

Clinical Laboratory COVID-19 Response Call

April 27, 2020

Speaker Panel

Jasmine Chaitram, CDC Division of Laboratory Systems

Carmen L. Wiley, American Association of Clinical Chemistry

Ann Salm, Quest Diagnostics

Brian Krueger, LabCorp

Bill Arndt, CDC Division of Laboratory Systems

Sara Brenner, U.S. Food and Drug Administration (FDA)

Tim Stenzel, U.S. Food and Drug Administration (FDA)

JASMINE CHAITRAM: *Good afternoon and thank you for joining us today. My name is Jasmine Chaitram and I am the Associate Director for Laboratory Preparedness in CDC's Division of Laboratory Systems. We're the CDC division that works to advance laboratory quality and safety, data and biorepository science, 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 have been supporting CDC's Emergency Operations Center by serving as an interface between CDC and the clinical and public health laboratory communities. Some of the tasks we have been focused on include laboratory biosafety, the regulatory requirements under the Clinical Laboratory Improvement Amendments, known as CLIA, additional laboratory quality issues, and the challenges associated with implementing laboratory developed tests. On these weekly calls, we will discuss hot topics and solicit this 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 of future calls accordingly. We'll be sharing slides on this week's call – we will post the slides online (along with the audio and transcript) later this week.

If you have a clinical laboratory-related question you'd like our team to address on future Clinical Laboratory COVID-19 Response calls, you can submit those for consideration by using the Question and Answer (Q&A) function in Zoom or emailing DLInquiries@cdc.gov.

For media questions, please contact CDC Media Relations at media@cdc.gov.

If you are a patient, please direct any questions to your healthcare provider.

JASMINE CHAITRAM: *(Show second slide) Before we move forward, here is a quick overview of some of the Zoom functions you may find useful during this call. For added security, participants will now use a password to join these calls. You can find this password (and other Zoom access information) online and in the LOCS messages we send out to that listserv prior to each week's*

call. And now, I'll turn it over to our first panelist – please welcome Carmen Wiley, President of the American Association for Clinical Chemistry.

Due to a technical issue, the first part of Carmen Wiley's presentation did not record correctly. Please consult the slides for additional information.

CARMEN WILEY: Labs are often competing against one another for the same devices and supplies. Better coordination is needed to ensure that labs, particularly those in hot spots, get the necessary equipment and supplies they need.

This level of uncertainty makes it really difficult for labs to increase the volume of testing. Next slide, please. We all know that some molecular testing requires very specialized training in high complexity labs, and not everybody can do it.

Also, COVID-19 tests can be very labor-intensive. Labs often borrow staff from other areas to fill this void. The fact that they need to run these tests 24 hours a day, seven days a week, if, in fact, they have the reagents to do it, contributes to an existing shortage of trained laboratory personnel.

Labs are incurring high upfront costs to acquire equipment, PPE, and additional staffing. Costs far exceed the level of reimbursement for performing the tests. This problem affects the entire health care system.

Another important point is that clinicians are getting confused and ordering antibody tests for diagnosis. There is a need to provide clear education around testing so the correct test is ordered at the correct time.

So in short, molecular or rapid PCR testing is done for diagnosis, and serological testing is done for past exposure to the virus. Next slide, please. So let's talk about our members' needs with respect to serology testing, because that's what we're really hearing and discussing a lot within the field.

We really need a serology validation panel. And what do I mean by that? We need a panel that consists of well characterized IgG, IgA, and IgM antibodies for SARS-CoV-2, and a true and well characterized negative.

This is critical for validation in clinical labs, and this is essential in establishing the analytical performance of serology assays. Many individuals with mild infections or asymptomatic infection will not have had the PCR test for SARS-CoV-2, and they will benefit from knowing their antibody status.

But how do we ensure proper timing for these tests? As we consider surveillance testing, we need to ask ourselves, are we set up for effective surveillance. Also, are we really ready for test and trace. This will be crucial for returning to safe social interaction. Next slide, please.

We all know that many factors, especially those of you who are on the call, can affect the sensitivity and specificity of antibody tests. Different viral loads, infection rates in the population, and so forth. These all impact the positive and negative predictive values.

