Clinical Laboratory COVID-19 Response Call

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Speaker Panel

Jasmine Chaitram, CDC Division of Laboratory Systems
Robin Patel, President, the American Society for Microbiology (ASM)
Greg Armstrong, CDC Deputy Incident Manager for the COVID-19 Response
Brad Smith, Centers for Medicare and Medicaid Services (CMS)
Tony Tran, District of Columbia Public Health Laboratory
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JASMINE CHAITRAM: Hi, everyone. I'm sorry for the delay. As I mentioned, I'm Jasmine Chaitram. I am Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. You are tuning into the Clinical Laboratory COVID-19 Response Call. This is our seventh call. Thank you for joining us. Thanks to those who've joined us every week.

My division, the Division of Laboratory Systems, works to advance laboratory quality and safety, data and biorepository science, informatics, and workforce competency across the US clinical laboratories. We also work closely with clinical and public health laboratories across the country to support emergency preparedness and response. And throughout the COVID-19 response, we've been supporting CDC's Emergency Operation Center by serving as an interface between CDC and the clinical and public health lab communities.

Some of the tasks that we have been focused on include biosafety, regulatory requirements under the clinical laboratory improvement amendment CLIA, laboratory quality in general, reporting of lab test results, and challenges associated with implementing laboratory-developed test. I'm showing you right now the agenda for today's call. We have a great lineup of speakers.

And before we get into our speakers, I'm going to give you a couple of announcements. Hang on, let me just control my slides. OK, the first one is that we are going to be asking for some of your feedback. We've been doing these calls since March 23. And we want to be able to assess the usefulness of these calls and continue to identify and address laboratory needs during the response.

And our team has developed a short two to three-minute survey to collect feedback from our participants. It's a voluntary survey. However, your feedback is valuable and important to us. So please visit the link on the slide and take a few minutes to complete the survey. Your anonymous responses will help ensure that we continue to meet the informational needs of clinical laboratories and keep these calls interesting, timely, and relevant to your work.

In addition, I wanted to also mention that CDC has posted a LOINC in vitro diagnostic LIVD test code mapping for SARS-CoV test results for clinical laboratories and instrument manufacturers. This specification supports the use of standardized LOINC and SNOMED clinical terms to improve the accuracy of reporting tests for the SARS-CoV-2 virus. And using these harmonized LOINC and SNOMED CT codes helps ensure that the same type of test is represented uniformly across the United States.

And on this slide, I've got the link to the LIVD specification. It's the first link on the slide. And we also sent out a LOCS message this past weekend, for those of you that receive those messages, with information about the LIVD specification. And we've had FDA on the last two calls, I believe, talk about the effort to put this together. And we hope that it will be a useful tool for you. So please download the LIVD mapping and share it with your IT group.

The test being performed should be represented with a LOINC code. The result answer and the specimen should be represented by the SNOMED CT code identified in the mapping. Using the identified code, as I mentioned, will make it easier to define triggers to initiate a digital case report and start contract tracing. So this is very important for surveillance as well.

Another announcement I have is that we are also trying to understand more about the education and training gaps that you're currently experiencing, so we invite you to send feedback to us via the email on this particular slide, LabTrainingNeeds@cdc.gov. And then the last bit of information that I have for you before we get into our speakers is how to ask a question. And this is also information here on the slide about using the Q&A button in the Zoom webinar system.

I do want to mention that we have a large number of participants on these calls and so we generally don't open the lines for questions. We do sometimes have our speakers answer questions directly as you're submitting in the Q&A box. So that's a possibility that that could happen. But if that doesn't happen, really, the point of having those questions submitted to us is to help us understand your concerns. And it helps us to shape the agenda for future calls.

So please keep on submitting those questions. We are using them. We are looking at them. And when we can, we do provide a response. And with that, I think I'm going to now open it up to our very first speaker, who will be Robin Patel, the president from the American Society for Microbiology. She's going to be talking about addressing COVID-19, the Clinical Lab and Beyond, a Perspective from a Scientific Society. Robin.

ROBIN PATEL: Thank you, Jasmine. Can you please go to the next slide? ASM and its members have been at the forefront of addressing the effects of the COVID-19 pandemic. The society has been doing the following across multiple areas to serve the public and our members. We're working to advance the science and support microbial research. We're supporting the thousands of clinical microbiologists in public and private laboratories across the country in multiple ways. And we're serving as a convener, sharing science-based information with the

press, advocating for science, public health, and clinical concerns with policymakers, and educating the public. Next slide, please.

