Clinical Laboratory COVID-19 Response Call

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Moderator
Jasmine Chaitram, CDC Division of Laboratory Systems

Panelists
Michele Owen, CDC Laboratory Task Force
Tim Stenzel, U.S. Food and Drug Administration (FDA)
Karen Dyer, Centers for Medicare & Medicaid Services (CMS)
James (Jim) Crawford**,** Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health, Lake Success, New York
Peter Iwen, Nebraska State Public Health Laboratory
Jasmine Chaitram, CDC Division of Laboratory Systems
Bill Arndt, CDC Division of Laboratory Systems

JASMINE CHAITRAM: I am Jasmine Chaitram, the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems at CDC.

Our division is focused on laboratory quality and safety, biorepository and data science, informatics, training and workforce competency across the US clinical laboratory community. We also work closely with clinical and public health laboratories across the country to support laboratory emergency preparedness and response activities.

Throughout the COVID-19 response, we've been supporting CDC's emergency operations center by serving as an interface between CDC and the clinical and public health laboratory community. Some of the tasks they've been focused on includes laboratory about safety, the regulatory requirements under the Clinical Laboratory Improvement Amendment (CLIA) additional laboratory quality issues, and the challenges associated with implementing laboratory developed test.

On these weekly calls, we will discuss hot topics and solicit the community's questions about the work that clinical laboratories are doing to support the nation's response to the COVID-19 pandemic. We want to create a platform for CDC and other government agencies to provide valuable information to clinical laboratories.

Because we anticipate a large number of participants on this call and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content to future calls accordingly.

We have slides for this week’s call, and these will be posted on our DLS website along with the transcript and audio file. If you have a clinical-laboratory-related question you'd like to ask our team, to be addressed on a future clinical laboratory COVID-19 response call, you can submit

those for consideration by using the question and answer function in Zoom, or you can email DLSinquiries@cdc.gov.

I've shown here on the slide some instructions for how to ask a question. If you are the media, please send your questions to CDC media relations at media@cdc.gov. And if you are a patient, please direct any questions to your health care provider.

We are now going to move to our first speaker, Michele Owen from the CDC Laboratory Response Task Force. Michele is going to be talking about performance evaluation of commercially developed serology tests and some other information.

MICHELE OWEN: I'm going to be talking about the use of serologic tests and some evaluation of serologic tests that are ongoing. So as many of you probably already know, there is now one EUA approved serologic test that was approved just a week or so ago from one manufacturer. That is the only one that's currently EUA approved.

However, there was a large number of serologic tests that were displayed on the FDA website that were just allowed to be marketed in the US but had had no actual evaluation by FDA. We realize that this is an important tool that many people would like to use. So related to that, HHS has actually stood up a multi-agency task force to look at the performance of some of these tests that were previously just listed on the FDA website.

This is a collaboration between BARDA FDA, NIH, the Department of Defense, the National Institutes of Health, and the White House Office of Science and Technology Policy along with CDC. The test will be evaluated on a standardized panel of serum that's being put together from various collaborators. There will be approximately 30 or 40 known positive SARS-CoV-2 based on PCR reactivity, and then a panel of negative samples on the range of 75 or so that will come from a time prior to SARS-CoV coming to the US.

So the plan is just to have this evaluation completed in about three weeks. I will say this is an initial evaluation to primarily see if tests are meeting a minimum standard of positive percent agreement with the PCR tests and the negative percent agreement based on the fact that the negative sera came to the US before the virus came to the US. I think that's my update.

JASMINE CHAITRAM: OK, thank you very much. And I'm now showing just the email address if you have questions about the CDC EUA assay. That's the real time PCR assay. Next up on the agenda we have Tim Stenzel from the US Food and Drug Administration. And he's been on previous phone calls before.

Today he's going to focus on answering some of the questions that have been submitted on the previous call. And we thank you all for submitting those questions. We do look at them. We do use them to help guide the topics on our agenda. And I want to thank him for responding specifically to some of those questions today. Tim, go ahead.

TIMOTHY STENZEL: I just want to go through the questions and then try to give answers, to hopefully address them. And then any new questions that come in between now and next week, I can address those or move on to other topics.