Understanding the limitations of serological tests is critical, and many on this call already recognize that. Serology tests do not detect the virus and should not be used for evaluation and early infection.

COVID positive patients are infectious to other people early in infection, and this is when serological tests can produce a negative result, giving a false sense of security. Timing of sample collection is really important.

Patients make antibodies a week or later after they first develop symptoms. Some patients, such as the elderly or the immunocompromised, may even have a further delayed immune response.

The prevalence of past infection in the tested population affects the interpretation. I believe, if I recall correctly, last week, there was a discussion about population prevalence and what this really means.

So recall that, if a serology test is performed where there is a 5% prevalence and the test is 95% sensitive and specific, the positive predictive value is 50%. It's as good as a coin flip, whereas the negative predictive value is 99%.

Rapid serological tests may provide qualitative results, but let's not forget there is a need for a quantitative result to determine immune status when we learn and study vaccination efficacy.

Also, we need to understand the cross reactivity. When we're looking at these patients who have been infected with other coronaviruses, which is probably likely common, we may have cross reactivity with the SARS-CoV-2 antibody tests. So how do we account for this and study for that?

There is a definite need for understanding how to evaluate the quality, and understanding the limitations, and how do we vet the manufacturers of antibody tests that are coming on the market. Without clear understanding and direction, this testing may actually do more harm than good.

So in closing, I'd like to highlight what AACC is doing to help during this pandemic. Next slide, please. On the serology front, we have partnered with the California State Task Force to provide expertise on developing a guide for the evaluation of serological tests. We are willing to help others with guidance of this type.

Experts from AACC are working to create a living document for the evaluation, use, and interpretation of serology tests. And this is useful for this and future pandemics. We have a

comprehensive COVID-19 resource site that includes the latest information on science and education, general outlook preparedness, our specific advocacy efforts, and key sites for keeping up to date on emergency guidance.

AACC has a discussion forum that's called [The Lab Artery](#), and it's available to everyone, whether you're an AACC member or not. And this is a forum for sharing real time questions and concerns, and seeking input from your peers.

AACC has also created a [testing directory](#) for lab professionals and hospitals of labs performing COVID-19 testing. As of Friday, there were 101 labs in the US in 31 states, and 55 non-US labs in 26 countries participating in this directory. We welcome others to participate.

With that, I'd really like to thank you for your time and giving me an opportunity to address everyone on the phone, and I'm happy to take questions when and if there's time. So thank you.

JASMINE CHAITRAM: Thank you so much, Carmen. That was a great presentation, and I'm sure a lot of folks on the phone were relating to things that you said. Because of the number of individuals that we have calling in to these types of calls, we actually don't take questions during the call.

But folks that are submitting questions, we will get them to you and you can help to provide responses specific to your presentation, and we will send those back out to the individuals that submitted them.

CARMEN WILEY: OK, thank you.

JASMINE CHAITRAM: One other thing I wanted-- sure. And one other thing I wanted to mention, because this just-- one of the questions did come up while you were talking is, availability of slides. And we do post the slides as well as the transcripts for these calls on the [CDC.gov/SafeLabs](https://www.cdc.gov/SafeLabs) under Tools and Resources.

And you can go back and see all of the transcripts and slide presentations for the previous calls. We've had six, including today, it's the sixth call. So please visit that website. Carmen, thank you again. And we're going to move to our next speaker.

And the next speaker is Ann Salm from Quest Diagnostics. And she actually does not have slides, so I am going to show some useful links that she provided. And Ann, would you like to go ahead?

ANN SALM: Sure. Thank you, Jasmine. Hi, this is Ann Salm. Can you guys hear me OK?

JASMINE CHAITRAM: Yes, we can hear you.

ANN SALM: Excellent, OK. My name is Dr. Ann Salm, and I am a member of the Quest Diagnostics field medical affairs division for infectious disease, and I'm here to talk to you guys today about our IgG test for SARS-CoV-2.

Quest launched our IgG test for SARS-CoV-2 the week of April 13. It was sort of a soft launch, and then we fully scaled up to our current capacity of 150,000 tests per day last Wednesday, April 22.