In late January, one of our first moves was to make available all published research in our journals related to coronavirus for free. This initially included more than 50 articles published in the preceding year. In late March, ASM's Council on Microbial Sciences convened more than 100 experts from around the world to discuss several key questions surrounding diagnostics, vaccines, and treatment for SARS-CoV-2 What research is urgently needed to find solutions for COVID-19, how can we coordinate efforts to fight this global threat, and what concrete steps need to be prioritized to accelerate research and slow the spread of the virus?

Following the summit, we published a paper in mBio, ASM's first broad scope, online only, open access journal. And then three weeks later, building on the work of the summit, we launched the ASM COVID-19 Research Registry. The research includes top-ranked COVID-19 research, curated by experts, spanning categories from basic virology to epidemiology to clinical diagnostics and more. Former ASM president Lynn Enquist serves as curator in chief, and Harold Varmus serves as our chief consultant. Please advance to the next slide.

We've been actively working to support our members in clinical microbiology who have been on the frontlines in addressing COVID-19. For 25 years, the ClinMicroNet listserv has been connecting clinical microbiologists around not only the country, but the world. ClinMicroNet, alongside DivCNet, are communications portals that allow our members to share challenges, solutions, and expertise, and have been invaluable resources throughout the pandemic.

Early on, ASM developed an emergency use reauthorization verification protocol for SARS-CoV-2 viral RNA testing. More recently, we've partnered with IDSA on a set of guidelines for diagnosis of the novel virus. Those guidelines are expected to be out any day now. ASM has been working to assist our members in addressing regulatory issues and barriers faced by laboratories, which I will talk more about on the next slide. Dr. Stefano Bertuzzi and I authored an op-ed that ran last week in The New York Times calling for a new National Guard and highlighting workforce shortages we face as clinical microbiologists. Please move to the next slide.

In recent weeks, ASM has been called to assist members of the White House Coronavirus Task Force with reaching clinical laboratories and better understanding where shortages of testing supplies exist, how the challenges are shifting day by day, and how to ensure capacity across the country. ASM is appreciative of ongoing open dialogue we've had throughout this crisis with both the CDC and the FDA. The FDA has been responsive to our concerns, related to both molecular and antibody tests, which have been different but equally important. And we've been working hard to support needs for greater backing for laboratory capacity, infrastructure, and surveillance.

Throughout all of this, ASM has maintained constant contact with congressional leadership and members of the House and Senate. From appropriations for the CDC, NIH, BARDA, and FDA, to

securing language in the most recent bill, ASM has been working to support all that's needed for clinical laboratories, whether they exist in public health areas, academic centers, or hospitals. We've also advocated for a comprehensive science-based national academies-like review of the response to COVID-19 when the immediate crisis passes.

It's important that we learn from our successes and failures. We believe that policy changes and funding needs may emerge from this. Last slide, please. Here are some links to the resources I've talked about this afternoon. I also want to note that ASM is offering a serology testing webinar tomorrow May 5 at 2:00 PM, Eastern Standard Time. The webinar will provide a brief overview of serology testing, followed by time for Q&A. To register for this free event, please visit asm.org. Thank you.

JASMINE CHAITRAM: Thank you very much, Robin. So as I mentioned, questions for Robin can be submitted through the Q&A, and we will work with her to answer, to provide responses, if she's unable to provide responses on the Zoom call right now. The next speaker is Greg Armstrong. He is the CDC deputy incident manager for the COVID-19 response. He'll be talking about testing strategies and priorities. And he does not have slides, so we will just be listening. Thank you. Greg.

GREG ARMSTRONG: Yeah, thanks, Jasmine. This is Greg Armstrong from CDC. I'm one of the deputy incident managers here. Our guidelines for testing patients with suspected COVID-19 have undergone a lot of evolution since the beginning of the pandemic and the beginning of the availability of testing in the US. At first, they were very restrictive. This was just a requirement of getting the EUA.

But we were actually able to very quickly work with the FDA to open that up to allow for discretion on the part of the clinician and the public health community. And then in late February, we were able to expand it out even further. And at this point, our prioritization, our testing prioritization for virologic testing focuses first on high priority patients, so patients who are hospitalized with symptoms that are consistent with COVID-19. Also in that high priority category are health care workers, workers in congregate living settings, and first responders who also have symptoms that are consistent with COVID-19.

And the third part of that high priority category are residents in long-term care facilities and other congregate living settings, including correctional and detention facilities or homeless shelters, who have symptoms. And then below that that first tier of priority, there is a second level, which we also consider to be a priority, which are, number one, persons with other symptoms that are not necessarily classic of COVID-19, but including things like shortness of breath, coughs, fever, muscle pain, new loss of taste or smell, vomiting, diarrhea, sore throat.

