Clinical Laboratory COVID-19 Response Call

March 23, 2020

JASMINE CHAITRAM: Good afternoon, everyone and thank you for joining today's call. My name is Jasmine Chaitram, and I am the Associate Director for Laboratory Preparedness at CDC's Division of Laboratory Systems. We are the CDC division that works to advance 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 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 safety; the regulatory requirements under the Clinical Laboratory Improvement Amendments, also known as CLIA; additional laboratory quality issues; and the challenges associated with implementing laboratory-developed tests.

This call is the first of a series of weekly calls we plan to host to discuss hot topics and to solicit the community's questions about the work that clinical laboratories are doing in support of the nation's response to the COVID-19 pandemic. We're convening this call to give CDC, other government agencies, and clinical laboratories a platform to engage with and learn from one another. We've structured the contents of this call based on frequently asked questions and inquiries that we've received from our partners thus far.

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 want this call to be useful and relevant to your COVID-19 response activities. We are all in this together.

If you have a clinical-laboratory-related question you'd like our team to address on a future clinical-laboratory COVID-19 response call, you can submit those for consideration by entering them into the chat box in Zoom or emailing dlsinquiries@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.

Before we get started, I'd like to introduce Triona Henderson. She is the medical officer for the Division of Laboratory Systems, and she has a lot more experience than I do with Zoom. So she also has some information for you about answering questions.

TRIONA HENDERSON: I will now present to you the technical details related to these calls. All non-presenter microphones are currently muted. Find the Chat, Question-and-Answer, and Raise Hand function on the black bar at the bottom of the screen of whichever device you're connected to. If you are experiencing technical difficulties during this session, use the Raise Hand function, and describe your problem in the chat only.

Please ask all questions through the Question-and-Answer function. Only use the Chat function for technical difficulties. All questions submitted today through the Q&A function or DLS inquiries will be addressed during subsequent calls.

WENDI KUHNERT-TALLMAN: I wanted to welcome everyone to the call and just give a brief situational update. At this time, we have 91 state and local public-health labs in all 50 states, including Washington DC, Guam, and Puerto Rico, who are successfully running COVID-19 diagnostic tests. Nationally, CDC and public-health labs have tested over 70,000 specimens. This testing process has been greatly streamlined and per new FDA guidance, state and public-health labs are no longer required to go through any confirmatory testing at CDC.

Public-health testing has steadily increased, and we continue to look at innovative solutions to ensure broader testing available across the country. The US has entered a new phase of testing, where we've brought massive commercial-testing capacity online. With this scale, we are facing some supply challenges for reagents, including extraction kits and other materials that are required to run diagnostic testing. This has impacted both commercial and public-health laboratories. We understand the frustrations that labs have across the country, and we ask for your patience as CDC, FDA, and other partners in the private sector are working together to resolve these issues as quickly as possible.

Communities experiencing shortages should consider prioritizing testing for health-care workers and hospitalized patients. CDC has shipped kits through the International Reagent Resource (IRR).

Nasopharyngeal swabs and oropharyngeal swabs remain acceptable specimen types. If both are collected, we do prefer that they be combined into a single tube to maximize test sensitivity, as well as limit testing resources. However, either swab alone is also acceptable with a preference for NP if there's only one swab attempt.

CDC also recommends testing lower-respiratory-tract specimens, if available, for patients who develop a productive cough. Sputum should be collected and tested. The induction of sputum, however, is not recommended. When it is clinically indicated, then a lower-respiratory-tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower-respiratory-tract specimen.

Moving on to talk a little bit about serology testing-- our lab has developed and validated an ELISA as well as a microneutralization test that can detect serum antibodies against SARS CoV-2. The ELISA detects antibodies that bind a viral protein, and the microneutralization test detects antibodies that bind and block the antibody from entering the cells. According to our new analysis, the assay is 97% sensitive and 97% specific. We are now looking to collaborate across a variety of partners to collect serum from patients and look at ways to assess, from a surveillance perspective, where we are with antibodies for COVID-19.