Our volume has not yet reached our capacity. We still have room. But we are ready, based on information and lessons learned from our molecular offering. We are prepared to scale up our capacity as demand requires, if beyond that 150,000 per day.

You can see on the links I provided there's a press release for the serology testing, which gives some of the specifics around that serology launch as well. In terms of our technology, we have three pillars of resources that we lean on when we talk about educating providers, or our field reps, or our internal stakeholders regarding the assay performance our assay.

We use the product inserts for the manufacturers that we get our assay from. We also use, as a second pillar, FDA language around our assays. And then finally, the third pillar or resource that we use when educating HCP's field reps and internal stakeholders is ACLA's language on serology testing for SARS-CoV-2.

So let me talk about the PI, the FDA language, and ACLA as a resource for educating on the technology behind the tests that we've run. The product insert has carefully outlined the performance characteristics of our assays, and so we are able to lean on that to explain to providers and anybody inquiring about how, perhaps, for instance, our assay deals with or, in the validation stages, ruled out cross reactivity issues.

So to Carmen's point in the previous presentation, there's much media hype about cross reactivity and how do we know that our IgG assay is effectively assessing an immune response to SARS-CoV-2 and other coronaviruses.

And so we use that product insert to talk about, here's how many samples were run in the validation of this assay. Here's how much cross reactivity played a role in the samples acquired to run that validation. And then we're able to speak to those questions using the product insert.

And, of course, because this is an evolving landscape, we really try to make sure that our messaging is concise and consistent from one person to the next. We also use the FDA language regarding the importance of impressing upon clinicians and the field, regarding the fact that the serology test is not a diagnostic test.

And this seems so obvious to those in the public health sector and in clinical microbiology, but it's something that we continually have to drum away with providers, because they think the serology test is diagnostic and it is not.

Now, this also feeds into the requirement, or lack of a requirement, for an EUA for the serology testing. Because the FDA doesn't require EUA for serology testing, we have to kind of go back and explain to providers that EUA isn't required because it's not a diagnostic test.

But then we do usually segue into the importance of the emergency use notification and how manufacturers, particularly the manufacturers we're dealing with, could opt to seek out an emergency use authorization.

So as of today, we have the good news that the one manufacturer that's doing the majority of our testing has been issued an EUA. And I think that that helps, you know, we aren't really sure exactly how we're going to frame the language.

But we do think that it helps to sort of substantiate or show that our manufacturers and our tests, our immunoassays, are meeting certain thresholds of acceptability and rigorous sort of investigation for cross reactivity sort of issues.

So we lean on the product insert, we lean on the FDA language, and then finally, ACLA also provides some pretty nice language regarding the fact that a serology test is not in and of itself going to diagnose or stand alone.

It's better to be used in the whole clinical picture, as all immunoassays are, or, you know, antibody testing to certain infectious diseases. But that also, it's important to do more testing in order to understand, do more testing and more research so that we can better understand how the body's immune response to SARS-CoV-2 may help inform return to work, a safe return to work, or to normal activities.

So at Quest, we lean on these three pillars, the product insert, the FDA language, and the ACLA language, to educate HCPs and the field, clinicians in the field. And then we also have a forum on our Quest COVID-19 website where people can submit questions.

So just as a public kind of goodwill offering, we have an inbox that we monitor 24/7 regarding questions around SARS-CoV-2 testing, both in the molecular and the serological. We get questions from people across the board to that inbox, so I've availed to you our Quest COVID-19 web page, which has that email inbox that you can link.

And then we also have provided, for clinicians, frequently asked questions just for serology testing for SARS-CoV-2, and that link is also provided on your screen as well.

So I appreciate the opportunity to talk to this group about our IgG test for SARS-CoV-2, and look forward to whatever questions people may submit through the typical channels. Thank you, Jasmine.

JASMINE CHAITRAM: Thank you very much for giving us your time today. The next speaker is going to be from LabCorp and talking about home collection kits. Brian Krueger? Brian, are you on?

BRIAN KRUEGER: Yes. Hey, Jasmine, can you hear me?

JASMINE CHAITRAM: Yes, I can. Thank you.