So the first question is, is there a list of tests authorized under EUA for COVID-19-specific IgM and IgG in blood? On the FDA EUA authorization page, we now have authorized one serology test. The rest of the serology tests that have not been authorized but are able to be marketed are on our frequently asked questions page.

One of the developers asked for when their test is going to receive authorization. So I would just say that, for any developers out there, that they reach out to their FDA reviewer to find out the status of their review. If you're a laboratory and you're waiting for somebody's EUA authorization, just reach out to the developer and ask them for the timelines and the current EUA status.

Third question-- what is your take on COVID tests that have been reviewed by the FDA and the results from these lateral flow tests such-- should not be used to diagnose COVID or SARS? So serology tests are not primarily used for diagnosis. They're used to confirm whether or not someone's been exposed and has developed antibodies against SARS-CoV-2. The labeling included in our approvals, our authorizations and on those that don't require EUA authorization and notification make this clear.

Question four-- why won't the FDA allow EUAs for any test that is reasonably applicable to today's emergency and let the treating physicians and performing labs decide. Well, that's not how our EUA authorization process works. It is a relaxed standard. We will work with all developers to help them get onto the market. We have a number of accelerated pathways as previously mentioned for even those that don't have to come in for EUA authorization. Next question is, would the current non-FDA approved tests for serology be LDTs? Oh, that's a good question. I think that refers to the tests that are listed on our frequently asked question page. And they would not be considered LDTs. If this didn't answer the question, you can address a question directly to our inbox at CDRH-EUA-templates@fda.hhs.gov.

We need clarification on the serology tests. Vendors are trying to sell these too, saying they fall outside the FDA oversight, so anyone can perform. So I would just point you to our FAQ page in what's allowed for these tests to be marketed.

Next, we'll change topics a little bit to supply chain, et cetera. Will all modifications, alterations suggested for CDC EUA assay apply for all other EUA commercial EUA assays? Yes and no. For labs that are using EUA authorized tests, they can make a modification as long as it falls under one of their categories on our frequently asked question page.

They do a bridging study, and they can begin testing without an FDA submission or amendment. Commercial manufacturers, if they make modifications to their tests, will come in for an amendment to be authorized to their original EUA submission and approval authorization.

If a test is FDA approved using VTM as an EUA-- this is the next question-- when a clinical lab uses specimen collection diluents other than VTM, does the lab need to submit an EUA request to the FDA? No. Available EUAs were approved using VTM. If we use nasal swabs or other diluents, do the clinical labs have to apply for EUAs?

Again, no. Do your bridging study and validate and then you can begin testing. Let's see. When a clinical lab modifies an EUA NAT test and changing anything else? Again, they can do a bridging study. They don't need an EUA amendment.

Moving onto home collection-- is home collection allowed? Yes, as long as there is an EUA authorization. And we are now authorized the first home collection this week. What about home collection? Yes, we'd like to hear from you about a home collection. That will require an EUA authorization.

Let's see. As a CAP-CLIA-certified high complexity lab, do we need an EUA or a 510(k) to produce patient collection kits with liquid Amies? I would recommend that you address that question to our email address. And other labs and even states have requested the ability to manufacture liquid Amies and other collection media. And we'll connect you with the right folks, if that's what you want to do, in order to move you forward with that desire.

Point of care testing-- can the validation process be abbreviated for rapid point of care, i.e., Abbott ID or Cepheid So we've authorized those tests. So I assume this is verification, if I'm incorrect. You would just do your normal verification. We've addressed the fact that these tests can be performed in your patient settings on our FAQ page.

FDA guidance states labs must validate POC tests. Has that changed? I don't know if this means for home use or home collection. So yes, but not for a POC. If we've gone ahead and allowed tests that are authorized to be used in such an environment, we'll make that clear in the authorization.

Is the UHG, United Healthcare Group, studying a nasal versus NP swabs sufficient to add that specimen type to an EUA or would a lab need to independently validate nasal swabs? As long as you use the swab that we recommend for that self-collection, which is a foam swab, that's fine. If you want to switch away from a foan swab, labs can simply do their own bridging study and commercial manufacturers would come in with an EUA amendment.

Does the additional types of swabs approved by FDA apply to all COVID-19 assays, including commercial assays or only the CDC EUA assay? The FDA makes clear that these are mixed and match. The CDC may have its own take on what can be used with an assay under their authorization.

