Clinical Laboratory COVID-19 Response Call
April 19, 2021

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JASMINE CHAITRAM: Hello everyone and thank you for joining the Clinical Laboratory COVID-19 response call. This is our 33rd call, and we're very happy you can join us today. I am Jasmine Chaitram, I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems and the Center for Surveillance Epidemiology and Laboratory Services at CDC.

The Division of Laboratory Systems works to advance laboratory safety and quality, informatics, data and biorepository science, training, and workforce development. We also have been working on preparedness and response topics with clinical and public health laboratories before COVID-19, and we continue to do that right now during this response. In particular, we serve as a liaison to the emergency operations centers for those laboratories and now, other testing sites as well.

We are very excited that this week is Laboratory Week, and I want to wish you all Happy Medical Laboratory Professionals Week. And thank you all for your service. We're also very excited because during this special week, we also have a very special guest, which is Dr. Rochelle Walensky, the CDC director. Before I turn to her for opening remarks, I do want to cover a couple of the normal housekeeping things that I go through. So just bear with me as I go through a couple of those items very quickly.

We just recently posted to the CDC COVID website guidance for reporting SARS-COV-2 sequencing results, and Vivienne Dugan, who has been with us a few times to talk about variants, will be talking a little bit more about this guidance. And this is for guidance for reporting to public health departments. We have our CDC Preparedness Portal, where it's a one stop shop where you can find a lot of information,

especially the archives for all of these calls with the transcript and the slides, as well as an archive of all of our Laboratory Outreach and Communication System emails, in case you've missed any of those communications and want to go back. We also provide links to other CDC websites related to COVID-19, so this is a good place to go for all of that information.

Our next call will be on Monday, May 3rd, from 3 to 4 PM. As a reminder, we have these calls every two weeks. We want to hear feedback from you on training and workforce development needs, and we have a specific mailbox for that - labtrainingneeds@CDC.gov. So please submit your questions or comments there, especially about education and training needs.

I also want to do a quick reminder about asking questions, and also just to reiterate that the types of questions that would be appropriate for this call should be laboratory-related or testing related questions. And when you do have a question, please use a Q&A button in the Zoom webinar system, and not submit it in the chat. We prefer that goes through Q&A because then we can track it.

We do try to answer as many questions as we can during the call live. However, it does become sometimes difficult to do that. And if we have your question in the Q&A box, along with your email, we can try to get back to you after the call. So please try to use the Q&A, and if you feel comfortable, leave your name and your email in case we are not able to answer your questions during the call, and we will get back to you. And with that, I think we are ready to hear the opening remarks from the CDC Director. Dr. Walensky, go ahead.

DR. ROCHELLE WALENSKY: Thank you Jasmine. And good afternoon, everyone. And it's so good to be here with you this afternoon. I've been making the rounds to various laboratory organizations, so I may have some of you before now. But for others, I am really excited to be seeing you for the first time today and thank you so much for inviting me to join. I know you have many important matters to cover on today's agenda, so I don't want to take too much of your time.

But first, I do want to wish you all a Happy Medical Laboratory Professionals Week. You have definitely earned this week of acknowledgment and appreciation. This really is an important time to recognize the essential services that laboratory scientists traditionally perform, and then have performed exceptionally over this last year to protect public health. Not just during a public health crisis, but every single day.

I'm here primarily to express my gratitude, my sincere gratitude and appreciation, for all of your incredibly hard work during the COVID-19 pandemic. So from the deepest part of my heart, I want to say thank you. We rely so heavily on your expertise every single day, especially during a pandemic. It's important for us to step back and ask how we can better facilitate the work that you do. You are unsung heroes.

I know we've made some inroads with better technology that allows you to more seamlessly communicate with us, as well as with other laboratory science partners, and CDC's NS3 surveillance system helps us to keep an eye out on a rapidly evolving pandemic landscape.

Over the past year we have invested in our public health infrastructure, and I am committed to sustaining this funding so that we cannot just be prepared for 2022, but more importantly for the next 20 to 30 years, and whatever public health threats may come. I was on the Hill last week at a congressional hearing, advocating for our public health infrastructure, and a key component of that is our public health labs.