BRIAN KRUEGER: Hey, everyone. I'm Brian Krueger. I led the development and validation and deployment of LabCorp's high throughput COVID-19 RT-PCR test. That also has an FDA EUA. And as many of you heard, LabCorp received an amendment to that EUA last week for COVID-19 testing that now includes the processing of home collection kits. CDC asked us to provide a very brief overview of this authorization and the work that was done at the request of the FDA for this recent approval milestone.

Next slide. So just a brief overview of the test itself. The LabCorp COVID-19 RT PCR test is actually a high throughput implementation of the CDC test. It was granted an EUA on March 16, but testing of that test began in the clinical lab on March 5th. We received an additional amendment to that EUA to approve it as a multiplex, which greatly increased our capacity and has enabled us to reach a throughput of approximately 65,000 tests per day.

Further automation over the next couple of weeks will allow us to double that capacity to somewhere over 100,000 available tests a day. This assay itself was multiplexed by changing the dyes on each of the key PCR probes. And at the recommendation of the CDC and the FDA, we dropped the N3 assay, which was the assay that state health labs are having a little bit of trouble with. In our assay, it had always performed very well. But we considered the suggestion of the CDC and FDA and ultimately decided to drop that assay from the test.

The validation of the multiplex assay on clinical samples was 100% specific and sensitive. And we also tested the assay against 26 potentially interfering respiratory organisms, and we saw no unexpected cross-reactivity. Similar to the CDC assay, our LOD using live virus from extraction was around 6.25 copies per microliter. And the assay was authorized by the FDA for the detection of COVID-19 in symptomatic patients.

Next slide. As the outbreak has progressed, it's really become clear-- and I'm sure everybody on this call is aware that conventional testing methods for respiratory viruses are appearing to be inadequate in dealing with the volume of the patients that are affected in doing this testing, and the traditional physician environment has become quite challenging. Asking patients to present in person also poses risks to them, the health care workers, the doctors, and other patients.

So one potential way we can alleviate a lot of those risks, while still providing very safe and effective testing for patients, is really to allow them to collect their own samples at home. The Pixel collection kit enables us to do this. Consumers visit the [pixel.labcorp.com website](https://pixel.labcorp.com) and

select the COVID-19 kit from test menu. Before a kit is shipped out to the consumer, they must answer a couple of short survey questions about their symptoms, which are reviewed by a physician ultimately, before the kit is released to the consumer and mailed out. This kit includes swabs for collection, a saline tube, a gel pack, a return shipping box, and a label.

And after collection, the consumer places the saline tube and swab into the return kit, schedules FedEx pickup, or they drop that off at a FedEx location for shipment back to LabCorp. And the patient generally receives results back in one to two days. We are a 24/7 operation, so we do process these on the weekends, although FedEx does not deliver on Sundays. So we have explicitly mentioned that within the instructions for use, that the consumer needs to be sure that they call for FedEx pickup or drop it off so that FedEx can ship it to us overnight, so that there isn't any extended time period where the sample is sitting in a FedEx box or on a truck.

This product was initially made available to health care workers and first responders. But we're quickly building kits for a much larger consumer release.

Next slide. The validation of the collection kit included three separate stability experiments. The first was a bench top stability study, where 20 contrived positives and negatives were collected and tested at zero hour, 24 hour, at room temp, and then after 72 hours of storage at 2° to 8° C for a total time course of 96 hours. These positives were contrived by spiking live virus onto a cotton swab, and then placing that swab into three mls of saline to create a final concentration of 10 copies per microliter, which is just below 2x the limit of detection of our COVID-19 RT-PCR test. During that time, of course, there was no degradation at all of the expected signal. There were no false positives and no false negatives.

Next slide. The second stability study was similar to the first, except the FDA requested that we perform an extreme temperature excursion study. 40 samples were collected, then 20 positives were contrived by spiking the swabs with live virus to a final concentration in saline of 10 copies per microliter. The samples were then cycled in an oven, according to the table below, where they spent six hours at 40° C, followed by 16 hours at 22° C, an additional two hours at 40° C, followed by 22 hours at 35° C, and ending with four hours at 40° C. Despite spending over 30 hours at over 35° C, there was no apparent decrease in the CT values, and the temperature excursion actually appeared to increase our ability to extract the virus. Again, we observed no false positives and no false negatives.