However, in general, the FDA thinks that these alterations are OK for all manufacturers. Otherwise-- all manufactured assays, although we'd say so. So labs can simply adopt them without having to do any additional validation as long as their medical director agrees with that according to the recent CMS guidance.

TIMOTHY STENZEL: What happens after the EUA expires with instruments such as Cepheid? So as with all prior emergency situations, EUA emergencies may expire. However, we have many open emergency EUA situations currently. And those tests are currently under EUA authorizations and listed on our EUA authorizations website.

There is a process, however, when an assessment comes in, one of these assays or another assay comes in for full approval or clearance or a grant if a de novo from the FDA. And that allows the FDA to actually remove similar EUA authorized tests from the market.

However, there may be good justifications to keep them on the market. So we do encourage developers that, if they want to continue to market their assays long term, that they would convert those assay. These are primarily for IVD manufacturers, I would think, to convert to a full authorization if they want to stay on the market afterwards. But as in previous emergencies, we're not really in a rush to remove our authorizations because there may be continuing needs.

And the last question-- we submitted our EUA more than two weeks ago. When can we expect to hear from the FDA? And I would say that just reach out through the FDA email. We are triaging. So if you're currently authorized through the pathway you're using to be on the market on whether you're a manufacturer who notified us or an LDT that notified us and you've submitted your EUA application within the 15 business days, then unless you hear from us, you're good. But you can reach out and ask for a status report. So with that, I am turn it back over. Thanks.

JASMINE CHAITRAM: Thank you, Tim. Our next speaker is from the Centers for Medicare and Medicaid Services, Karen Dyer. And she is going to give us additional CLIA guidance for testing laboratories. This was a topic on last week's call. And so this is an update. Karen.

KAREN DYER: Thanks, Jasmine. Good afternoon, everyone. Just want to let you know we appreciate getting all these questions. It gives us an opportunity to make sure people have the correct information. So please, continue to send them and so that we can make sure everybody has the most up to date information.

I wanted to start off with talking a little bit about CLIA requirements and test complexity. We did get a few questions about that. So CLIA requirements for clinical labs are based on test complexity, i.e., the more complex the test, the more stringent requirements for that test.

Laboratories are either waived or non-waived. The non-waived includes moderate high complexity testing. Labs performing moderate high complexity must meet the CLIA requirements for that level of testing. For waived testing, the testing is considered simple with little risk of error when performed correctly. Laboratories that perform COVID-19 testing must be CLIA certified. The settings in which an EUA can be performed are listed in the letter of authorization. And those are found on the FDA website.

When the FDA authorizes point of care tests under an EUA, such tests can be used in laboratories with certificates of waiver, compliance, or accreditation. Point of care designation in the EUA's assays intended use may include patient care settings, such as hospitals, physician

offices, urgent care centers, outreach clinics, and temporary patient care settings that have appropriately trained personnel to perform the test.

There are several test kits that can be used by certificate of waiver laboratories. And we recommend that labs check the FDA website for a complete listing. Some of them are the Xpert Xpress SARS-CoV-2 test, BioFire COVID-19 test, ID NOW COVID-19, and Accula SARS-CoV-2 test. And again, please check the website for any updated tests that may appear.

So as COVID-19 testing has not been assigned to specialty or a subspecialty classification by CMS at this time, laboratories may determine what specialty subspecialty this type of testing falls under unless your state makes a determination as to the specialty and subspecialty. States are able to have more stringent standards than CLIA.

Per the FDA-- and we've heard some information about this earlier-- there is currently one FDA EUA authorized serology assay that can be used in laboratories that meet the requirements for high or moderate complexity testing. For those serology assays that have not yet been reviewed, authorized, or received a CLIA categorization from the FDA, these default to a high complexity test and, again, must be performed in a CLIA certified laboratory and meet the requirements for high complexity testing. There are currently no waived serology tests for COVID-19.

As always, laboratories must follow the manufacturer's instructions for the EUA test regarding quality control and verification of the test. I just want to refresh everybody. I know we put out guidance probably about a week or so ago about remote testing and PT. And I'm going to talk a little bit about that right now.