The stalwart services of laboratory scientists throughout this pandemic has been nothing short of heroic. Your role is not just to a support function, you are critical to this response. I can tell you on March 6th, when my pager went off, March 6th, 2020, when our pager went off with our first case in Massachusetts, it was from the lab. So we have asked a lot of you. I know you continue to do extraordinary work to deliver more than a year into this pandemic.

So I want you to know that we're here to support you with whatever help, and support, and resources you need in our laboratory science partners to meet what has really been an unrelenting demand in the public health emergency. I really do want to take this opportunity to thank each of you for your stellar work in the interest of public health. Not always celebrated by everyone who should celebrate it, but we are celebrating you here today, and this entire Professional Laboratory Week. So now, I will turn things back over to Jasmine.

JASMINE CHAITRAM: All right, thank you so much Dr. Walensky for being here with us, we really appreciate it. And with that, we will go to our first speaker. Vivien Dugan, Dr. Vivien Dugan. She has been with us before several times to talk about variants, and she's back. And Vivien, I'll just turn to you, just let me know when you want me to turn slides.

DR. VIVIEN DUGAN: Thanks, Jasmine. Go to the first slide. That's a hard act to follow, the CDC Director, but I'm going to do my best. So thanks, everybody, for coming today, for joining the call. I'm going to review some of the high-level data that we have. Most of it is available on our CDC COVID Data Tracker. So many of you have probably noticed that if you've gone to some of the links that we've had in web pages has now been migrated to the COVID-19 Data Tracker on its own little tab. So hopefully this will be an easier way to kind track of how we're updating data on a weekly basis.

So for this first slide, this is just an overview of where we are with sequencing. These are all the genomic sequences that have been put into the public domain, either by CDC, CDC contractors, or the public health labs. And you can see there on the far-right bar chart, in the public health labs alone, over 48,000 total sequences have been put in the public domain to date. And then there's 70-- I think there's more than that. Over 4,800 sequenced put into the public domain from the public health labs. Just from the past week.

And then for CDC, NS3, those numbers on the slide aren't right, that we've gotten over 66,000 total sequences. And you see on the actual bar chart there, are over 10,000 sequences from the last week that we have data for in April. Next slide, please.

OK, so here are the US sequences that are publicly available in the public repository from all US submitters. And so if you look at the total numbers, the orange bar-- line shows the US sequences submitted to GISAID were up to 260,000. And so this is tracked every month or so as far as the total numbers that we put down on the graph, but you can see every day we're getting more and more data from the US that are putting into the public domain, with the NCBI, so Genbank sequences, showing about 119,000.

We do update this. Again, there's a link there that I can also put in a chat. Oh, it's already in the chat, great - the COVID Data Tracker. So we've got 120 into GenBank, and so these numbers are climbing every day. And so we intend to update this every week on Tuesday. We will continue to do that, and so check it out. Just, to give you an idea about the COVID Data Tracker is. You haven't to explored it, I certainly recommend it. It's a lot more interactive. It's certainly better than I can show on a static slide here.

You can hover over the different numbers and actually see the data pop up with you with certain information across all of these different data points we're going to show today. Next slide please.

Again, these are sequences by state. So when we parse the data, all of the data in the public domain, we're looking at the total sequences publicly available by state. You can see on the left-hand side that's what that map represents. And again, if you hover over it in the data tracker page, you can actually see those numbers. California being some of that darker blue, Texas as well, and then Florida and New York also having some of that medium blue for the number of sequences. From the total community. So these are all scientific researchers, academics, clinical lab, everybody, putting data into the public domain.

And then we look at it as a percentage of cumulative cases sequence. These are just raw numbers. And so you can see the data is a little different way, which is often a question that I think comes up a lot, is how much are you sequencing by case? So that's where that data lives for now. Again, also in the data tracker. Next slide please.