Another thing I wanted to touch a little bit upon was interpretation of test results. A negative result for this test means that SARS CoV-2 RNA was not present in the specimen above the limit of detection. However, there are two important caveats for a negative result. A negative result does not exclude the possibility of COVID-19 and also, should not be used as the sole basis for treatment or patient-management decisions.

So finally, I know that a large proportion of nucleic-acid-extraction kits are available in research labs-- this is a concern that we have heard from many-- and that getting this stock back into clinical labs may help to ease the crunch for testing. CDC is happy to collaborate with APHL and others to explore this as an option. However, I think that there are always concerns as we attempt to move reagents out of one setting and try to get it back into the clinical setting. But happy to discuss further as needed. Thank you.

TIMOTHY STENZEL: So we've been working hard at the FDA. We've authorized a number of assays They're all listed on our website.

We also have our frequently asked questions page for those that are in the situation where they cannot get the supplies that they wish. We give alternatives there. We also have a hotline, and we have an email address for questions.

We've certainly relaxed some of the EUA provisions. We have now over 80 labs that have notified us that they are beginning testing and have validated the assay. Also, for commercial manufacturers, they can notify us and launch as long as they submit an EUA within 15 business days. This doesn't apply for IgM, IgG serology tests. The March guidance update should be followed though. And with that, I turn it back.

SCOTT BECKER: Hi. Good afternoon. I'm Scott Becker. I'm the chief executive officer of the Association of Public Health Laboratories in our member labs, our state, and local, and territorial public-health labs, and have been working with many partners over these many, months to respond to the coronavirus pandemic.

As Wendi mentioned, there are 91 public-health laboratories that have verified at least one of the FDA, EUA assays for SARS CoV-2. That includes 56 state public-health laboratories, including a number of branch laboratories that are included in those state labs, the DC Public Health Laboratory, Guam Public Health Lab, Biological and Chemical Lab in Puerto Rico, and the remainder are large city and local public-health laboratories across the country, including many in California and Texas. APHL's goals for this response is to ensure that public-health labs have the timely diagnostics to perform the quality testing in their jurisdictions, and very importantly, to facilitate reporting of test results since we really do need a national picture here.

Like many of those of you on the line, our public-health laboratories are facing shortages in reagents and other ancillary supplies, and that's been reported both in the media and through a number of different mechanisms. We are closely monitoring different funding requests and supporting educational efforts to increase awareness of the need to continue to support laboratory-testing needs.

One area I want to touch on and was mentioned by Tim is the March 16 updated policy for diagnostic tests during this emergency. In that policy, there were a number of different actions. First, the FDA implemented a policy for states to take responsibility for tests developed and used by labs in their states, indicating that states can set up a system in which they take responsibility for authorizing those tests. And labs will not need to engage with the FDA.

Second, FDA stated it doesn't intend to object to commercial manufacturers distributing it, and Tim talked about that. We are aware that many states do not have such regulatory-oversight programs and may not be able to pursue this option of implementing a system to approve LDTs. So please keep that in

mind for labs. Labs can certainly still utilize an LDT and work through the FDA to secure the EUA as the policy states.

APHL continues to emphasize a quality laboratory is essential at all times. It's important and essential that all labs conducting testing, regardless of location, have that appropriate expertise, equipment, training to provide that quality testing. We encourage anybody to review our website at aphl.org for more information about our response.

And, you know, we're all in this together, so I want to thank the CDC's Division of Laboratory Systems for including APHL on these calls, but importantly, to begin the dialogue across the nation between clinical laboratories, commercial laboratories, and public-health laboratories.

JANET HAMILTON: Thank you so much for having me. My name is Janet Hamilton. I'm the senior director of science and policy for the Council of State and Territorial Epidemiologists. We represent those epidemiologists in state, local, tribal, and territorial health departments that are on the ground doing the disease-detective work and case investigations.

We are very grateful to be part of this call with CDC and are working in close collaboration with them, as well as our partners at APHL and representing the state public-health laboratories. We are very grateful for the commercial-laboratory sector for bringing up laboratory testing and for your continued partnership.