So during the public health emergency in regards to remote testing, we are exercising our enforcement discretion. And we will not enforce the requirement to have a separate certificate for laboratories or laboratory professionals that are located at a temporary testing site, provided that the designated primary site or home base has such a certificate, and you're using the address of the primary site, and the work being performed in the temporary testing site falls within the parameters of the primary site certificate.

Laboratories that choose to utilize temporary testing sites-- for example, for remote review and reporting of slides or images-- may do so if they meet the criteria listed in the memo that we issued. This is not limited to pathologists only. Other laboratories can utilize this option if the criteria listed in the memo is met.

So we had some questions about surveys and when we would look at a prioritization of our surveys. We were allowed about three weeks from the 23rd of, I think, March, it was-- 23rd of March. Time's going by very quickly. So around about April 13-- I don't have a definite date yet-- CMS will re-evaluate the prioritization of surveys and make a determination as to whether to extend it for more weeks.

We are also working on a process internally that we can use to address the expired soon to be expired certificates so that we have minimum disruption to clinical laboratories during this time.

For proficiency testing, just a reminder, that only CMS may allow suspensions of CLIA required PT activities while patient testing continues.

In the event that a PT provider would need to postpone, suspend, or cancel an event, that PT provider must immediately notify CMS, accrediting organizations, exempt states, and their laboratories that it needs to postpone, suspend, or cancel an event.

Laboratories will not be penalized for lack of PT results under this condition. However, the labs should consider performing their own self-assessment during this time. Laboratories should document the event, including the notice that they received from the PT program as for the reason to postpone, suspend, or cancel.

One final question-- we got some questions regarding billing codes. Those questions need to be referred to a reimbursement person in your laboratory or on your staff that deals with that, as CLIA is not involved with payment or reimbursement issues. And we think that they would be the best people to talk to about which code to use. Jasmine, I'll turn it back over to you.

JASMINE CHAITRAM: Thank you very much, Karen. Thanks for answering some of those questions. We're going to do something a little different than we've done in the past on these calls. We're actually going to have two speakers from the front lines. The first one is going to be Jim Crawford from the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health Lake Success New York. Jim, are you ready? And I can turn your slides for you.

JIM CRAWFORD: Thank you for the opportunity to speak. These are slides that I initially-- a process that I stood up at the start of the event at Northwell Health. And I've been pushing them out to peers nationally. And you may use these slides as you see fit for your own practice environments.

Next slide, please. So I'm going to show four data slides. And these are a sampling of the kinds of data that I provide to our health system leadership, especially the clinical providers, so that they can adapt and guide the use of laboratory testing.

Shown here is COVID-19 testing by PCR by the intake clinical site. And you can see I started tracking this on March 11. We initiated the CDC manual assay on March 8.On March 11, we initiated semi-automated testing and on March 18, we initiated all the automated testing on the larger platforms.

And you can see that we had a very constrained ability to do testing until we turned on the larger machines. And it was limited by the supply chain. We actually had machine capacity and personnel capacity to result up to 1,000 tests per day starting March 11. But the 100 to 200 only was a constraint of the supply chain.

Now that we brought up basically a full portfolio of testing, we could easily test north of 3,000 to 4,000 per day based on our machine capacity. But again, we have continued limitations in supply chain so that we have been steadily resulting around 2,000 tests per day since March 21.

You can see that hospital emergency department is the primary matter intake for our hospitals. The patients present. The nasopharyngeal swab is performed. And we have a 40% admission rate from our emergency departments. And that is roughly twice the pre-COVID admission rate.

In the orange, there is testing that's done on the floor. That is testing for patients where suspicion increases. But we do have repeat testing showing up for patients who are admitted with suspected COVID and the initial nasopharyngeal swab comes back negative.

The thin gray zone is ICU testing, which is almost entirely repeat testing on ICU patients. The other major intake for our patients is our urgent care centers. These are either walk ins or physician referrals. These patients must meet high priority criteria for testing or they are turned away for both constraints on nasopharyngeal swabs and testing capacity.

We have a limited ability to do other testing, primarily high priority ambulatory sites, including home draws, where we've trained our phlebotomists to go to the elderly frail in particular to do nasopharyngeal swabs.