So where are we with the variants? I think this is always a question on everybody's mind. Again, there's another tab, also, in the COVID-19 Data Tracker that shows the different proportions at the national level of the variants. And so you can see here, on the bar that says 327 at the bottom, those are the collection dates. So those are when the specimens were obtained some from people, from patients, and then the sequence data is shown by lineage in the bar charts.

And this shows the breakdown of the different lineages over time. And what you can see here is that we've got all of our variants of concern and variants of interest in that table to the right, and this essentially shows not just the variance of interest and concern, but all the top circulating variants of lineages that are circulating in the US by these different two-week time slices.

So overall, B.1.1.7, a variant of concern, remains the most frequent lineage that's been sequenced. And you can see that orangey kind of color increasing over time, with the estimated prevalence right now

44.1% nationally. In the last few weeks of data that we have there, we see a small decrease for the B.1.427 and the B.1.429 variants of concern. The P.1 variant increased a bit from the last two weeks of data, dated March 13th when settlements were collected. That's up to about 1.4% nationally.

And then the B.1.351, that variant of concern increased from 0.5% to 0.7%. And then we look at the variant of interest, the B.1.526 lineage, that one, overall, is increasing nationally. And so we will update this data tomorrow evening, so be on the lookout for some of these updated numbers. And so this is where our data lives, and again, the COVID Data Tracker is a really nice feature where you can hover over all of these different bars and look at the different proportions and percentages across all over time. Next slide please.

OK. And one of the things I wanted to mention quickly that Jasmine mentioned in the beginning, in her opening remarks. This is the new guidance that has been posted for reporting SARS-COV-2 sequencing results the public health departments. And so we recently posted this new guidance for electronic lab reporting of the sequenced results specifically for any labs that are performing sequencing and are going to report the data to the public health departments for SARS-COV-2.

So in this page in the key points - there is some regulatory information, how to report SARS, and the more the technical guidance, which I'll show on the next slide. And some different reporting scenarios that may be important. You can go to the next slide please.

But essentially, this guidance used existing reporting electronic streams to standardize how the information for SARS-COV-2 genomic data, or lineages, are reported back to public health departments through electronic lab reporting. And states may use this information lots of different ways. The need it to track variants with their jurisdiction. They need it for epi investigations or public health decision-making. So it's really important.

And so any laboratories that are performing SARS-COV-2 sequencing really should follow up with the state health department for any specific reporting requirements for these different variants. But essentially, this is again our recommendation for health report-- the sequencing results electronically. We have examples there. Essentially, you're not sending a genome or a sequence, it's sending a lineage. So that's based on the PANGO lineage, and we have some examples there showing the B.1.1.7 lineage, or B.1.351.

But essentially, all of the public health departments are very interested in getting all of the lineage data, not just the variants of concern or variants of interest. So really, this is all the original patient demographic data. There's a lot of data that can be included. And so we've just shown some of the data elements that we're recommending. We're also recommending that any labs that are performing sequencing of SARS-COV-2 positive specimens should upload their data to a public database. Either National Center for Biotechnology, NCBI, or GenBank, or GISAID, the Global Initiative for Sharing Avian Influenza Data. That's all I have for now, but I'm sure there'll be questions, so I'm happy to try in the chat. Over.

JASMINE CHAITRAM: Thank you Vivien. We did have a couple of questions. I'm going to ask you just because we have a lot of time today. Is B.1.526 a candidate for changing from a variant of interest to a variant of concern? And then there were some other questions about how its prevalence is expanding, but I think you already covered that when you showed the proportions chart. If you could just comment on if B.1.526 is going to change from a variant of interest to a variant of concern.

DR. VIVIEN DUGAN: Yeah, I mean, I think this is an ongoing discussion that we've had in CDC, but also, it's part of our interagency activities. So we have an interagency group called the SIG, SARS-COV-2 Interagency Group. It's made up of members from NIH, FDA, BARDA, HHS, Department of Defense, I'm probably forgetting a couple. And so we have scientific experts, and subject matter experts, and leadership all involved in making these decisions at the interagency level. Where we look at the data that we have, that are available, either generated publicly or generated by the interagency group to make that. It is a decision that we are thinking about, and if that changes, and we will certainly put out new guidance to address that so that everybody is aware of any changes that may happen to be the B1526 lineage.