What I wanted to highlight for you all is the recognition around reporting and case investigations that are occurring for this immense response. COVID-19 is a reportable disease in all jurisdictions. And laboratory data serves as one of the most, and sometimes, the only method for case identification, which then triggers the epidemiologists to initiate a case investigation.

If you are considering or have begun testing, we are asking that you please reach out to your state health department as early as possible in the process to ensure effective results reporting. State and local health department epidemiology programs are currently requesting both positive and negative laboratory results reported to the State Health Department in line-level information and detail so that those case investigations can be initiated.

All state health departments are also set up to receive laboratory results electronically. And that is the preferred method for this response. If you begin testing and you're unable to submit those laboratory results electronically, please work with your state health-epidemiology programs to begin to transition as soon as possible.

I also just want to highlight as much as possible to help work with us on your clinical partners to ensure that full patient information is submitted at the time of test order. Those data are what public-health epidemiologists use to summarize and describe the cases-- for example, the proportion of male and female. The address information and phone numbers increase the ability for epidemiologists to rapidly contact cases and conduct those investigations. So your partnership to ensure as much as possible that these critical pieces of information are submitted at the time of test order is greatly appreciated and contributes to this national picture for this rapidly moving outbreak. Thank you so much.

KAREN DYER: CMS is committed to taking critical steps to ensure America's clinical laboratories are prepared to respond to the threat of the COVID-19 and other respiratory illnesses to ensure patient health and safety. The intent of the CLIA program is to ensure that test results provided to individuals and their health-care providers are accurate and reliable.

During this state of emergency, CMS's inspection efforts are focused primarily on addressing immediate jeopardy situations, and CMS is generally exercising enforcement discretion for activities that do not rise to that level.

The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs or penalties authorized by the Social Security Act. The CLIA program does not fall into this category of programs.

However, CMS has identified flexibilities under our current authorities during the current public-health emergency. We plan to issue a memo within the next few days that will provide important guidance for CLIA laboratories in regards to the following-- remote review of pathology slides, proficiency testing during a public-health emergency, alternate-specimen collection devices, requirements for a CLIA certificate during the COVID-19 public-health emergency, laboratories that are located at contiguous buildings on the same campus, and further guidance on laboratory-developed tests.

All guidance in the memorandum would only be applicable during the COVID-19 public-health emergency. Laboratories that are accredited must follow accrediting-organization requirements. All laboratories need to also follow any state laws governing laboratories, which may be more stringent than CLIA.

And finally, we've been receiving lots of comments, lots of questions, and we are doing our best to get them answered and get them out to you. We ask for your patience as we try to respond to all of them, and we will try to get that information back out to you as quickly as we can.

BILL ARNDT: Good afternoon, everyone. My name is Bill Arndt, and I am currently serving as the biosafety program lead in the Division of Laboratory Systems at the CDC. Additionally, I am also serving as the lead laboratory biosafety SME on the CDC Laboratory Response Task Force.

As Jasmine mentioned, our division works closely with the clinical and public-health-laboratory community on a variety of topics. One area in particular is laboratory biosafety. Because of our expertise, our division has taken the lead in drafting the agency's laboratory biosafety guidance and FAQs related to COVID-19. Following review and clearance by the Emergency Operations Center, that guidance is posted to the CDC's COVID-19 website. The CDC's current laboratory biosafety guidance is primarily intended for the public-health and clinical-laboratory community.

I will now provide a quick overview of the current guidance and highlight a few of the recommendations that I think are particularly important for the clinical-laboratory community. I want to stress the importance of minimizing risk to clinical and laboratory staff who handle specimens from patients with possible SARS CoV-2 infections.

First, the specimens should be labeled accordingly by specimen-collection staff, and the laboratory should be alerted to ensure proper specimen handling. Second, laboratories 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 personal-protective equipment, such as laboratory coats, gowns, gloves, and eye protection.

Third, you should know that diagnostic testing of specimens can be handled in a biosafety level 2, or BSL-2, laboratory using standard precautions. For procedures with a high likelihood to generate aerosols or droplets, use either a certified class II Biological Safety Cabinet, BSC, or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include PPE, such as surgical mask or face shield, or other physical barriers, like a splash shield, centrifuge safety cups and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

Lastly, it is important to emphasize that all biosafety decisions should be based on site and activity-specific biosafety risk assessments to determine what biosafety precautions are warranted based on facility-specific needs.

