection over the summer, this would mean requesting that influenza A-positive samples from ICU patients that are not subtyped in the clinical labs would need to be submitted to the state public health laboratories for subtyping. So based on preliminary assessments and analyses in our branch, we think that an increase in influenza-- in testing like this over the summer would yield maybe about 150 specimens or less per week across the country. And so based on preliminary discussions with some partners, it seems that that number would be manageable for public health labs, again, if we focused on patients in the ICU.

This could be done in different ways, depending on what works best for the hospital. Ideally, it would be sending influenza A-positives from ICU patients for which subtyping was not performed or the sample was subtyped but was negative for both H1 and H3 on testing.

We recognize and we've heard from partners that identifying specimens from ICU patients in particular may be a challenge. If clinical labs are unable to separate ICU samples from samples of other hospitalized patients, they could also submit influenza A-positive specimens from hospitalized patients if needed.

And so our goal in speaking with you today-- we've started to socialize this idea with other partner organizations. We think that you're important partners. Are interested in hearing questions, hearing feedback, reminding partner groups to remain vigilant for influenza over the summer. We're talking to clinicians, clinical labs, public health labs, epi colleagues, and more over the next few weeks.

We think this is an important step for continued vigilance around H5 in the US, especially in the summer when influenza testing is not necessarily as top of mind as it is during the flu season, but also when respiratory virus illness is lower than it usually is, and this may not be as burdensome at this time of year as it could be during peak influenza season. So we wanted to get on today and just talk a little bit about that enhanced surveillance over the summer, and are interested in any questions that you might have or feedback that you might have for the next few minutes.

Sean Courtney: All right. Thank you for that update. I do not see any questions currently in the chat. We can hang out and see if anything come up. But if they come up later, we'd like to ask that you please hang around and maybe answer them within the Q&A function within Zoom to address them. If not, we can reach out to you later if questions pop up. But thank you again for joining our call today and providing the avian influenza update.

Carrie Reed: Great. Thanks. Yeah, we'll be on. Both myself and John will be able to answer questions. Thanks.

Sean Courtney: Great. Thank you so much.

Okay, so we're going to move ahead. Unfortunately, we don't have one of our callers right now, so we're going to move to Dr. Cindy Friedman, who's going to present on aircraft wastewater surveillance for early detection of SARS-CoV-2 variants. All right. And Cindy?

Cindy Friedman: Yeah, I'm on. Thank you.

Sean Courtney: Thank you.

Cindy Friedman: OK. Today, I'm going to talk about the Traveler-based Genomic Surveillance Program. In particular, the aircraft wastewater surveillance aspect of the program. So I'll take the first slide. Great, thanks.

So I just want to refresh everyone's memory. Some of you may have recalled-- I know I've given this talk for CSTE on some of the state calls before about our Traveler-based Genomic Surveillance Program, which has two main goals. It was set up as a pilot in September of 2021 at three airports, and the two goals are to enhance early detection of new SARS-CoV-2 variants and to fill gaps in global SARS-CoV-2 surveillance using travelers as sentinels. And the program tests through self-collected nasal swabs in volunteer travelers in airports.

And the program has been quite successful. I'll show you some data in a second, but we've started out at three airports. We've expanded to four airports during the Omicron surge, and most recently were in seven airports that you can see here on the map. Let's go to the next slide.

So just to refresh your memory, on this part of the program there are the seven airports. And we're actually now the second largest contributor to US sequencing and GISAID, and our data can be found on COVID Data Tracker. We report positivity by week.

One of the features of the program is that we pool samples, traveler samples, and then we sequence them both individually and in the pools. And we've had 195,000 participants since its inception, which is about-- we get about 7,500 volunteer travelers. As they're getting off planes, coming through customs, they're greeted, and they'll give us a self-collected nasal swab and fill out a few anonymous questions. We don't collect any PII.

And we've sequenced about 3,000 pooled sequences. You can see some of the data there. We collect-- we target flights from 35 different countries representing every WHO region.