JASMINE CHAITRAM: Next question is, B.1.2 the original virus?

DR. VIVIEN DUGAN: That's a good question. So I think you have to go back and look at the PANGO lineages just to see, but B.1.2 is was one of a kind of older one that's been around. I have to go back and double check to see if it has, like, I think it has most of these viruses, in fact, the majority of them have that 614 D to G change, so you could probably go back. But there's going to be, within any of these lineages, at least the sequences that we're showing, or that the proportions that we show, there's going to be a certain level of variability. So try not to take it as showing the evolution of the virus, it's really a snapshot of the lineages that are co-circulating all at once.

But you can see the B.1.2 kind of shrinking as far as how many we're seeing every two weeks as data becomes available. So you see this contraction and expansion that is happening. And so it's interesting to watch, but certainly, I think that might be more representative of the older viruses, but I have to go back and check. I could probably follow up with that question.

JASMINE CHAITRAM: OK, great. And then another question is how do clinical laboratories that want to add next-generation sequences participate? So how could they contribute to this overall effort?

DR. VIVIEN DUGAN: So I think it's really important to note that the data that we showed there is all CDC-generated data at this point. It's data that either-- specimens that were sequenced at CDC, or specimens that were sequenced by our contract lab. And the reason for that is because we have tried to design new systems to be representative baseline specimens. That's not saying that other contributions aren't happening at the state level.

And so one of the efforts that we're trying to work on right now is a way for state public health labs to tag their sequences so that we at CDC know that they are baseline representative. Meaning that they're not

common outbreak, or they're not from a study, so that we can actually try to look at that data, and then maybe even consider combining it with the data that we have posted.

So one way that you can contribute is, if you are sequencing, is to get that data into the public domain. I think there's a lot of analysis going on at the state level and local level, that it's been really useful for. So making that data public is something that could be really helpful as far as contributing.

JASMINE CHAITRAM: Great. And then another question is, are the weighted variant percentages potentially skewed? For instance, selection bias since providers are sending specimens from patients in whom they have increased concern for variants.

DR. VIVIEN DUGAN: Yeah. So Kind of back to my past answer. So the data that we show on variant proportions is based on the CDC, either the CDC contract labs, or CDC National Screen Surveillance that Dr. Walensky mentioned in the beginning remarks. And so we know those data are meant to be, or are designed to be as randomization can be, although no surveillance system is going to be perfectly random. And so those are really just the CDC-funded or CDC-generated data. Doesn't include everything that's in GISAID or GenBank.

So we, the idea is that they are more representative and not skewed by exactly that situation, where certain patients or clinicians are still focusing down on specimens that are associated with severity of disease. That said, I think that we try to make them as representative as we can, just really based on what the labs have available for them. And so the way that the specimens are weighted in that chart, which is really good point, I'm trying to account for some of that bias, that underlying bias, that may be there in the CDC system.

JASMINE CHAITRAM: Great. And the next question is about the reporting guidance. And I'm not sure if you are going to be able to answer this one, Vivien, or I can help with it. But the question is, what's the difference between scenario one and two that’s shown as examples at the bottom of the technical guidance page?

DR. VIVIEN DUGAN: Yeah. I'm reading now. I'm not sure exactly, Jasmine, do you--

JASMINE CHAITRAM: Yeah. I can take it. So this one is about, the first scenario uses the parent-child sort of relationship to link the sequence results with a PCR result. And then scenario two is just how to send them, how to send the results without that linkage, so hopefully that answers that question.

OK. The other question, Vivien I'm not sure if you'll have an answer for this one either, is somebody's to asking about testing their lateral flow assays for variants, both antibody antigen test, and they need access to specimens which are confirmed to contain the variants. You know of any sources where laboratories can get these specimens?