Next slide, please. The positivity rates are being tracked by intake site. The red is hospital based, which is predominantly ED. And you can see, despite the increase in our testing capacity 30-fold from March 8 to March 20, our positivity rates went up.

I couldn't help but feel that we are on the backside of chasing the virus as it spread through our communities. With a steady testing capacity, the positivity rate for hospital intake leveled off at about 70%. In the last three days, it's gone down a little bit. I do not know if this is a lead indicator for what our local civic leadership is calling plateau. But I'll take any lead indicator there is, and it'll be interesting to see how this goes.

The green is our urgent care centers and the blue is our other. You can see we've had a very high rate of positivity throughout our region. This is true for other health system providers in the New York region. It's just a staggering positivity rate. And again, whether this is a lead indicator of a plateau, time will tell.

Next slide. A collateral indicator is use of the routine respiratory virus panel testing. And you can see on the left that we had, in essence, a usual rate of RVP testing during the flu season. The green is total tests. The red is a positive for a routine respiratory virus. And a gap started opening up on March 3.

We turned on our CDC assay March 8. We turned on our semi-automated March 11. And you can see this huge gap in negativity opening up with our RVP testing, what I call the COVID-19 gap. And in that gap, the majority, a slight majority it's about 55% to 60%-- test positive. This is important RVP testing uses up real estate on your machinery, particularly if you're using the semi-automated machines in your hospital sites. And so we have discouraged use of RVP testing in favor of COVID testing, just to ensure that we're optimizing our laboratory resources.

Another problem we've on the right is the fact that hospitalized patients with fevers, the doctors will order blood culture. And while our central microbiology lab is built for around 18,000 blood

bottles per day for a two week period, we exceeded what was a reasonable capacity for blood cultures and were at risk of not being able to provide results should any of our machines gone down. And you can see on the same scale the amount of COVID testing that was done.

Next slide is just from this morning. We've been messaging very strongly that physicians should not order blood cultures on COVID patients unless there is reason to suspect super infection. And fortunately, with this messaging systemwide, the blood culture utilization has gone back to what we would consider normal values.

Last slide is the issues that we are dealing with now. Given the fact that a patient in an ED admitted to hospital with presumed COVID winds up with a not detected result, the patient is still presumed to be COVID positive. And so there is an intense discussion going on in our health system about the negative predictive value of a not detected PCR.

Second, you've just heard discussion of serologic testing. This is a huge issue, both for our workforce as well as for community testing. Third is Northwell's decisions yes or no to deploy a more rapid point of care testing. Fourth is the deployment of testing at our hospital sites versus our reference lab.

Fifth is rapidly becoming an acute issue, which is what I would call need to know whether a patient is COVID-19 positive or negative prior to surgery or other invasive procedures. And lastly, Northwell is preparing for use of convalescent plasma. It is our intent to participate in the randomized controlled trial. So this is a report from the front line, the issues that are hot. Thank you.

JASMINE CHAITRAM: Jim, thank you so much. We really appreciate the time you took to prepare and to be on this call today. I know you're extremely busy where you are and we are very grateful for everything you're doing.

JIM CRAWFORD: My pleasure.

JASMINE CHAITRAM: Our next speaker is also on the front lines. It's from the Nebraska State public health laboratory, Peter Iwen. And he's going to talk to us a little bit about the experience from the public health, the state public health laboratory perspective.

PETER IWEN: Yeah, thank you Jasmine for inviting me.

PETER IWEN: Thank you, Dr. Crawford, for your overview of what you're seeing out in the New York area. Of course, in Nebraska, it's quite different. Our capacity to test is much lower. I would like to give you just an overview of what we're seeing in Nebraska from the public health side.

I did put a timeline together to show you that we've been talking about testing in Nebraska since about the last part of January because we were told that we would get some repatriated Americans from China sent to our national 14 unit. And we began validation of a WHO-- the WHO assay at that time.

On January 29, we were told that we might end up with 250 individuals in Omaha and we were very concerned about that because we didn't have an assay available to test for COVID-19 at that time. If you look down the list where the WHO declared an emergency on the 30th of January, Omaha was designated as one of four sites for federal quarantine of people in the United States.

On the 6th of February, there was a national declaration of public health emergency. And then on the 7th, of course the NPHL was offered the EUA from the CDC that we could order from the IRR warehouse. On the 8th, we have 57 people arrive in Omaha for a federal quarantine.