But that's not what I want to talk to you about today, so if we go to the next slide, I wanted to update you on another part of the program, which is the Aircraft Wastewater Testing Program. And both of these programs are complementary. They bring different pieces to the surveillance puzzle.

The wastewater piece has the advantage of no direct interaction with travelers, just with their waste. And you can see on the right-hand side-- and I'll show you some other pictures-- but that's how aircraft are

emptied. There are laboratory tanks. So when you go to the bathroom on a plane, it fills up a tank. There are about three to four tanks on a plane, depending on the size of the plane.

And then when it comes in and they're taking the baggage off on the tarmac, this truck comes over with-- attaches this device and drains the waste. And you can see here we're collecting a sample in that bottle off to the side. Next slide.

So this is the workflow for the program. The international flight arrives at the airport. The sample is collected. We work with the ground handling crew at the airport and the airline. We have a staff member-- I should say off the bat, this is a public-private partnership, so our partners are XpresCheck, which is on the ground at the airport. And one of their staff will be standing here, handing the device to the ground handler collecting the waste.

And the other partner is on the laboratory side, which is Concentric by Ginkgo, which is Ginkgo Bioworks. It's a biotech company in the Boston area. And we send the samples to their lab network for PCR testing. The positives are sequenced, and then the testing and sequencing results are shared. And the timeline for testing and sequencing-- collection, testing, and sequencing is about eight days. Next slide.

So this is a device, a custom device that gets attached to the plane and to the hose. And it's the standard fittings that every plane has. And then it has a side arm that has a one-liter bottle where the sample gets drained off. And you can see the spigot. And so as the waste is coming off into the tube in the second panel, we open the spigot, collect some, close the spigot, and then they switch tanks. If there's three tanks, we would open the spigot from the second tank, get a third of the bottle, and then likewise for the final tank.

This whole process takes, like, two minutes. It really-- we've never had any spills. We've done hundreds of sample collections. There's no delay for the ground handling operation. And we sort of work seamlessly with the ground handlers.

And then the bottle is taken off. The device is taken off. The device-- the bottle is put in a package, and it's sent to the lab. The tank on the plane, just so you know, is rinsed with a glycol solution after it's drained. And we have several of these devices. They're cleaned and a new device is used each time, this connector device. Next slide.

So this is some of the lab-- the high-level technical summary. And this is courtesy of Ginkgo. I'm not going to go through everything here, but I'm happy to try and answer any questions afterwards. I'm not a lab person, but I think a few key points are our reported lineage cutoff is for 70% coverage. We do varying calls based on consensus sequencing, which is a little bit different than community wastewater because we don't think that many people are contributing to positives in the wastewater. It's probably one or two travelers on a flight that are contributing the sequence. And I'll move on to the next slide for the sake of time.

So we did a pilot when we first started this program in August to September of last summer in JFK. And this was recently published a couple months ago in the new-- in the MMWR. And basically, we collected 88 samples. We collected them from three flights that were coming in from either France, the UK, or the Netherlands.

And from those samples, 80 samples had positive PCR results. And then from those 65 samples went on to sequencing, and 25 of those were successfully sequenced. And the lineages that were found in those sequences were consistent with the lineages that were circulating at the time. Obviously, this was last summer, so it was-- BA.5 was the predominant lineage. And if you look at the data in GISAID or from WHO, what was circulating in Western Europe last summer, it was predominantly BA.5.

OK. And we can go on to the next slide. This is just another illustration. And each country had about-- a similar proportion of lineages that were BA.5 subgroup. Next slide.

This is just that slide again, but just to summarize what I just said, that it really was one to two minutes to collect these samples. There was limited disruption to the ground handlers' regular duties. 81% of the samples from the aircraft were tested, and the genomes were consistent with what was circulating in Europe. Next slide.

So we think that aircraft wastewater surveillance and traveler-based nasal swab surveillance are complementary approaches. They both have pros and cons. So for example, in the traveler-based program, the nasal swabs, not all travelers participate. And so we have to target multiple flights to get an adequate sample size from each country that we're targeting.