DR. VIVIEN DUGAN: So you need specimens. So to be clear, all of the viruses that we are isolating as part of a subsampling, all these specimens that we're going in, we put those and make those all available in BEI Resources. I don't think that they have clinical specimens. So that would be something we'd have to go back and try to look into as far as a repository. It's certainly a new request. Maybe the diagnostic side, we can go back and ask to see if they have any options. Because for us, we're not creating a huge amount of resources of primary specimens right now.

But FDA or others may have other helpful resources for that. Or the interagency, I can go back and ask them to see if they have some resources available.

JASMINE CHAITRAM: All right, thank you so much, Vivien, for being with us again today. We appreciate your time; we know you're super busy. I hope you're enjoying Lab Week as well.
Alright, we're going to move to our next speaker. There may be two people, but I know we are going to start with Dr. Ellen Kersh. She's with the Testing and Diagnostics Work Group at the US Department of Health and Human Services. She's going to talk about a program for the expansion of US testing capacity using coordination hubs. Ellen, thank you for joining us.

DR. ELLEN KERSH: Thank you. I also want to wish all of you a Happy Laboratory Professionals Week and thank you for the invitation to speak to you about our new and upcoming initiative for the expansion of US COVID-19 testing capacity using our coordination hub. We have also referred to this project as Operation Expanded Testing, or Operation ET. It is being stood up by the federal government. The COVID-19 HHS Testing and Diagnostics Work Group which is led by Rear Admiral Michael Iademarco. I'm Ellen Kersh I'm deployed there. My regular job is as the Laboratory Branch Chief at CDC. Next slide, please.

So the goal of this program is to expand national COVID testing. Our most immediate goal is to reopen K through 8 schools, and also reach underserved populations. This will be a national public-private partnership. We're hoping to make accessible 25 million tests per month as a target. And the program is budgeted for initially $650 million. Next slide, please.

So to achieve this ambition, we're hoping to put to use spare testing capacity and establish new partnerships. We envision there will be four coordinating centers, shown here the different colors on the map. They will facilitate testing and reporting across their own geographical regions. So we here, in the federal government, are setting the strategic direction. We will be responsible for managing external affairs, communication, and of course, we're providing the resources. We're also responsible for guidance on tests and kits.

The other partners are testing laboratories. So we want to access unused capacity and untapped talent to expand testing. For example, in large university commercial laboratories, laboratory consortia, or other non-profit organizations. Depending on their circumstance, they would need to partner with existing CLIA laboratories. There will be an additional award for technical support. So technical subject matter experts

will be available, for example, on school testing. These experts will support us here in HHS, and more importantly, will support schools, coordination centers, and laboratories with implementation.

They can advise on school testing program design, available technologies, regulatory issues such as CLIA, quality assurance, and other areas related to collection, handling, processing, and result management. And we here in HHS will continue to maintain lists of available tests, suppliers, and supply chain issues. Also known products with excess capacity, as we have throughout this pandemic. Next slide, please.

So here is more information to describe this public-private partnership. So the Coordinating Center will interact with local jurisdictions and schools and determine the local needs, schedules, and testing requests. The jurisdictions remain in charge of determining their collection sites, and where the testing is needed. The Coordinating Centers, however, will assign testing to the laboratories that participate, and the laboratories will remain in charge of results reporting, sample receipt, and all the work you all do. The objective is to make the turnaround time less than 48 hours from sample collection to reporting, and no more than 72 hours at all time. Next slide, please.

So here is how we had described target characteristics of these partners in our informational webinars and materials. And also extensive questions and answers during the announcement process. And those are available on beta.sam.gov. So the Coordinating Centers. We were hoping, of course, to find geographical distribution, quality project management ability, ability to establish or leverage existing lab networks, ability to have existing innate data and tech infrastructure to support logistics requirements. Our technical expertise was diagnostics and clinical data management. They should be able to ensure regulatory compliance. And they should have experience collaborating with public health and state authorities. In the laboratory, we were also hoping for a geographical distribution. We were hoping that they could reach, or they have excess capacity to reach 150,000 tests per week quickly across all participating laboratories without interfering with what they are already doing, and currently testing.