And also patients who don't have symptoms but who fall into other groups that are a particular concern for the public health standpoint, so number one are members of racial and ethnic minority groups, such as African-Americans, American Indians, Hispanics, Latinos. There is quite a bit of data out there now to show that there are elevated rates in all those groups. The data

about whether that risk is related specifically to race, ethnicity, or whether that risk goes away after controlling for other risk factors, such as comorbidities, like diabetes and chronic lung disease, as well as things like obesity, the data is still somewhat conflicting in that regard. But what is clear is that those groups do have elevated risk for COVID-19.

Finally, in that same level of priority are persons with symptoms who are prioritized by health departments clinicians, including residents in congregate housing facilities and homeless shelters, long-term care facilities, correctional facilities. There's quite a bit of evidence out there right now, as most of you know, that there is a lot of asymptomatic infection that is part of COVID-19. And we've seen very high rates in groups of young adults, young otherwise healthy adults, who have been tested for one reason or another who are asymptomatic.

We oftentimes find that as many as 50% or sometimes more of the infections that we're discovering there are actually asymptomatic. And it's quite possible that in younger kids, the rates are even higher than that. We still, at this point, don't have a whole lot of data about COVID-19 in children. But there's a lot of speculation that the fact that we're not seeing a lot of disease among symptomatic kids is because the kids are mostly asymptomatic.

But there have also been some very well-publicized events and published in MMWR and other publications of outbreaks in nursing homes, for example, where a high proportion of the residents with infection are asymptomatic. And so there's a growing recognition of the public health committee community that we need to be testing asymptomatic individuals in settings like that, such as nursing homes, if there is any suspicion of an outbreak. And we don't have firm guidelines on that yet, but we hope to have those in the not too distant future.

Some people may have questions about what we recommend in terms of serologic testing. We, again, don't have routine recommendations for people to get serologically tested at this point. We are following very closely, seroprevalence in the United States. We're working with some large reference laboratories to get specimens, remainder specimens, to test those. We're also getting specimens from blood banks. And there's also an increasing number of serologic surveys to get more representative samples that are either just starting or are still in the planning phases. So I'll stop there and turn things back to Jasmine.

JASMINE CHAITRAM: Great, thank you so much. We have gotten a lot of questions over the last few weeks about testing priority, so I think that was very helpful. Our next speaker is Brad Smith. He's with the Centers for Medicare & Medicaid Services. And my understanding is that he's managing all of the testing supply chain challenges. And so this is a good follow-up to the information that you just heard from Greg. So Brad, are you ready?

BRAD SMITH: I am. Thank you so much for having me. So good afternoon. This is Brad Smith.

JASMINE CHAITRAM: Go ahead.

BRAD SMITH: Can you hear me OK?

JASMINE CHAITRAM: Sorry. Yeah, sorry, I was just letting you know that I have your slides and I can change them for you.

BRAD SMITH: Oh, perfect, excellent. Thank you so much. So this is Brad Smith with the Center for Medicare and Medicaid Innovation. I've been deployed with the White House Task Force for the past eight weeks or so, and over the past three or four weeks I've been working to help ramp up laboratory testing supplies across the country. If you want to go the next slide. Together through the partnership, with each of the states, we've made great progress over the past several months.

And if you flip to the next slide, you'll see the significant increase in testing that has happened week over week. And our goal in partnering with each of you is to continue this trajectory as we go in and through the month of May and into June as well. If you flip to the next slide, there are really four main efforts that we've been focused on in helping support states. And this is all of government effort, including the CDC, including FEMA, including folks from DoD, et cetera.

But there's really four main lines of effort. The first is really around specimen collection supplies. And specifically, this is meant to supplement the supplies that are already available in the private market. And what's happened is, we'll talk through more in just a second, is the federal government has procured a large amount of swabs, transport media, and collection tubes that we are going to be distributing to states.

The first shipments went out last week, and additional shipments will be coming this week and then every week throughout the month of May and June. These shipments, as I share more on in a second, will be going directly to states. But the first line of effort we have is around specimen collection supplies. And in this realm, the federal government is actually purchasing those supplies to supplement what the states have and shipping them directly to states. And again, I'll spend a little bit more time on the logistics of this here in a second.

The second line of effort we have is really around lab testing capacity and technical assistance to the states. Unlike in the first category, specimen collection supplies, the federal government is not procuring the lab testing supplies. Instead, since there's a very concentrated number of manufacturers, we're working to connect states with those manufacturers to be able to procure the supplies that they need. The only exception to that is public health labs, which will continue to be able to request reagents and other lab testing supplies through the IRR. And again, I'll spend a little bit more time going into depth on lab testing capacity.