As we expand, there are several other countries looking at doing a global surveillance of travelers from flights. And if you had expanded hubs, that would improve the scope. And what I mean by that is, for example, if we're wanting to cover travelers from Africa, we have to get travelers that both come directly from Africa, which are limited flights, and also travelers that may connect through other countries, which we do. But if you want to increase the number of travelers from Africa, you might want to have a hub in Europe, because a lot of travelers end their trip from Africa to Europe or another country.

Also, sampling individual travelers can definitely be resource-intensive. Our approach to get so many travelers to participate is we have a lot of staff on the ground, meeting them and greeting them as they come off the flights and walking with them as they're exiting the airport to get that sample, to collect the 10 pieces of information about where they're traveling on an iPad. And then they get a take-home antigen test to go as a gift for participating. But it is resource-intensive. Pooling does help with that because it does cut down on some of the lab testing sequencing, and so forth.

On the aircraft wastewater side, the downside there is that not all travelers will use the lavatory, so it's better to do this in long-haul flights. There was a study by Jones and colleagues that showed that the chance of defecation on a long-haul flight over six hours was around 36%. There are-- when we talk

about viruses beyond SARS-CoV-2, there are other viruses that are more prevalent in urine, so it still doesn't rule out aircraft wastewater as a modality for looking for other pathogens.

Not all the travelers may originate in the flight country of origin. You don't get the level of metadata on the wastewater side that you do when you interview individual travelers and find out where they got out of bed in the morning.

And then there's-- people have asked about the potential for residual virus in laboratory tanks, which may make attribution challenging. But we've done some preliminary investigation and we're looking at this further on the ongoing surveillance that we're doing, and it doesn't seem to impact. We see very low levels of virus. We've collected wastewater post-rinsing with glycol and we don't find virus. But we're ongoing-- we're doing some ongoing work in that area. Next slide.

So just to summarize, airports and borders I think are key nodes in travel flow. And as we enter sort of a period now post-emergency, we may be a little bit in the dark, but we think that using travelers and airports and travelers as sentinels, it can really play an important role in surveillance to detect and prevent transmission of pathogens, and beyond SARS-CoV-2.

Aircraft wastewater is cost-effective. It's much less labor and resource-intensive to obtain a sample, and you don't have to engage the traveler. And you can still preserve some key information like the country of origin of the flight.

We think that these programs aren't just limited to the United States. They can be implemented in middle- and lower-income countries at airports to detect multiple pathogens and reduce cost.

Obviously, this is going to require a lot of coordination for standardization of methods, analysis, data sharing, and engagement of partners beyond public health. A key piece of this is that this is a whole society approach. We really need buy-in from the airline industry, from the ground handlers, to the airlines, to the airports, as well as public health to make this work. Next slide.

And where our program is heading right now, the expiration of the public health emergency will not impact our program for the next year. We will sustain the current footprint on both the nasal swab side and the wastewater side. And we're going to be integrating multi-pathogen targets as well, both on the nasal side and the aircraft wastewater side. And we hope to expand to two to three new airports in the coming year.

So I will stop there. I think I just have an acknowledgment slide and some references that we can share separately. And I see some questions were popping up. I don't know if you want me to take them now, or how do you want to do this?

Sean Courtney: Yeah, thank you so much, Cindy. I really appreciate it. It's definitely a hot topic, so I appreciate you joining the call today. I will ask you a couple of the questions, but then yeah, obviously, I'm

not going to go through all of them. So if you could hang out and maybe answer them within the Q&A function, that'd be great.

Cindy Friedman: Sure.

Sean Courtney: First one-- and our first question is, are all PCR-positive samples sequenced at Ginkgo, or-- and also, do they have a CT cutoff? Or is there a CT cutoff for sequencing? Sorry.

Cindy Friedman: So all the PCR-positive samples are sequenced at Ginkgo. And there are-- a lot of the ones with a high CT value don't yield a sequence. And I assume this is about the wastewater. But I don't-- I think there is a cutoff, but I don't want to say the number because I'm not exactly sure what it is, but it sort of-- there is a point where we don't get any sequence. The specimen doesn't yield a sequence.