They should achieve a 48-hour turnaround time from sample collection to reporting, and they should have the ability to do electronic results reporting. They should also have the ability to preserve specimens, and document referral pathway for positive test results. And they should have space and personnel to operate this testing, and hopefully also available infrastructure or ability to grow. Next slide, please.

So here is the timeline we communicated, and I'm happy to report that we're largely meeting it. So we initially announced this in February, on February 18th, when we posted a request for information to industry. And notably, this was before the American Rescue Plan was approved. In early March, we held informational sessions, first a webinar, and a few days later an industry day. Then we had an application period, and we received around 100 white papers, and made 52 requests for proposals back.

So they are being evaluated, and have been evaluated, and we are on track to meet our goal of having the first center awarded by the end of April. And with that on last slide. Next slide. I want to thank you for

your attention, and I hope that there's questions, that I can answer them. I have brought my colleague Matthew Humbard for-- if the questions get very difficult, he will also be available to answer any.

JASMINE CHAITRAM: Thank you so much Ellen. There are a number of questions. And so I will just ask the question, and then you or Dr. Humbard could answer. Whichever one wants to take it. But the first question is, how would you register to be a testing hub for this program?

DR. ELLEN KERSH: Well at this point, the applications are in. So there's no further ability to register as a testing hub. So the applications have been submitted, and we're in the process of making the awards by contract.

JASMINE CHAITRAM: OK and so the next question is very similar to that one, so I think you've already answered it, but I'll go ahead and say it anyway. How does a private testing laboratory become a test laboratory for the national public-private partnership, or are these already finalized for each state?

DR. ELLEN KERSH: So these will be coordinated by the Coordinating Center, so any participating labs would be in contact by this time with those Coordinating Centers.

JASMINE CHAITRAM: OK, how can we be considered for the test manufacturers list? What is the contact info and process? We are in Milwaukee and a hub, too.

DR. ELLEN KERSH: So we have an extensive list of all available tests that have received emergency use authorization, and I believe CDC does as well. The lab tests were there. So you can email me and I'll refer you to get that to you.

JASMINE CHAITRAM: All right. The federal government distributed large numbers of BinaxNOW rapid antigen tests to state public health systems. Are these largely unused tests to be used in the case rate school testing program?

DR. ELLEN KERSH: So the intention of these coordination hubs is mainly to use laboratory-based testing. So the Binax test is a point of care test with rapid turnaround time, so it would not be the ideal test for this. Although there is some flexibility here. But a comment about the distribution program, which I was heavily involved in. So yes, we have distributed millions of these tests, and have just produced a report of what their distribution and usage has been, so while there's some unused, a majority have been used and have found their use in states and elsewhere. So yeah, I just wanted to mention that here as well.

JASMINE CHAITRAM: OK. Is this just for PCR testing? Or does it include antigen/antibody testing?

DR. ELLEN KERSH: I believe there is some flexibility, but again, it's intended to be mainly laboratory-based testing. Which there are antigen laboratory tests, I'm aware of that. Although I believe the majority of laboratory-based testing is still NAAT, so that's my answer. The majority of these tests will likely be the

molecular tests, with some possibility of using other tests if it fits the needs of meeting the turnaround time, and the throughput, and all that we're hoping for here.

JASMINE CHAITRAM: And the point of this is to detect current infection, so antibody tests would not be used in this program, right?

DR. ELLEN KERSH: That's correct. That's correct.

JASMINE CHAITRAM: OK. And then another question about pooled testing. Pooled PCR rapid testing, is that an option?

DR. ELLEN KERSH: It is an option, and I do want to mention that we received many questions on this, and we have a posted list of these questions and our answers. So there is a long section on pooling there that you can find on beta.sam.gov. And yes, it is an option, but you don't have to do pooling.

JASMINE CHAITRAM: OK, and then another, I guess, point of clarification here. Have the four Coordinating Centers been selected? There's a lot of confusion on the selection process.