And we received the EUA on that date, and we were able to validate our EUA within a day so that we were one of, I believe, six public health labs who was able to validate the EUA for the CDC assay. And on the 17th of February, we did receive 14 people from the Diamond Princess, 12 of whom were positive for the coronavirus at that time. Some of these folks were admitted to our biocontainment unit. And on the 13th of March, our governor in Nebraska declared a state of emergency.

Next slide, please. I've never actually seen a state of emergency document. But this is what the document entailed. And there is such a thing as a fancy document when you have state of emergencies declared.

Next slide, please. And I just wanted to show you that we do have this national quarantine unit. This is actually when it was being built like six months back. It actually opened up the day before our quarantine travelers showed up in Omaha so that we actually had it open at that time. So it's a larger facility. It is supported through the DHHS/ASPR, which is one of the federal organizations.

Next slide, please. I just want to give you a little bit of information about what we had with our federal quarantine travelers. The people that came from the Diamond Princess actually were in quarantine a median of 21 days. Some were let go at 14 days and some were actually quarantined for up to 33 days. And during this time, the public health lab was asked to do serial testing on these folks.

If you look at the day one when these people arrived, 12 of the 14 were positive for the coronavirus. And 12 of those people had nasopharyngeal positive specimens. Seven had throat specimens that were positive. We did retest these people again on day 10, and we did serial testing after that time. Nine of those were positive by NPs and two were only positive by the throat.

It was at this point that we were communicating with the CDC. And ultimately the CDC dropped the testing of throat samples at that time, which wasn't very reliable. We did serial testing on the patients, because we needed to have three negatives in a row 24 hours apart before they could be released from our facility. This was a decision that was made by ASPR and the leadership at the University here.

We did run a total of 205 specimens on our quarantine travelers, 100 of which were negative, 77 positive. And interestingly we had 28 inconclusive results. As these people got close to the end

of their quarantine period, we started seeing more and more high CTs and only getting one of the two targets positive. So that was kind of an interesting finding as well.

Next slide, please. These two documents here, I just want to share, because of the shortage of reagents to our public health lab, we actually looked in Nebraska and tried to come up with a way where we could obtain more testing with less use of reagents. And we were aware of a group testing of pooled samples through our blood banking department as well as through our STD programs, that this was a common procedure that was used to save on reagents.

We realized that, even discussing this, we were outside the box of our CLIA because we were looking to do this with the CDC assay. And we actually had the governor declare that he gave us full authority in the letter on the left to be able to do pool testing. And then ultimately, we received a letter from the FDA that they would allow for us to do pool testing of up to five specimens at a time if our percent infectivity did not go over 10%.

Next slide, please. And just to share a little bit. This is up to the 30th of April. We now have pooled 939 specimens in 189 pools. And we've had 50 pools positive. If you look at how many extraction kits were used and how much PCR reagents were used, we used 441. And we were able to save 498, which means we had a savings of 53% of our reagents.

Just today I was checking with the lab, and we did 40 pools today of 200 specimens, of which 10 of the pools were positive. And now we would be repeating those tests individually. So 40 plus 50 means that we've done 90 extractions with PCR reagents when, in fact, if we would have done all 200 of these people separately, we would have had 200. So we did save about 55% as well.

So pooling has been something that has worked for us. I will tell you that, if there's any interest in pooling, that we have written a paper. It has been submitted as a proof of concept paper. It is available on the MEDRXIV, and it's M-E-D-R-X-I-V site as a prereview paper that you can access and actually look at what we did and how we decided the statistics as such for our pooling, if you're interested.

Next slide, please. This is just an overview of what has been seen in Nebraska up to the 1st of April, what different laboratories are being used to test for COVID-19 in Nebraska. Our sister hospital at Nebraska Medicine is actually using the Roche Cobas test to run their samples and then of course the public health lab.

And then we have a spattering of some reference labs within the state that were samples that were being sent from our state to these reference labs. So it isn't a huge number of tests being done in Nebraska at this time. It's not even close to what, of course, is being seen in New York.