Sean Courtney: OK, great. Thank you. Next question is, for the travelers who get screened and there is linking information, are the positive pool metadata shared with health departments of the states of residence of the travelers? And is the pooled testing followed up to get individual positivity?

Cindy Friedman: So a couple of things. So one, the pool is done to see if there is a positive in the pool. And as of last January-- or this January, 2023, we collect two swabs from every traveler. So one goes into the pool and the other one, if the pool is positive, we run every individual in the pool. And then those positives from the individual samples in the pool get sequenced. So if the pool is negative, we don't run the individual samples.

And then in terms of the metadata that we collect, we don't collect where the traveler is going. So all we collect are age group. Really, the most important piece that we want to know is where they got out of bed in the morning. So where did you originate your travel from? Not just the flight number that you just got off of.

We ask some other questions about ethnicity and then if they've had a COVID booster and if they've had COVID previously. But we don't follow-- there is no consequence management in this, so we don't know where the traveler is heading. So many-- like for example, if you look at Dulles Airport is one of our airports, many of those travelers will be getting on another flight or driving to another state or connecting. At the beginning of this program, we tried a few different approaches to this, and we did try and do some consequence management. And what we saw was that travelers went-- we had every state covered. And we were only at four airports at the time, and we had travelers going to every state in the United States, so we don't have that information.

All of our information is up on GISAID, and anything that's posted by Ginkgo Bioworks is from our program on GISAID. And you can pull open the metadata. It does say traveler or airport sample on the GISAID form, and then you can open up and there is some additional data in there.

Sean Courtney: Great. Thank you. And I'll ask you one last question because there are, like I mentioned, quite a few in the Q&A that you can hopefully answer after.

Cindy Friedman: I'll try and answer them.

Sean Courtney: Yeah, I appreciate that. And the last one is, is the wastewater produced chemically treated on the plane? And could that interfere with testing?

Cindy Friedman: So-- right. And we looked at that. We did some spike studies at the beginning before we ever went to a plane. But they use a glycol solution called blue juice in the toilet. It's not really-- it doesn't kill viruses, so it hasn't been a factor in this. And that's what they rinse the tanks with between flights. But we haven't had any issues with that.

And there are other groups that have done this. A lot of the original studies were done with Qantas Airlines in Australia. They did a lot of the original work looking at this and showing that you could collect aircraft wastewater and sequence-- and test and sequence virus from there.

Sean Courtney: All right. Great. Thank you so much. And again, thank you for joining today's call. Really appreciate that update.

Cindy Friedman: Thank you.

Sean Courtney: All right. So we are going to move to our next presenter. And we have Sarah Bennett from the Centers for Medicare and Medicaid Services. And she's going to be providing us with an update on CLIA-related policy changes after the end of the COVID-19 public health emergency. Sarah?

Sarah Bennett: Thank you, Sean. All right. Next slide, please.

Sean Courtney: Sorry. You're a little quiet. I'm not sure if you can be closer to--

Sarah Bennett: Hear me now? Sometimes it takes a couple of seconds for my voice to kick in.

Sean Courtney: That is perfect. Thank you.

Sarah Bennett: It's a Zoom thing. I don't know.

Sean Courtney: Thank you.

Sarah Bennett: All right. Next slide, please. This is the disclaimer that we put on all of our slides that basically said this is for informational purposes only, and that our end all and be all is the regs. So next slide, please.

All right. First thing I'm going to talk about are the emergency declarations. There are actually two. Under Section 319 of the Public Health Service Act, that is the one that ended on May 11th. But there is also another declaration, the 564 of the Federal Food and Drug and Cosmetic Act, and that's the declaration that covers EUAs.

I'm not going to go into a whole lot of detail except for the next two slides, except the big takeaway here is that the 564 declaration is not dependent on the 319 declaration. And that's key for EUAs being used-- allowing EUAs to continue to be used. Next slide, please.