Next slide. Finally, we performed a shipping study using samples collected by 30 lay volunteers. Each participant was given two saline tubes, two swabs, and these Pixel collection instructions that you see to the right. After collecting samples, half the tubes were spiked with a live virus and then shipped back to the lab via FedEx. Transit time through FedEx was 72 hours. Samples were received, unpacked, and tested using the LabCorp COVID-19 RT-PCR test. Again, we observed no degradation of the expected CTs of the contrived samples, and we didn't detect any false positives or false negatives.

We really believe that Pixel self-collection kit represents a powerful new tool in our battle against COVID-19. And I'd be happy to take any questions that you forward to the CDC. Thank you.

JASMINE CHAITRAM: Thank you very much, Brian. Our next speaker is going to talk about laboratory biosafety. And Bill Arndt has been on all of these calls. He is the CDC Division of Laboratory Systems biosafety subject matter expert, that's also serving on the Laboratory Response Task Force in the CDC Emergency Operations Center. Bill, are you ready?

BILL ARNDT: Yes, I'm here.

JASMINE CHAITRAM: OK, go ahead.

BILL ARNDT: So, thanks, Jasmine. So as Jasmine mentioned, I'm the biosafety program lead in the Division of Lab Systems, as well as serving on the CDC Laboratory Response Task Force. So over the last couple of weeks, we've been receiving a number of questions related to serology and the type of PPE staff should wear, and if a BSC is required when performing these types of assays.

In response to these questions, I decided to provide an overview of the CDC's current laboratory biosafety guidelines that we believe apply to the majority of these serological-based assays that had recently been approved by the FDA for COVID-19 testing.

First, laboratories should perform a site specific and activity specific risk assessment to identify and mitigate the risks present. The risk assessments and the mitigation measures are dependent on the processes performed, identification of the hazards involved in the process and/or procedures, a competency level of the personnel who perform the procedures, the laboratory equipment and the facility itself, as well as the resources available. It is important for facilities to conduct these types of biosafety risk assessments to make sure they have all the appropriate safety measures in place to address the risks present.

Secondly, we believe the laboratory biosafety guidance provided on the CDC interim laboratory biosafety guidelines for handling and processing specimens associated with COVID-19 are still applicable to the serology-based assays that were recently approved by the FDA. These guidelines state that routine diagnostic testing of specimens-- we consider most serological-based assays to be routine-- can occur in a BSL-2 laboratory, and the laboratory should follow standard precautions when handling and processing the specimens.

Standard precautions start by treating all clinical specimens as if they potentially contain infectious materials. Additionally, standard precautions include following proper hand hygiene-- so washing your hands regularly and thoroughly with soap and water-- and using personal protective equipment, such as lab coats, gowns, gloves, and eyewear. For the serological assays that are conducted outside of a BSL2 laboratory, such as in a point-of-care setting, the CDC still recommends staff follow standard precautions when handling these specimens.

The last thing I'd like to mention is that if your risk assessment deems that there is a high likelihood to generate aerosols or droplets of potentially infectious materials, use either a certified class 2 BSC or extra precautions, such as additional PPE, like a surgical mask or face shield or other physical barriers, like a splash shield, to reduce the risk of exposure to laboratory personnel.

I hope this information I just provided helps answer your biosafety questions that have come in on this subject. If not, please do not hesitate to submit additional questions using the Q&A feature in Zoom, or by emailing dlsinquiries@cdc.gov. We will respond to your questions as soon as possible. I'll turn it back over to Jasmine to see if she has any questions she would like to ask that came in from the previous calls.

JASMINE CHAITRAM: Thanks, Bill. And so, as we've done for previous calls, we do look at the questions that we receive by email or even on the call and try to address a few of them on the future call, which is today's call. And so I do have a couple of questions picked out. And I'm going to ask you them now. The first one is, what is the process if a staff member spills a suspected or confirmed COVID-19 specimen on the counter or floor?