The third area is really around personnel, which CDC is leading and helping to deploy folks to different states. They currently have more than 650 personnel deployed or embedded inside of different states. And the last piece, which just got covered by Greg, is guidance. So I will go a little bit deeper, if you want to flip to the next slide, on specimen collection supplies and then lab testing supplies.

So as I mentioned, for specimen collection supplies, we have worked with each state and each governor's office to understand what their goal is for testing in the month of May. We are then working to provide them specimen collection supplies to hit that goal. I would say there's two exceptions to the goals that the states came to us with.

The first is, we had a small number of states whose goal was less than 2% of their entire population in May. For those states, we made 2% the minimum. So we said, we're at least going to send supplies for 2% of your state. We also had a handful of states that we were very excited about who had very ambitious goals, that were more than four times the clinical number of tests they have completed to date. For those states, we said, we're really excited about supporting you in your goal. We're going start by giving you enough supplies to hit 4x what you've done to date. And then if you're able to get a run rate that's higher than 4x, we will send you more supplies in the third week of May.

Typically what we're sending to folks are swabs, transport media, and collection tubes. The swabs are a combination of nasal and nasopharyngeal swabs. It starts with about 40% of the nasopharyngeal going down to about 20% over the course of the month. The transport media is a mix of saline, MTM, and VTM. It's about 50% sterile saline and about 20% to 25% MTM, and the remaining is VTM. The supplies will be going out weekly to each of the states in the quantities that we've agreed with the states.

We've been having one on one calls. Many of you on the webinar have probably participated in them. The supplies will be getting shipped to a single location within each day. And then from that location, the state is in charge of distributing those supplies across the state as they see fit, both, of course, within their public health labs, but also across their entire laboratory capacity and health care capacity, provider capacity, across the state.

What we've found, when we've been getting requests and through FEMA, is states are typically requesting about 50% in media of the amount they're getting in swabs or they're requesting in swabs. We found this is largely because many of the states are, and some of the labs in the states, are building their own transport media. But instead of the 50%, because we want to make sure every state has everything they need, we're going to be providing a 75% of transport media relative to the number of swabs. So for example, if we're sending a state 100,000 swabs, they would be getting 75,000 in transport media.

And as I already mentioned, in addition to the initial allocations that are coming out of the states, we also have several million swabs and other items in reserve for states who show that they're going to be able to beat the pace of 4x. We will be able to send them additional supplies in the latter half of the month. And again, these supplies are meant to be in addition to what folks were already getting through commercial labs and other suppliers in the market. If you want to flip to the next slide.

In addition to the specimen collection supplies, we've also been very focused on lab testing capacity. As I mentioned, our strategy related to lab testing is a little bit different than our

strategy related to specimen collection supplies. And that for lab testing, we are not planning for the federal government to procure large supplies of things like reagents, et cetera. Instead what we're really focused on is helping provide supports to states and connections and facilitating introductions to states to be able to procure these supplies themselves.

What we have done so far to assist in that effort is we have provided a map to each state and a spreadsheet to each state of each machine in their state that is capable of processing COVID-19 tests. This is over 7,000 machines across the country. And what it shows us is, at least from a machine perspective, there is more than enough machines, well than more than enough machines, to be able to do all the tests that we might want to do, both in May, June, and well beyond.

In addition, we from the federal government have assigned a technical expert, either from CDC or from the military, others from HHS, to provide technical assistance to each state and work with them one on one to build a strategy to help their state ramp testing. In addition, we have made introductions at very senior levels to the CEOs and others at the large manufacturers. I think so far, every state that has come forward to us wanting an introduction has been able to both get connected to that manufacturer. And especially in the case, which I'll talk about a bit more, of some of the manufacturers who have large amounts of capacity in May have been able to secure the procurements they need to be able to ramp up their state.

And the final piece is around the high demand platform. So what we have seen is, in certain platforms, like Hologic Panther and the Abbott ID NOW and Cepheid platform are in high demand. Other platforms, most prominently the ThermoFisher, there's a large amount of supply. And so what we've been encouraging states is to try to focus their efforts on ramping up supplies around things like the ThermoFisher platforms. The Hologic Panther is also coming onto the market, so there is some additional supply in May. But really, those platforms that have new supply in May that is greater than what existed in April.

And then for some of the more in-demand platforms, like Abbott ID NOW and Cepheid, we're working to work with them to make sure that we are distributing things across to different regions across the country. And we'll be having more details over the coming days on both of those platforms and how we're partnering with those companies to ensure there's adequate distribution across the country. So again, our goal here is to provide the support to the states that they need to be able to ramp up their testing.