But we are trying to keep up as best we can. Our percent positivity rate now is around 9% to 10% in Nebraska. It has gone up in the last week or so from about 5% to 10%. And as we start testing more and more in our rural sites, we're starting to see more and more positivity for the COVID-19.

Next slide, please. I have to just show you that we hope spring comes and we hope spring is much nicer than it is right now as it pertains to our environment as well as pertaining to the laboratory. I want to acknowledge the staff at the Nebraska Public Health Lab in our biology section because we actually have only four individuals who are qualified and cleared to run testing for COVID-19.

They are operating in the laboratory seven days a week, at least two shifts every day with four people. And it's been very daunting for them to keep up. We hope that we can sustain this. I don't know how long we can sustain, but we're doing the best we can. We also hope that we can keep the reagents flowing to Nebraska.

We are very concerned that we are running out of automated extraction reagents. And we will have to go to the manuals again, which we have in the past. Once we get to the manual extractions, of course that's going to cut down our ability to run more and more tests within the state.

So is it sustainable? I don't know. Of course, we hope it is. We are trying the best we can out in the rural environments as well. And we know that the wave is now just starting to hit us. We've been told that about May 1 will be our peak. We don't know what that peak will be. But we have a lot of people wanting requests for tests. And we're just trying to do the best we can to keep up. So I'll leave it at that. And if there's questions later, I'd be happy to entertain them.

JASMINE CHAITRAM: Thanks, Peter, really appreciate you taking the time to talk to us today. And it sounds like you've got a lot going on. You're working 24/7. We do appreciate all that you're doing and hope that things do get better as far as reagent and access to material.

I wanted to say a few things about reporting data because I know we've received a lot of questions about that. Right now the federal government is reviewing laboratory testing data from clinical testing laboratories across the US to ascertain, among other things, the number of tests ordered, performed, resulted, and understand the demographics of those who do test positive, such as age, sex, zip code, et cetera.

These data are also used to identify hotspots of COVID-19 positivity and possible reagent and PPE shortages based on testing volumes that we're seeing. On Friday, March 27, the CARES Act was passed into law and one provision states that laboratory testing for SARS-CoV-2 must report data to the Department of Health and Human Services.

Following this, a letter was sent to hospitals from Vice President Pence instructing laboratories in hospitals to send testing data to DHHS if they were not outsourcing their COVID testing to five specific reference commercial laboratories.

CDC has received a number of questions about data reporting. The first response to these questions is that you should continue to report to your state health departments as you normally do through your existing reporting mechanism. State public health laboratories should continue to send data to CDC as they normally do.

Laboratories located in hospitals or servicing hospital systems should send data to the Department of Health and Human Services using something called the HHS Protect System. And more information about that should be coming out if it hasn't already. And you should also continue to report to the CDC national health care safety network and NHSN through their normal reporting channel.

Data should be reported to the HHS Protect System by 5:00 PM Eastern Daylight Time daily unless until otherwise directed. And DHHS has or will be very soon releasing an FAQs document to help answer some of your questions about reporting. And as soon as we get those links, we will provide them with our PowerPoint.

CDC is developing other solutions to obtain data from hospitals, clinical and commercial laboratories. A short-term solution will be for each state to, through its emergency operations center or its health departments, send aggregate testing data to CDC.

A longer-term solution that we're looking at is for all the laboratories that I just mentioned to send a copy of their electronic laboratory reporting message to CDC. If you are a laboratory that is performing COVID-19 testing but not reporting electronically to your state health department and need assistance, please contact CDC through the DLSinquiries@cdc.gov email.

And as I said, until these solutions are in place or until otherwise directed, you should continue to send the data through the normal channels and laboratories and hospitals should continue to send data to DHHS. Our last topic for today is a biosafety update. I'm going to turn it to Bill.

BILL ARNDT: Thanks, Jasmine. My name is Bill Arndt, and I am the biosafety program lead in the division of lab systems at CDC. I'm also serving as a lead laboratory biosafety SME in the CDC Laboratory Response Task Force. Last week I provided an update on the CDC's recommendation for transporting suspected and confirmed COVID-19 specimens by pneumatic tubes.

We received several questions for clarification on this topic. So I wanted to provide additional details on this recommendation to hopefully address those questions. So all specimens collected for laboratory testing should be regarded as potentially infectious. Health care personnel and laboratory personnel should transport clinical specimens within a facility, should adhere to standard precautions, and select the appropriate biosafety practices based on a site specific and activity specific risk assessment to reduce the risk of personal exposure.