BILL ARNDT: All right. Thanks, Jasmine. So the laboratory should have standard operating procedures, or SOPs, already in place for spill cleanup. And staff should be trained on those SOPs. In general, staff should decontaminate the work surfaces, in this case, the counter or floor, and equipment with the appropriate disinfectants. So use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2. And we recommend that you follow the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

JASMINE CHAITRAM: OK. Is it safe to send COVID-19 swabs through the hospital tube system? If so, are there extra packaging recommendations?

BILL ARNDT: All right. So, yeah, we had a-- we talked about this a few weeks ago. 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 these respiratory specimens, including NP and OP swabs, nasal mid-turbinate swabs, anterior nares swabs, nasopharyngeal wash, nasal aspirates, pleural fluids, tracheal lower respiratory tract aspirates, bronchioalveolar specimens, and sputum. However, other types of specimens, such as blood and urine, are still OK to transport through the pneumatic tubes. It is important to note that facilities should ensure that all personnel transport specimens within pneumatic tubes are trained in safe handling practices, specimen management, and spill decontamination. Next question?

JASMINE CHAITRAM: OK. Last question I have for you today. Are there any changes or specific recommendations in PPE protocols during regular phlebotomy venipuncture, due to COVID-19 pandemic?

BILL ARNDT: OK. If-- the current guidance provided by the CDC is, if laboratory personnel-- and this includes phlebotomists, from our perspective-- 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 these patients. These recommendations can be found in the CDC's interim infection prevention and control recommendations for patients with suspected or confirmed COVID-19 in health care settings, which is on the CDC's COVID-19 website under Health Care Professionals and Infection Control. There is a greater risk of exposure due to being in close proximity to patients. This is why the CDC is recommending laboratory personnel should follow PPE recommendations for health care providers in the presence of patients. That's it.

JASMINE CHAITRAM: OK. Thank you. And I just wanted to quickly note that there are questions coming through the Q&A feature on the Zoom line. And some of our speakers are responding to those questions directly. So, thank you very much to the speakers that are doing that. And I am going to move to the last agenda item today, which is FDA, Tim Stenzel and Sara Brenner, who have participated before. This is the US Food and Drug Administration. And they're going to give an update on the serology testing, point-of-care testing, and laboratory data harmonization. Tim, you want to go first?

TIM STENZEL: Thanks. I appreciate the opportunity to speak today. And I'll speak briefly on one topic and then cover some questions that we received last week. And then Sara will take over. The first is that since Friday and over the weekend, we authorized six new EUAs for SARS-CoV-2. Four of them were serology tests, and two were molecular, and then, there were in addition, two amendments to previous authorizations. The four new serology authorizations are for DiaSorin, Ortho-Clinical IgG, Autobio, and Abbott IgG. They all appear to have high specificity, as measured in their submissions, above 99%. So, I think that's welcome news.

Then I wanted to go to the previous questions. There were some questions about serology. One question was, what does the FDA review with regard to pathway D, non-approved, EUA serological assays? So, the FDA is not reviewing the validation data of those pathway D developers who notify us, agree-- confirm that they validated their tests, and agree to label the product as being given in our March 16th guidance.

What are the current approved uses for serology? There are now, I count, eight EUA authorized serology tests. They all are for the detection of IgG and/or IgM, or, if they don't distinguish, it's usually a pan IgG test. So, there are no other specific real claims for those tests. They are not for-- they should not be used for sole diagnosis. And that's what their language in their authorizations specifies.

There was a question about potentially high false positive rates in point-of-care, anti-SARS tests in the community. I believe that's probably referring to rapid serology tests. To my knowledge, none are FDA authorized tests that were used in the community. Serology tests are known to potentially have false positive results. Those that have been authorized by the FDA have the false positive rates listed in their package inserts. Also, we do recommend that a secondary

confirmatory serology test by a different method be considered for all serology tests, because even a very highly specific serology test, above 99% or at 99%, in a low prevalence population can have a low positive predictive value. So, it's important, to know the prevalence of disease in your population, to properly interpret the results of any test, but in particular, serology tests.