All of the manufacturers have supplied us the amount of supplies that they are sending to states in the month of May. We're still waiting for one of those manufacturers to get us the data. But assuming we see what we think we'll see from that manufacturer, in every state, they will have more than enough lab testing supplies to be able to support their testing goal.

It really comes down to making sure those lab testing supplies are getting to the right location and being utilized in the right way. And so I think that's quite a partnership with our federal experts. And technical assistance support will be really helpful working with each state to make

sure each state's able to ramp up to their goal. But based on what we're seeing in the data, we feel confident that every state will be able to have what they need for a lab testing supply perspective to ramp up to their state's individual goal.

And again, we'll be working with individual states as they have questions. I think for the sake of time, I won't cover the next two slides, which really focused on the CDC personnel that are being deployed to states. As I mentioned, there's a little over 650 folks who have already been deployed, as well as the guidance that was already discussed that CDC is rolling out. But again, at the high level, our goal is to be here supporting states and helping make sure that you get connected to all the resources that you need to scale your testing efforts over May, June, and then beyond. And so with that, we'll end my presentation. And I look forward to answering questions.

JASMINE CHAITRAM: Thanks so much. So as you can imagine, there were a lot of questions coming through while you were speaking, a lot of interest in this particular subject. Could you just, for clarification-- I see a general theme about contact information and who labs should be contacting. Should they contact their state health department or their state public health lab? Can you give a little bit more guidance on who they should contact to obtain supplies if they need them?

BRAD SMITH: Yeah, absolutely. So from the federal level, we have been reaching out to the state health officer, the lab director, public health lab director in each state, the head epidemiologist in the state, and the governor's office. And we have been providing all the information directly to them. So I would think that any of those folks-- and it might depend on the state-- but that would be folks who would have all the information that the federal government has been supplying to the states. And so I think those folks on the phone from different labs connecting with any of those leaders in their states could be a great starting point.

JASMINE CHAITRAM: Great, thank you. Thank you very much. In the interest of time, I am going to move to the next speaker so we can get everybody in that's on our agenda. Our next speaker is Tony Tran from the District of Columbia Public Health Laboratory. And he'll be talking about expanding SARS-CoV-2 testing in the District. Tony.

TONY TRAN: Great, thanks very much. I hope you all can hear me OK. Jasmine, I'm good?

JASMINE CHAITRAM: You're good.

TONY TRAN: Great. Thanks everybody. Thanks for the time. I have a bunch of slides so I'm just going to go ahead and get started here. In the District, we have about 700,000 people. We are the only public health laboratory, along with eight hospital labs as well. So there is quite a bit of testing that is actually done here, but it's a little bit on a different scale. So I just kind of wanted to set that up. Next slide, please. OK, there we go.

All right, so March 3 is when we started testing. And I'm sure many of you out there were in the same situation as we were. We were doing manual extractions, trying to get these Qiagen kits in, as well as we were dusting off our EZ-1's. And so we had a large-- large for us-- but our entire molecular diagnostics unit, which is four people that you see on the screen there, were pitching in to get a maximum capacity of 50 or so specimens or samples per day. These are not patients. Because when we started with the CDC assay, again, on March 3, we could get up to four samples per patient.

So we had a capacity of about 50 or so. So next slide, please. And then shortly thereafter, we continued to see an increase in demand. However, what we were trying to do and keep up with, again, was I'm sure what a lot of you all had issues with, which was getting reagents in stock. So as soon as the CDC decided to have more of these extraction platforms online, we started to move to other extraction platforms, especially more automated platforms.

So we ended up bringing on and dusting off again our compact lines, so our magNA Pure compacts. And by doing that, because where we were more on an automated workflow, we were able to increase our capacities to about 100 samples per day. So next slide, please. But still utilizing all four of our staff. So then the e-mag came on next, along with our compacts, so kind of a full automated extraction protocol. Including one of our e-mags as well as two of our compacts, we were able to get up to 150 samples per day.

At that point in time, we kind of leveled off with the average amount of daily patients at about 21 or so. However, there was something that was coming along down the pike-- next slide, please-- where we really needed to move to full automation. We were fortunate enough to be one of the very few labs in the country to actually have a Panther Fusion sitting there. We were actually getting ready to implement it for routine testing of ILIs, so non-influenzas, if you will, to conduct that sort of surveillance. And we were actually working on a project with Hologic to kind of look at their non-novel coronavirus panels to bring that testing on.