All right. This is just a summary of Section 319 of the Public Health Service Act. This is the emergency declaration that ended on May 11th. And this is related to actual COVID-19 as a disorder or a disease with significant outbreaks. And so this is the declaration that ended on May 11th. And next slide, please.

Now, the other one that we talk about, which really more directly affects the laboratories from our perspective at CMS, this is the one that allows the FDA to authorize those EUA test kits that you all have used throughout the pandemic. And this did not end on May 11th like what we refer to as the PHE. So next slide, please.

So what does this really mean, right? This means that an EUA can remain in effect beyond the 319-- the end of the 319 under the 564 declaration. EUAs remain authorized. New EUAs continue to be authorized. And then the authorization continues until the test is approved and categorized or the 564 emergency declaration ends. This is not a CMS decision. This is information that will come from the FDA, but I did want to put it up here just as a general reference.

But what this really means for CLIA-certified laboratories is that the laboratories can continue to use the EUA test kits past May 11th as long as the FDA allows those tests to be marketed as an EUA or until they categorize those tests. So I don't want anybody to panic that all of a sudden on May 11th you have to stop using your EUAs. Next slide, please.

So the next thing I'm going to talk about is actually the memo that came out on Friday-- Thursday, sorry, May 11. And this has to do with the CLIA post-PHE guidance. And in case any of you all have had a chance to read that memo, there is lots and lots of information in there, so hopefully you've had a chance to digest that. Next slide, please.

The good news for CMS is-- and for laboratories is that CMS only has the authority to require SARS-CoV-2 test reporting during the PHE. And when that 319 declaration ended on May 11, so did the CLIA requirement to report SARS-CoV-2 test results.

However, we do want to say that there may be additional reporting requirements that are not enforced by CMS-- for example, state requirements-- that may still be in effect. And so we recommend that

laboratories verify current reporting guidance before they discontinue reporting test results. But again, the CLIA reporting requirement for SARS-CoV-2 ended on May 11th. Next slide, please.

Now we're going to talk a little bit about the exercise of enforcement discretion and other flexibilities. As you all know, we had FAQs. We had memos. We had all kinds of public-facing information about flexibilities and enforcement discretions that CMS allowed during the public health emergency.

And so what this memo does is kind of ties them all together. And so any previous guidance that was public-facing that was related to the topics in the memo, this memo supersedes all that previous guidance.

Many of the enforcement discretion and flexibilities that we used during the COVID-19 pandemic we believe may no longer be needed. And the allowance for not following CLIA requirements ended with the termination of the public health emergency.

But we also do want to say that laboratories that are accredited, you all should contact your accreditation organization for specific guidance related to the information in the memo because they may have more stringent requirements. And the same would apply to laboratories that are located in states that have state licensure requirements as well. Next slide, please.

So the first thing that I'm going to talk about is digital clinical laboratory data, digital results, and digital images. We allowed staff to review digital information remotely during the public health emergency, and we will continue this enforcement discretion post-PHE. This enforcement discretion will apply to pathologists and laboratory personnel who are reviewing digital data, digital results, and digital images remotely under a primary location CLIA certificate. Next slide, please.

OK. So in order to ensure appropriate oversight of these remote sites, we have put in the memo criteria that must be met in order to allow for the remote review of this digital information. And I'm going to go through these. There's a fair number of them. The first one I think is what I would say is just common sense. They have to have a current CLIA certificate. In other words, they can't have revoked-- they couldn't have had a CLIA certificate, and now they don't.

The laboratory has to comply with any other applicable federal laws, including HIPAA. So the remote-- that falls the remote sites as well. And then the laboratory director of the primary site is responsible for all of the testing that occurs under that CLIA certificate, including the review of digital images and data, et cetera, at the site where the person is working remotely.