Now because of the potential for exposure to infectious aerosols or droplets, it is not recommended to transport respiratory specimens from patients with suspected or confirmed COVID-19 through the pneumatic tube system. Examples of respiratory specimens include nasopharyngeal swabs and/or oropharyngeal and swabs, nasal mid-turbinate swabs, anterior nares swabs, nasopharyngeal wash and aspirate, or nasal aspirate, pleural fluids, tracheal and lower respiratory tract aspirates, bronchial lavage specimens, and sputum.

At this time, for other types of specimens, ensure that all personnel who transport these specimens via the pneumatic tubes are trained in safe handling practices specimen management

and spill decontamination procedures. The facility should also have standard operating procedures for the pneumatic tubes, including training and competency assessments for lab operators, to ensure safe use of the tubes and decontamination of the pneumatic tubes by maintenance or service providers.

CDC is in the process of drafting a LOCS message to further distribute this information to the clinical laboratory community.

JASMINE CHAITRAM: Bill, I'm going to try to ask you some questions really quick that we got from our participants. The first one is, have the transportation requirements for COVID-19 and SARS-CoV-2 changed?

BILL ARNDT: So we updated the recommendations for packaging and shipping of SARS-CoV-2 a couple weeks ago. The CDC currently recommends suspected or confirmed SARS-CoV-2 patient specimens, cultures, or isolates be packed and shipped as Category B UN3373 Biological Substance. We are not recommending any stars SARS-CoV-2 specimens, cultures, or isolates be shipped as Category A.

JASMINE CHAITRAM: And are there any updated recommendations for lab staff to protect themselves while performing regular testing, CBC's chemistries, et cetera? Should bench tech be wearing masks and eye protection?

BILL ARNDT: The current guidance provided by the CDC recommends that routine diagnostic testing of specimens be handled in a BSL 2 laboratory. So if these activities are occurring inside a lab, staff should follow standard precautions when handling clinical specimens, all of which may contain potentially infectious materials.

Standard precautions include hand hygiene and the use of PPE, such as coats, gowns, gloves, and eye protection. That's it.

JASMINE CHAITRAM: And last question is, what type of PPE should phlebotomists wear when collecting samples from suspected and confirmed COVID-19 patients.

BILL ARNDT: Good question. So the current guidance provided by the CDC recommends that, if laboratory personnel-- and this includes phlebotomists-- have direct contact with suspected or confirmed COVID-19 patients, they should follow the recommended PPE for health care providers while in the presence of those patients.

There is a greater risk of exposure due to being in close proximity to the patients. So this is why the CDC is recommending laboratory personnel-- and phlebotomists, they're included in that-- should follow the PPE recommendations for the health care providers.

JASMINE CHAITRAM: Thank you, Bill. As we close out for today, I just wanted to share this photo of a package of COVID-19 samples that was recently submitted to us by Dr. Bill Pasculle from the University of Pittsburgh Medical Center. As you can see, it's a nice note to the laboratory professionals that play a pivotal role in maintaining the health of our nation.

And we are so grateful to each of you for the work that you're doing every day to help our country respond to this pandemic. We encourage you all to request that your laboratory be added to the Laboratory Outreach Communication Systems (LOCS) so you can receive communications from CDC as well as information about these calls and share those with others.

It's LOCS@cdc.gov. This concludes our call for today. These calls will take place every Monday at 3:00 PM. These slides and transcripts and audio from this call will be posted to the DLS by the end of this week. If you can find it on CDC.gov/safelabs and if you click on the Resources and Tools box, then on the link for Clinical Laboratory COVID-19 Response Weekly Calls, and we will be sending this out in our LOCS messages so that you can find it easily.

Our next call will be on Monday, April 13, and we encourage you to share that information with your colleagues and other laboratory professionals. If you have any questions, please submit them either through the Q&A function on Zoom or to DLSinquiries@cdc.gov. Please make sure to include an email address with your questions so that we can get back to you. We are actually answering some of these questions when we receive them if they don't end up being answered on these calls. Thank you again, and apologies for going over.