So we quickly shifted March 16 when the Panther Fusion became FDA EUA approved to move to that platform. The capacity here is, for our purposes, running about a shift to shift and a half would be anywhere between 300 to 500 samples per day. At that point in time, we were increasing our sample input on request up to about 75 or so patients. Now we're looking at patients because we are doing NP swabs only, about 75 patients per day.

And as you can see, the staff dramatically dropped. And actually, this is one of those things where it moved from our molecular diagnostics unit over to our immunology virology unit. And we only have, really, one staff working on that per shift. If we need to, if we get a large day, we'll put them on before the night is up. And then the next day we'll have samples and results ready to be reported. It's been a fantastic shift.

The first sample takes about two hours and 20 minutes. But then after that, it just comes out every couple of minutes. So it does have a sample capacity of anywhere between 90 to 120 per run. But it is random access so you can add samples at any point in time. We estimate, again,

about 300 samples per every eight hours, or up to about 500 if we run about a shift and a half. So we are able to run them overnight and they get the samples the next day.

The other nice thing is, because we are a small public health laboratory, we have about 51 FTEs. In a very small immunology serology group, we're able to have one to two people be able to run this test and still significantly increase our capabilities, so really, sample to answer, which is really, really nice. The other thing that's been really nice about it is that we have been able to procure a lot of these reagents directly from Hologic, without having to worry about the shortages of these extraction kits.

So it's been a real boon for us. And next slide, please, you'll see why we had to go to full automation. So just like I'm sure many of your jurisdictions, the drive-through kind of walk-up clinic phenomena happened at the end of March as well. So we have been getting, first starting off with three days a week, Monday, Wednesday, Friday, walk-up, drive-through clinics that are being offered by the city. And these are in addition to, excuse me, the ones that are being offered by our hospital systems within the district. But we were running our own there.

And so for us to be able to handle that added volume that this would bring, we really needed something that was going to be more sample to answer. And something that recently has happened in conjunction with the testing that has been rolling out in the District, we've enlisted a lot of high-end celebrities, if you will. So I'll give you an example. Michelle Obama, actually, will be calling you if you're a resident of the District in order to get you to come out and get tested if you so felt the need. So that has actually increased our volume quite a bit. Next slide, please.

So here is where we're looking at and why we are trying to increase this testing capacity. So folks may have read this article that came out in The New York Times-- I think it was April 17 there-- that refers to a Harvard study. And it talks about, you basically need, for every 100,000 people within your jurisdiction or state, 152 people tested. So for us, that ended up being about 1,064 samples per day across the District that needed to be tested right, 164, really, people that needed to be tested. And that's really to reopen by mid-May. Next slide, please.

So I kind of want to give you a little snapshot and give you a little bit of an update from the last five days kind of to have you understand where we were then and where we are now. So this is as of April 28, over 19,000 people tested, and so that equated to about 2.7% of the population. I just ran the numbers again today, and we're up over almost 24,000 people now tested, so about 3.3% of the DC population being tested.

The overall percentage of positivity remains about the same, about 21.4% on the 28th. We're up to 21.7% today. And so that equates to about over 5,000 positive patients so far that have been tested and reported to the health department. As of the 28th, the Public Health Laboratory tested just under 2,600 patients. And our overall positivity was just under 35%. As of yesterday-- so these are numbers as of May 3, we had tested 3,369 with a positivity of about 33%. So it's dropped a little bit for the population that we have tested.

And I've separated the numbers into two different categories here, so the first being drive-through walk-up testing. And we were at 1,400 with a 23.7% positivity. And as of the 3rd, we're up to 1,815 people tested, again, about 23.5%. So what that leaves for us-- and this was presented a little bit earlier by Dr. Armstrong-- is kind of these vulnerable populations that really are being tested by the Public Health Laboratory here. So a lot of these would be the long-term care facilities, Department of Corrections, and also homeless shelters.

So we're getting a lot of those samples as our hospital community has been able to develop their own testing capabilities and/or are sending them out to commercial laboratory for testing. So that provides us the opportunity to be testing these high-risk, vulnerable populations. And again, as you can see, kind of a striking number I feel that, of the 2,000 people that we had tested last week through the 28th, 48% of those were positive.

And the numbers, as of yesterday, were up to 1,554, of which 44% are positive. So I think that, obviously, we're hitting the key populations here. And just to kind of give you a snapshot of where we are in the last five days, we're at over 900 samples tested per day now. So that's District-wide. So we're approaching that 1,000 people per day goal. So next slide, please.

So part of our deployment plan outside of just testing here is also, then, providing these Abbott ID NOW that were given to us by the Health and Human Services. So we're very grateful for that. We got 15 of these instruments. And if anybody is familiar with them, they're kind of more molecular isothermal amplification point of care type instruments, not really appropriate for a high volume laboratory.