And if there are any citations when we come in to survey, if there are any citations, they will be cited under the primary laboratory certificate. And if any enforcement actions are needed, which we hope they are not, then they will fall to be taken against the primary laboratory's CLIA certificate. Next slide, please. All right. The primary sites test report. We have a requirement in CLIA that wherever the testing occurs, that information must be on the final test report. We have heard your concerns about using home

addresses for this. And so what we're allowing is that the laboratory can use a coding system to identify where those remote sites are. But if a CLIA-- if a CLIA certificate-- sorry, a CLIA surveyor asks for those, they must be available upon request.

The primary laboratory must be certified in the specialties and subspecialties of the work performed at the remote site. What this means is the primary site must have all of the specialties and subspecialties included on their CLIA certificate that covers all the main laboratory and all the remote sites. In other words, the primary laboratory, if they have chemistry, hematology, general immunology on their CLIA certificate, they cannot perform pathology at the remote site. If there's pathology being performed at the remote site, it must be on the primary site's laboratory CLIA certificate as a specialty that the laboratory is performing.

And should see-- oh, back one slide. Thanks. And if the CMS asks for lists of the staff working remotely, it will need to be provided upon request. Thank you. Next slide, please.

And there's more. The primary location is responsible for retaining all of the documentation. This is already a CLIA requirement. And for those, the documentation generated by the staff working remotely, the primary site is responsible for retaining all of that documentation.

And any individual performing remote review must be on the laboratory's form. And I'm sorry. This should be CMS 209-- I thought I had corrected it-- which is our personnel form. So if you have somebody who's working remotely, even if they're a contractor for the laboratory, then that person's name must be on the CMS Form 209, and the laboratory director is responsible for that work. Next slide, please.

OK. Physical slides. We also during the pandemic allowed for remote review of physical slides. As of the 11th of May, this enforcement discretion will not continue post-PHE. So pathologists, cytotechnologists, and other laboratory staff, if they're reading physical slides, it cannot be done remotely under the primary location's CLIA certificate. This is a return to pre-PHE requirements. If a site is reading physical slides, then it must have its own CLIA certificate, and it must meet the applicable CLIA requirements. Next slide, please.

All right. We would consider a microscope and other laboratory equipment to be a laboratory. And we also have a requirement that if you transfer samples from one laboratory to another, if you refer them, then they can only be referred to a CLIA-certified laboratory.

And this would include pathologists and other staff working for a primary site location. So in other words, if you have a pathologist who's working at laboratory A but they also-- they work and review physical slides in their home, and those slides somehow get to that home, whether they're couriered or they're brought by some other means, than that secondary site where that pathologist is working at home must have a CLIA certificate. Next slide, please.

OK. Expedited-- I'm looking at the time-- expedited review of CLIA applications. Prior-- during the pandemic, we allowed laboratories to begin testing without paying the applicable fees so that we could ramp up testing very rapidly. We are going to not continue this post-PHE. Laboratories may only begin testing after they pay their applicable fees and they receive a CLIA number, or they have-- or receive their CLIA certificate. Next slide, please.

All right. Molecular and antigen point-of-care testing on asymptomatic patients. During the pandemic, we did issue guidance that we would temporarily allow labs using molecular and antigen EUA tests on asymptomatic patients outside of their authorization.

As you all know, the FDA has authorized numerous antigen and molecular and over-the-counter tests that allow for testing on asymptomatic patients. And these IFUs, these Instructions For Use say that individuals suspected of COVID-19 by their health care provider, we would consider that if a health care provider ordered that test that this would not be a modification, as long as the IFU says this, and that the decision of suspected COVID-19 rests with the health care provider, not the laboratory.

And along that same line, many of the IFUs indicate serial testing or subsequent testing. It is not the laboratory's responsibility to ensure that that testing occurs. It is the health care provider's responsibility to ensure that the patient does the additional testing. So as a result of all of that, this enforcement discretion will not continue post-PHE. Next slide, please.

There are multiple site exceptions. We did put out some guidance during the PHE that laboratories on contiguous buildings, on the same campus, and temporary testing sites, we were exercising some flexibility for that. This was already in the regs pre-pandemic, so even though it was identified as a flexibility, it really was already allowed in the regulations. So it's business as usual for that. The same requirements for multiple site exceptions apply now as did during the pandemic and post-pandemic. Next slide, please.