JASMINE CHAITRAM: OK, so that's all of our speakers for today. I will have Bill answer a couple of biosafety questions that we've received, and it may be a little bit repetitive from some of the information you just went over, but it doesn't hurt to hear it twice.

So our first question is, what is the recommended biosafety level for handling suspected or confirmed SARS CoV-2 patient specimens?

BILL ARNDT: So the current recommendation for routine diagnostic testing of patient specimens, is to use Biosafety Level 2 facilities, laboratories, using standard precautions.

JASMINE CHAITRAM: OK. And our next question is, how should point-of-care testing be conducted outside a traditional laboratory?

BILL ARNDT: For diagnostic testing of specimens conducted outside of a traditional clinical laboratory, such as rapid respiratory testing, again, the recommendations are to use standard precautions to provide a barrier between the specimen and personnel during specimen manipulation.

JASMINE CHAITRAM: Got another question for you-- are certified class-II biological safety cabinets required to process COVID-19 specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified class-II biosafety cabinet?

BILL ARNDT: So clinical laboratories that perform routine diagnostic tests on serum, stool, blood, or urine specimens should follow standard laboratory practices, including standard precautions, when handling potential COVID-19 patient specimens. However, as I've stated before, any procedure with the potential to generate-- high likelihood to generate aerosols or droplets should be performed in a class II BSC. However, if no BSC is available, additional precautions can be taken, such as I mentioned earlier, related to additional PPE, such as surgical masks, and face shields, and other physical barriers, such as splash shields, centrifuge safety cups, and centrifuge rotors-- sealed centrifuge rotors.

JASMINE CHAITRAM: OK. How should laboratory personnel remove biohazardous waste from the laboratory or testing areas for decontamination and disposal?

BILL ARNDT: Handle laboratory waste from tests from testing suspected or confirmed COVID-19 patient specimens as all other hazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

JASMINE CHAITRAM: OK, what disinfectant should personnel use to decontaminate work surfaces and equipment?

BILL ARNDT: Decontaminate work surfaces and equipment with the appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against SARS CoV-2. Follow the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

JASMINE CHAITRAM: All right. What specific packaging should personnel use when shipping suspected or confirmed SARS CoV-2 patient specimens, isolates, or cultures?

BILL ARNDT: The current recommendation provided by the CDC recommends that pack and ship suspected or confirmed SARS CoV-2 patient specimens isolates or cultures as a category B, UN 3373 biological substances in accordance with IATA and the Dangerous Goods Regulations.

JASMINE CHAITRAM: OK, that's it for the questions that we have for today. Clinical laboratory leaders and staff members can find this information on CDC's COVID-19 website in the section called "Information for Laboratories." To find this page, navigate to CDC's COVID-19 website, scroll down to the section titled "Information for Healthcare Professionals," and click on the link for Laboratories.

I hope you will bookmark that page for future reference. We will continue to update the information on that page as the response progresses, and we will inform clinical laboratories and other partners about such updates through our Laboratory Outreach and Communication System, known as LOCS.

We encourage you to request your laboratory to be added to LOCS. That's the Laboratory Outreach Communication System to receive ongoing laboratory communications related to the COVID-19 response. To opt in, email locs@cdc.gov.

And this concludes our call for today. I'd like to thank all of our speakers for taking the time to be on the call. I'd like to thank all of you that have joined us. I know everybody is super busy.

These calls will take place every Monday at 3:00 PM Eastern Daylight Time. And we hope you will join our next Clinical Laboratory COVID-19 Response Call on Monday, March 30, and encourage your clinical lab partners and colleagues to join us as well.

Again, if you have any questions that you'd like to submit for consideration, please enter them into the chat box in Zoom, or email dlsinquiries@cdc.gov. We look forward to continuing to work with you. And thank you again for everything you were doing to help our country respond to this pandemic.

That concludes today's call. Thank you.