So what we wanted to do is really distribute these out to facilities that could use them. And so some of the facilities that we're looking at distribution would be the homeless shelters, Department of Corrections. St. Elizabeth's is a psychiatric institution here in DC. Mary's Center is a private clinic that actually serves an underserved Latino population.

And then we're looking at potentially a long-term care facility, as well, where we already did a mass sampling. And this would basically be, they would bring this assay in so that they could kind of maintain testing capabilities moving forward. And here are some photos of some of the facilities and trainings that we've done. Next slide, please.

So part of this, in any sort of provision of these sorts of CLIA-waived, if you will, testing, from my experience, is that, the more input the laboratory has to that testing facility, the better the testing is going to be. So requirements for us placing these instruments and providing them these test kits are that we have to do an initial site assessment. We have to work with them to be sure that there is an area where the test can be conducted and walk them through and have them walk through with us what their workflow is going to be.

They do have to complete a site-specific risk assessment. It is very important. This test is more or less an open type test, where there are potential biosafety and biohazards that can happen. And so we wanted to be sure that those were mitigated appropriately. We want to identify one

or two staff to be trained per site. We didn't want this large mass-testing effort. We wanted it to be controlled.

And then from there, they can do some train the trainer, to be able to train more of their staff to test. The training would be conducted by folks here at the Public Health Laboratory, so we actually formulated a team to go out on site to do the initial site assessments, as well as trainings and company assessments. And then we're actually purchasing proficiency testing material for them so that they can participate in these events at least twice annually. Next slide, please.

So here's a training that we actually held at our facility. You can see the social distancing. We kept it to a minimum amount of people, under 10. A lot of this can be done, actually, online. But we actually had a discussion with them afterwards about how we were going to deploy it, what kind of quality system we wanted to provide to them, and then kind of walk them through the steps of how to become competency assessed, and then actually receive these instruments. So next slide, please.

So again, as part of our initiative to increase testing, the motto is, if they won't come to you, then I guess we'll just have to come to them. So again, thanks to our federal partners, the NHANES, that's the National Health and Nutrition Examination Survey, which is right there in Beltsville, Maryland, not far away from us in the District, they offered to provide us a mobile testing truck. And so of course, we jumped on that opportunity. And you can kind of see a little bit of the rebranding that we had there. Next slide, please.

And so what's nice about this truck is that it actually has on board an examination area as well as a laboratory with a biological safety cabinet, a small biological safety cabinet, but still a class II biosafety cabinet nonetheless. And so we actually took possession of that a couple of weeks ago. And then we have actually started to go out into the community now, and we've outfitted it with testing supplies.

So this is not just sampling, but this is actually mobile testing. We call this our mobile testing unit, where we have placed now-- next slide, please-- three Abbott ID NOWs, as well as a four-module Cepheid GeneXpert. We actually have a throughput of about 50 per every four-hour shift, although we are, after being out for about a week now, looking at changing this up a little bit, where we actually would probably take out the GeneXpert and actually add to of the Abbott ID NOWs, because it does give results a little bit quicker. So we'll probably have about five of those on the truck. Next slide, please.

And here are some of the photos of us kind of setting up for that testing of the Abbott ID NOWs, as well as the GeneXpert. Next slide, please. And again, just a little bit of a demo of the lab area. It's pretty spacious. You can see our folks are in full PPE with N95s, face shields, gloves, and gowns. So they have to keep those on at all times. We always have a partner system as well to ensure that there's no issues with PPE. And then our folks then provide the results at

the end of the day to each of these facilities. And then the final reports are actually provided once we get back.

So next slide, please, this is my last slide. And I think this is just to kind of show everybody the efforts of an entire laboratory, of an entire public health laboratory, in the COVID response. As I told you, we have about 52 staff. And we've had about 45 people that are involved in this effort. So it's been a Herculean effort, but I think this is an example of, when you put your mind to it, what you can kind of do to ensure that everybody does get tested who needs to be tested. So with that, I'm happy to take any questions. Thanks.

JASMINE CHAITRAM: Thank you, Tony. We are running a little bit past our time so I'm just going to keep moving. And we'll probably forward those questions to you later. Quick reminder-- the next two speakers will not have slides, but the slides and the transcript from these calls are online a few days after the call. So if you missed anything in the slides or what the speaker said, the information will be there under cdc.gov/safelabs, under Resources and Tools. And all of the past week's transcripts are there. Our next speaker is Bill Arndt. He gives the weekly biosafety update. Bill.