DR. ELLEN KERSH: So again, or Dr. Humbard may have to help me. So none of the-- none of the awards have been announced. And my information is that on April 27th, we're expecting to make the first announcement. It may not be for all four, but it will be at least for one.

JASMINE CHAITRAM: OK, will laboratories have the ability to apply locally for testing?

DR. ELLEN KERSH: That I would also, may need some from Dr. Humbard if he's on, if there's still an opportunity to do that. Mostly, I believe at this point, the laboratories would have already applied and are in contact with the Coordinating Centers that will be selected. So the selection will be for the Coordinating Center, and they collaborate with those laboratories and their coordinating system. So the application at this point would not come to us, that, I believe, is largely over.

JASMINE CHAITRAM: OK, and while we're just making sure that Dr. Humbard was able to connect to our panelist line. In the meantime, I'm going to just help answer a couple of simple questions that I can answer. Like, one question that we got was, will slides be available? And I did mention at the beginning of the call that we have a preparedness portal where we archive all of our calls, our transcripts, and our agendas, and all that information. So you can find the slides for previous calls there.

So if you just go to our preparedness portal, this is a DLS Division of Laboratory Systems web page that has this information. I think another question that we got was an email address for you, Ellen, but what I'm going to say to everybody, since this is a very large audience, and to try to manage your email inbox, is that the best way to reach our speakers is to send an email to our LOCS mailbox, LOCS@CDC.gov, and we can connect you to the right individual or help with getting an answer to whatever your question is.

I think somebody asked about contact information for California. And yeah, the testing hub in California. Is there, would they work through you guys to do that, or is that through the state?

DR. ELLEN KERSH: So at this point, the coordination hub for California is not announced, so we would not be able to put anyone in contact with their Coordinating Center, because it's not been selected, essentially. But once the selections are made and communicated, it's going to be public information, yes. There should be a way to contact the coordination hub leadership and connect with them.

JASMINE CHAITRAM: All right. It looks like Dr. Humbard, we were able to add him to the panelists. So if you want to add anything, you can unmute your line Dr. Humbard and add anything to what Ellen's already said at this point.

DR. MATTHEW HUMBARD: I think Ellen's done a great job explaining the project so far. Just to reiterate a couple of points. One hub will be awarded by the end of April. And the following three hubs will be awarded shortly thereafter, sometime in May, by mid-May. And so, since the proposals are under review right now, no decisions have been made about any of the hubs. And so there's no mechanism to put people in contact.

The hubs that are under review did come in with partner labs, but that doesn't mean that if you have a lab in that region, that you shouldn't contact them offering services, or offering capacity once they're announced. The mechanism of testing was largely left up to the hub applicants, how would they achieve the goals. And so we anticipate that there will be some adjustment once the program is underway.

JASMINE CHAITRAM: OK I think I have a few more questions for you guys if you're willing to answer.

DR. ELLEN KERSH: Bring it on.

JASMINE CHAITRAM: Hang on one sec. So one question that we're getting is about the ELC, the Epidemiology and Laboratory Cooperative Agreement, and how this project is syncing with those timelines. Can you guys make a comment about that?

DR. ELLEN KERSH: I'll take a stab at this and Matthew if you need to rescue me please do. So first of all, our program was announced in February, so before the ELC program. And we have worked diligently to get it stood up and started. So there is a possibility that we will be operational, as you just heard, in May, and that we can start this testing. And that was our intent all along, is to work as fast as we can to get this stood up and ready.

That said, those are complementary programs. So they're not mutually exclusive. And we hope they all contribute to strengthening school-based testing. I do want to point out that our-- this coordination hub program can also serve other underserved populations. For example, homeless shelters or other such institutions. So there's a difference. And yeah.
Matthew, do you have anything to add?

DR. MATTHEW HUMBARD: I think that was a great explanation. I think the-- a big difference in between the two programs, and a good way for people to visualize it is, the ET project is really just free tests. It's free tests for schools and for those underserved populations, while the ELC program is money to states so they can invest in testing. And so, sort of two different mechanisms with similar goals. We have, we are coordinating as best we can. We do think it's-- independent actions that can be very complementary in the field.