Next question has to do with home collection. When will a home saliva PCR test be authorized by the FDA? We certainly have interested parties. As soon as we are able to receive their data, and there's data sufficient for authorization, we will do so.

There was also a question about point-of-care molecular tests. It has to do with the proper handling of samples outside of the laboratory environment, and this may be in a near-patient care setting. The question is, does the FDA expect patient care settings outside the clinical laboratory environment to be familiar with standard laboratory practices as it relates to handling specimens and for performing amplification tests? And there was concern expressed for point-of-care tests in near-patient settings.

So it's obviously a potential risk. There have been three point-of-care molecular tests authorized under this emergency. All of them have single-use, disposable cassettes, and all systems to date have previously received CLIA waiver. So that the types of settings that these tests should be used in, those that hold a CLIA waiver certificate, are presumably experienced or can be experienced in this kind of testing. And so-- and today, we have not, under this EUA, seen a situation which might reflect any sort of issues related to the use in this setting of these instruments. I would say that anybody handling patient specimens should, of course protect against potential-- any sort of contamination.

The next question is, could you identify current tests that are EUA approved? I would just direct you to our FDA EUA website, which lists all the currently authorized tests. Once they're authorized, they are fairly soon after that loaded onto our website.

And then the last question, I'll leave for Sara, as well as any other topic Sara may wish to present. Thank you.

SARA BRENNER: Thanks, Tim. I'm just going to make a couple of comments on the issue of laboratory data harmonization, which is a very important but often overlooked issue, preceding the pandemic and will go on for quite some time afterwards, but it's particularly acute right now. So, FDA, CDC, CMS, and numerous other stakeholders are currently working together very quickly to address the issue of consistent laboratory data coding and interoperability. And we're doing that through a public-private partnership here at FDA called SHIELD.

So currently, surveillance efforts for SARS-CoV-2 infection and COVID are hindered due to inability to pool and compare data derived from lab diagnostics, unless harmonized reporting practices have been adopted. And at the core of this problem is a fundamental inconsistency in how tests are described, where the same test is often described in a different way between labs

and across the country, which leads to ambiguity in the meaning of the test data and the results.

So as part of our SHIELD public-private partnership, in looking at lab data interoperability, we are working in concert with diagnostic manufacturers, APHL, laboratories, standards developers, and agencies across HHS, to help ensure that the same SARS-CoV-2 molecular diagnostic tests and antibody tests can be described in the same way. Specifically, we're working on a cheat sheet catalog of available testing within the US, created with CDC and other partners, which assigns appropriate, harmonized terminology standards. And those are LOINC and SNOMED CT codes for each test that's being developed. And that will be available for sharing and iteration.

Lab data harmonization efforts will also be extremely valuable for other things beyond this. But immediately, addressing diagnostics-related shortages, evaluating the performance and clinical validity of tests, and linking patient specimen, device platform, and clinical data, including the ability to assess the effectiveness of clinical or therapeutic interventions, in terms of health outcomes, as we move forward.

While this topic feels pretty technical and deep in the weeds, I'm going to point out it does have a huge impact across our pandemic response, perhaps far beyond what most people are aware, with ripple effects across the entire health care system. So, without consistent standards, our ability to make data-driven decisions related to diagnostics and everything that follows at the federal, state, and local levels is hindered. SHIELD represents an important fundamental step in advancing the goal of truly interoperable health systems. And I would encourage each agency and stakeholder to look at what opportunities they have to advance interoperability along the continuum, all the way from laboratory data through clinical care and health outcomes.

We have established an email address that you can reach out to us for more information, or to get involved. And that email address is SHIELD-labcodes@fda.hhs.gov. Thanks.

JASMINE CHAITRAM: Thanks very much, Sara. And the harmonized codes that Sara mentioned will be posted on CDC Division of Laboratory Systems website in the very near future. As soon as we get that up, we will announce that through a LOCS message, which reminds me that we encourage you to sign up for those LOCS messages. You can send an email to LOCS@cdc.gov. I want to thank all of our speakers today for taking the time to prepare and to be on the call and to answer some of the questions in the Q&A. The next call is going to be on Monday, May 4th. We hope you can join us. And thank you again for all that you're doing for this response. And that concludes our call for today.