Alternate specimen collection devices. We will not continue this post-PHE. We did allow labs to use alternative transport mediums, and it was up to the laboratory director to determine if additional validation studies were needed. At this point, this is no longer needed to continue this way. So if the instructions for use do not include the alternative specimen collection device or media, then the laboratory must establish performance specifications before reporting patient results.

But CLIA, it's not really prescriptive about how the laboratories establish those performance specifications, as long as they meet the regulatory requirement to establish and that all of the areas are covered. And just a note, that it is the laboratory's-- director's responsibility that the regulatory requirements related to establishment studies. It's his or her responsibility. Next slide, please.

Use of expired reagents. We did during the pandemic allow laboratories to use expired reagents because of supply chain issues and as long as the QC was acceptable. Post-PHE, laboratories cannot use expired

reagents. If they do, we would consider it a modification and they must establish performance specifications. And as you know, then the test would default to high complexity. Next slide, please.

The Abbott i-STAT. With regards to the G3+, which is blood gas testing, we are not going to continue the enforcement discretion that we published or issued an FAQ about in 2020. The analytes on the G3+ blue cartridge are identical to the CG4+ with the exception the CG4+ has lactate, and the CG4+ has been categorized by the FDA as moderate complexity.

However, with regards to troponin, we will continue the enforcement discretion post-PHE with the troponin, the i-STAT troponin cartridge, that they can continue to use those cartridges as moderate complexity tests until the FDA clears the cartridge and puts the categorization on their website. However, I will say that laboratories that are accredited must contact their AO, their accreditation organization for guidance. Next slide, please.

Surveillance university genetic variant testing. During the pandemic, we allowed facilities who were performing this type of testing to not require CLIA certification as long as they weren't reporting patient-specific test results. Even though they were running them, they weren't reporting them. What they would do is they would tell individuals that they needed to go to a CLIA-certified laboratory for additional testing, and they would not give the patient the test result, whether it was an individual or a pooled result. And so as of Thursday, if they're performing any of this type of testing and they're reporting out patient-specific results, they are required to have a CLIA certificate, which is the requirement pre-pandemic. Next slide, please.

This is just a recap, a summary table. It is also in the memo where we go through everything that I talked about one by one. And it's there for your reference. Next slide, please.

And in addition, we had some FAQs that were published with the memo. But they aren't actually specifically mentioned in the memo, so I wanted to cover a few of those. These are questions actually that we have received at CMS, and so I thought I would just kind of throw them out there for you.
Will CMS continue to use the remote survey process after the PHE is over? The answer is no. Our expectation is that all of the surveys will be performed onsite as they were pre-pandemic. Next slide, please.

Has SARS-CoV-2 been assigned a specialty by the FDA? As you know, early on in the pandemic, CMS-- there was no specialty assigned to this. Since-- as the pandemic has evolved, it has been categorized under analyte specialties. Virology here is just an example. There are also tests that have been categorized in the analyte specialty of general immunology as well.

So you can always check the FDA CLIA complexity database-- the link is here in the slide-- to see if the test that you are wanting that has been cleared has been given-- it should be given an analyte specialty if it's on the FDA complexity database. Next slide, please.

So will PT be required for SARS-CoV-2 testing after the PHE has ended? With respect to virology, PT is required if you are performing tests for viral antigen or viral structures tests. So both of these would fall under the specialty of-- subspecialty of virology. And so laboratories will need to enroll in PT if it's available. Next slide, please.

This is a big question that we get, right? So if a laboratory has previously verified a EUA test, will it need to re-verify once it's been-- the FDA clears or approves that test? And from our perspective at CMS, as long as the product has not changed at all in its intended use, its design, the chemistry it uses, any of these other things, basically as long as it's an identical test then it does not need to be re-verified once it's been cleared or approved. Next slide, please.