And so states can use the money to invest in areas that they think need additional help, and they'll have more control over that, while the hub program is just free tests.

JASMINE CHAITRAM: OK. Here's another question for you. Can you please speak to the obligations which schools have? In our state, we work diligently to work together with schools, but that's not working well.

So is there anything from the federal government perspective? Or is this really going to be at a local jurisdictional level, to have schools implement testing?

DR. MATTHEW HUMBARD: Want me to do that one?

DR. ELLEN KERSH: Yes.

DR. MATTHEW HUMBARD: So there's-- Project ET does not have a top-down mandate. There's no mandate from HHS that the program be implemented, or any sort of endpoint for school attendance, or anything like that. It is really up to the hubs, and the regional labs, and the outreach teams to get buy-in from the community for the testing. And once again, this is really a program to offer a large level of free testing to the community, and it can be distributed based on how that community feels it would be best used and utilized. The goal is to safely open schools and provide testing to gather the data to show that it can be done safely.

JASMINE CHAITRAM: OK. Thank you. Do the state health jurisdictions and existing lab networks in the regions have opportunities for input on the Coordinating Centers, or with the Coordinating Centers?

DR. ELLEN KERSH: Yes. My answer would be yes. So we are hoping that the coordinating centers take a leading role in involving their constituents, their local regions, their laboratories, the schools in that area. So one of our selection requirements is that management experience, and that partnership building experience. So we do hope that that will happen. It's envisioned that way, and we will obviously monitor this to this extent, and encourage from our side to have this be a partnership. Yeah.

JASMINE CHAITRAM: Thanks, I'm just looking through the questions here. I think, you know, we've got a lot at the same time, and I think you've answered them all. I think in general, from this community, a lot of the questions have been around, how can I participate? Is it too late? And how can I sign up? And I think

I'm also hearing a little bit of frustration that they didn't have awareness of this opportunity. And can you just state how it was announced, and you know, where that information was posted publicly so that people could, or facilities could apply?

DR. ELLEN KERSH: OK. Thank you. I'd be happy to. We did publish these. So these are contracts to my understanding, and there are websites where government contracts are posted. So was this one. So this is on beta.sam.gov, which I can also send you that link, and post that. But we did hold webinars, and we have information channels that we use. We have a newsletter here in HHS it goes to our state contacts. We have weekly communication. We have a state engagement team.

We did try to communicate best we could, but we do understand that, or I'm sorry to hear that many of you feel that you may not have heard about it. We did have good participation in our webinar in March, and also an industry day which was based on submitting a request to attend that was issued at the webinar that preceded it, and we were really hoping to cast a wide net and invite many of you to participate and apply. Over.

JASMINE CHAITRAM: Thank you, Ellen, and I do appreciate you sharing that information. Obviously, there was a lot of interest in this particular topic because we got a lot of questions, and there are still some in the chat if you want to go in and answer them. Or otherwise, I could work with you to answer them offline. They're all very similar in nature, about getting involved, and if it's too late, and things like that. But I think I'm going to end it here because you've answered a lot of questions. I put you through the ringer already.

And then that way, also, people can take some time to enjoy Lab Week. And so with that, I just want to thank you again for being here today, both of you. And appreciate your time. And just a reminder, again, that our slides and our transcripts from the call are on our website. So if you missed anything, or you want to go back and review them, just give us about a week to post them. We do go through the whole audio and transcript to make sure that the information is accurate.

We also have our social media websites, if you want to check out the latest that CDC is saying. And finally, just want to, again, especially this week of Lab Week, thank you for all of your tireless work. Especially this last year, more than a year. I know a lot of you out there just been working around the clock, just like many of us at CDC, to really try to support this response and help the American people get through this pandemic. And we appreciate you, and they appreciate you. And hope you can join us again for our next call on Monday, May 3rd, and we will see you then. And take these 15 minutes to celebrate your work and take a break. Take care.