BILL ARNDT: Thanks, Jasmine. My name is Bill Arndt and I am the biosafety program lead in the Division of Laboratory Systems at CDC. I also serve as the lead laboratory biosafety SME in the CDC's Laboratory Response Task Force. So today I'm going to talk about some of the biosafety issues of point-of-care testing. Over the last couple weeks, we have been receiving a number of questions related to point-of-care testing and the biosafety precautions recommended in conducting these types of tests.

As always, the first step of getting a new instrument such as this or these conducting these types of tests is to conduct a site-specific and activity-specific risk assessment to identify and mitigate the biosafety risks present. For the risk assessment, it is important to consider the procedures performed, the hazards involved in the process or procedures, the competency level of the personnel to perform the procedures, and laboratory equipment and the facility, as well as the resources available. However, the CDC has come up with some general recommendations for using point of care instruments for detection of SARS-CoV-2.

Those general recommendations are to use the instrument in a location associated with the current CLIA certificate, follow CDC's published interim laboratory biosafety guidelines for handling and processing specimens, this COVID-19, specifically the portion in there that's related to point of care testing. As I mentioned before, perform a site-specific and activity-specific risk assessment to identify and mitigate risks. Train staff on the proper use of the instrument and ways to minimize the risk of exposures. Follow standard precautions when handling clinical specimens, which includes hand hygiene, use of PPE, such as lab coats, gowns, gloves, and eye protection.

A lot of these point-of-care tests, you utilize the swab. So one of our recommendations is to minimize contamination of the swab stick and the wrapper by widely opening the wrapper prior

to placing the swap back into the wrapper. What we've seen is, in a lot of cases, the patient will be swabbed, that swab will be put back into the wrapper, and that wrapper can be contaminated, the inside as well contaminate the stick. So we have a recommendation for that.

Change gloves even after handling the specimen swab when using the instrument. And then decontaminate the instrument after each run. And then we just refer to the packaging instructions for how to decontaminate the instrument with the appropriate disinfectants. Thank you for your time today. And don't hesitate to reach out to us if you have any questions on this topic. I'll turn back it over to Jasmine.

JASMINE CHAITRAM: Thanks, Bill. The last speaker is Karen Dyer from the Centers for Medicare & Medicaid Services, just giving a CLIA update. Karen. Karen, are you on?

KAREN DYER: I am now. It was muted, sorry. Good afternoon, everybody. I just want to give you a couple quick updates. Last week we did publish what we call an infographic. I think there was a link sent out to it in the last week some time from CDC. And it's basically a three-page document. And we're very, very proud of it. A lot of work went into this. The first page has testing requirements for the SARS-CoV-2, breaking down to the test kits, the laboratory-developed tests, and what can be done at home.

The second page is where the Medicare beneficiaries can get tested. It kind of breaks down what the options are and some of the things that they could do and where they can go to get testing done. And the very last page of it is that most current Medicare payment for lab services. And it breaks it down per test. So if you check your emails from last week, you should have a copy of that. If not, I think we can post it again, Jasmine, I think, this week.

The next update we had was on the i-STAT. The FDA on April 9 actually cleared the CG4+ flu cartridge for moderate complexity testing. And it was for arterial and venous specimens. We have updated our FAQs and our memo to reflect that information. Jasmine, do I have time to go through some of the questions from last week?

JASMINE CHAITRAM: We really don't. I'm sorry. We're over time.

KAREN DYER: No problem, we'll handle that next week.

JASMINE CHAITRAM: We'll schedule that for a future call. Is that it, Karen, as far as updates?

KAREN DYER: That was it. Thank you.

JASMINE CHAITRAM: Thank you very much. And the email that Karen mentioned would have come from LOCS, that's our Laboratory Outreach Communication System. So sign up for that if you don't receive those emails now. And we did send out a message about the infographic that CMS has.

A couple of other quick things I want to mention-- the LIVD mapping tool that I spoke of earlier, I just want to let you know that we will be updating that weekly, so continue to look for updates for that document, especially if you're using it to reference your LOINC and SNOMED CT codes. The survey that I showed earlier to get your feedback on these calls, you can fill that out at any time, so please do that.

And again, these slides will be posted on the CDC website if you need to refer back to the link. Thank you to all of our speakers for taking the time to be on the call and preparing their presentations. As I mentioned, sign up for LOCS. And our next call will take place on Monday at 3:00 PM. That's May 11.

And if you have any additional questions that didn't get submitted today, you can go ahead and submit those to dlsinquiries@cdc.gov. And again, we'd like to thank you all for all that you're doing on the front lines. And thank you for your time today. And that concludes our call.