So what happens if-- what does the laboratory do if there was a sample type that was authorized under the EUA but it's not a sample type that's listed when the FDA clears or approves that test? If it's not listed in the cleared or approved test, then the laboratory is going to have to establish performance specifications for that sample type.

So in other words, if there are two sample types-- say four sample types in the EUA but there are only two sample types in the cleared test and the laboratory wants to use one that's not clear, they're going to have to establish performance specs for that sample type that is not in the cleared instructions for use. Next slide, please.

OK. Well, this is the last slide. And I thought as I was reading this, I think it was really important because I think we can all agree that these were unprecedented times. And I think we hear a lot about everything that everybody did to pitch in and all that. But I think for me, it's the people who worked day in and day out, plugging along, just ordinary people who just did what they had to do to get through a difficult time. And so I thought that this quote from Christopher Reeve was very appropriate. "A hero is an ordinary individual who finds the strength to persevere and endure in spite of overwhelming obstacles."

And I believe that is the end of my presentation, Sean. I know that was a lot of information.

Sean Courtney: Yes, Thank you so much, and we really appreciate you joining the call today. There are some questions in the Q&A function, but since we're a little short on time I want to make sure that we give Tim some time with FDA to give us an update. So if you could just hang out in the Q&A feature and maybe address some of the questions there, that would be really helpful.

But thank you for joining our call today. We really appreciate the input and the update from CMS. And so with that, I-- thank you. Yes. And with that, I want to turn it over to Tim Stenzel with FDA to provide any updates that they have.

Tim Stenzel: All right. Thanks, Sean. And thank you, Sarah. That was really excellent and very detailed. I don't have much time, so I'm going to briefly go through what happened at the end of the public health

emergency on May 11. So first and foremost-- and Sean, let me know if sound is not good. I can go off camera.

FDA EUA authorities are still in place, and that means that all EUA-authorized tests can still be used without a full marketing approval. We are still-- it also means that we're still receiving EUA test requests, and we're still reviewing them and still authorizing them for the current priorities that we have.

The FDA finalized in April final guidance for the transition period away from EUA authorities for COVID. There is a 180-day notice, public notice, that will be given that gives kit manufacturers 180 days to get their full authorizing marketing submission into the FDA for review. If they meet the deadline for submission within that 180-day period, they can stay on the market in their tests can continue to be distributed. So this is to ensure continued availability of EUA-authorized COVID kits while we transition to full authorization of COVID tests.

At the end of this 180-day notice period, EUA authorities will end. Those that haven't come in that are kit manufacturers will have to stop distribution. It also means that for laboratory developed tests for COVID we will return back to our non-emergency enforcement discretion policy, which means that LDTs can be developed for COVID and launched as long as it meets the LDT definition in the transition guidance. So I'll end there in case there are any quick questions.

Sean Courtney: All right. Thank you. I appreciate you joining us, and apologies for such a brief update slot there. But I think you addressed some of the questions that were in the chat as well with your update anyway, so appreciate that. And I actually do not see any other questions in the Q&A feature at this time. So again, really appreciate you joining our call and providing an update on FDA's guidance post the PHE ending, so thank you.

Tim Stenzel: You're welcome. Thank you.

Sean Courtney: All right. And with that, we can end today's call. I want to remind everybody that our next scheduled call is actually going to be on Monday, June 26. This is in observance of the Juneteenth holiday the week before. So the next call will take place on Monday, June 26, at 3:00 PM.

Again, we'd like to ask everybody if you have any suggestions for topics for future calls that just to email us-- email them to us so that we can continue providing any hot topics or addressing any of your lab and testing community's needs. And as I mentioned before, we will post the audio transcript and slides from today's call on the website, hopefully within the next week or two.

And so you can find us on-- find CDC on Facebook, Twitter, Instagram, and LinkedIn. So please follow those to stay up to date with the latest news and recommendations. And again, we want to thank everybody for joining us today, and we continue to be grateful for your work. And we'll talk to you again on Monday, June 26. Thank you. Have a good one.