Clinical Laboratory COVID-19 Response Call

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Panelists

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Corrisa Miliander, Mayo Clinic Laboratories
Janet Hamilton, Council of State and Territorial Epidemiologists (CSTE)
Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
Karen Dyer, Centers for Medicare and Medicaid Services (CMS)
Tim Stenzel, U.S. Food and Drug Administration (FDA)

JASMINE CHAITRAM: Hi, everyone. This is Jasmine Chaitram at CDC. I am the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. Thank you for joining our eighth Clinical Laboratory COVID-19 response call.

My division, the Division of Laboratory Systems, hosts these calls weekly to provide information to the clinical and public health laboratories about the response. We also, in our day jobs, before we started doing the response, provided information about laboratory systems related to quality and safety, data and biorepository science, informatics, workforce competency, and training. And we also, for years, have been helping clinical public health laboratories with preparedness and emergency response activities.

And so today, we are going to-- I'm showing you the agenda. We're going to have a focus on reporting. We've had, as I mentioned, eight calls so far. And we've covered a variety of topics through these calls. We've done several updates on CLIA, that's the Clinical Laboratory Improvement Amendments, we've covered topics on biosafety, we've talked about the challenges of laboratory-developed tests, and we've covered EUA assays, serology tests, a number of issues. Quality issues, as well as requirements for doing testing right now.

And for today, I wanted to also give you some other information. Let me just control my slides here. So the next thing is that we have a survey that we have been trying to get your feedback on the calls that we've been conducting. And we would like for you to please take five minutes to-- about five minutes, that's how long it would take to complete the survey. I'm showing, here, the link.

And thank you to those that did complete the survey last week. We got a lot of really good information. And I think we had about 300 respondents. So we are looking at the data, and we are using it to improve our calls. So please take some time to do this survey. It shouldn't take very long.

And sorry. Also, here are some general links that we've shown pretty much each week, information that would be useful to laboratories, including the CDC's guidance for collecting, handling, and testing clinical specimens, our links to our Laboratory Outreach Communication System. You can go there to see any of the emails that we've sent out.

You can also-- we've recently posted a LOINC in vitro diagnostic test code mapping. We've mentioned this on the last couple of calls, I think. And so go there to get information about LOINC and SNOMEDcodes.

Also, we've covered biosafety topics, as I mentioned. And so we have some resources here on this page for you as well. And you can send any inquiries to DLSinquiries@CDC.gov if this information is not helpful.

We are also interested in understanding your training needs. So we put up this email for any information you might want to tell us about training needs. And this will help us inform some of the activities going forward, and maybe even some topics on this call.

And to ask a question-- we've always mentioned this as well-- to use the Q&A button in the Zoom webinar system and type your question in the Q&A box. I know sometimes people submit them in the chat area, but we really want them in the Q&A section.

And we have-- I've mentioned this before that these questions are important for us to understand the concerns of the laboratory community. It helps to shape the agenda items for each call. We will do our best to get responses to the question if it's not addressed in an agenda item. Sometimes we are able to provide specific answers to your questions while you're on the call or after the call.

But this is also an opportunity for you two to submit topics, and topics for future calls and things that you're interested in. We will do our best. We cannot promise that all of those topic ideas will be submitted, so please be patient with us.

And a couple more things before I turn it over to our first speaker. There will be no biosafety update this week. I know that many of you tune in for those updates. But we didn't have any new information, so there will not be an update from our biosafety subject matter expert, Bill.

Also, reminder that these slides are posted after each call as well as the transcripts. So if you miss a call or you want to share information with somebody else, you can always go to CDC.gov/safelabs, and then go into the tools and resources section to find information about our previous calls.

And I think that was all of the updates that I have. Our first speaker is Corrisa Milianderfrom Mayo Clinic Laboratories, and she's going to be talking about lab reporting to government health agencies during an outbreak.Corrisa, are you ready?

CORRISA MILIANDER: Yes, I am.

JASMINE CHAITRAM: OK. You can start whenever. And I will move your slides for you.

CORRISA MILIANDER: OK. Good afternoon. I'm here today to share some challenges our organization has faced in reporting coronavirus reports to the various state agencies. I work for Mayo Clinic as a quality management coordinator, and I'm part of a team that sets up the reportable disease reporting for delivery from our labs.

Mayo Clinic has multiple sites performing laboratory testing situated throughout its enterprise. The enterprise consists of Jacksonville, Rochester, and Scottsdale sites, in conjunction with many hospitals and clinicals within the Mayo Clinic Health System. Mayo Clinic laboratories have clients located in states across the country, and our team works with each of the state health departments to provide notifiable disease reporting.

Each of the 50 states has a defined list of reportable conditions, and the list varies from state-to-state and reporting criteria for commonly-reported conditions may also vary between state agencies. For coronavirus, some states have defined specific reporting criteria, and the remaining states reporting falls under the reporting criteria for outbreaks. Next slide.

I'm going to briefly share how we report to state agencies. As tests are implemented in our lab, or test changes occur in LIS, reporting filters are set up to report results to states per applicable reporting requirements. Transmissions are set up for each state agency within the reporting applications.

At defined intervals, LIS test reports are sent to the reporting application, which organizes reports into the files for each state. The collated filters are sent out via defined transmission routes. States can receive HL7 messages reporting via ELR and by secure fax reporting. Next slide.

I'm going to acknowledge some of the difficulties we've had with reporting COVID-19. Due to the ever-changing environment, changes funnel to our reporting team from every angle. We have internal pressures, such as prioritized implementation of new tests that require short turnaround times for setup of reporting within the application, paired with frequent review of test changes for the existing COVID tests in our catalog. And the differing needs of the enterprise sites increases the complexity and the number of test codes offered by the laboratory.

External pressures come in the means of frequent communication of individual state reporting changes, some of which may require modifications to the application setup, along with simply trying to keep up with the reporting updates on the internet. In general, it is a challenge to locate and organize each of the state's agency's requirements. Reporting requirements may live in multiple departments within the state's website, and requirements may not be combined into one resource or reference.

Reporting frequencies vary from state-to-state, but the reporting system reports at the same frequency for all transmissions. The reporting system needed to be modified to report more frequently for COVID, to meet the reporting needs of some states.

Not all of the state agencies are equipped to receive ELR. Fax reporting is cumbersome for states, especially with the volume of test results being reported to them at this time. The printed mailed reports that MCL sends to some states had to be discontinued due to staff relocation from the office building to remote work. These agencies needed to establish fax reporting for reporting continuity.

We received several requests for alternative reporting services. For example, state governors' offices requests for customer report data that we were already reporting to their State Department of Health. And we had to decline and focus our staff on the mandated reporting. And we had a lot of new partnerships with non-traditional clients that presented new challenges to overcome. Next slide.

One of the biggest challenges we faced is the receipt of patient demographic information upon test order. We've been working with new and existing clients to improve inclusion of information needed by our state health agencies. We've come up with some creative solutions, and we have kind of broken down some barriers that we've had. We continue to make progress, but there's opportunity for further improvement.

Our team looks forward to onboarding remaining state agencies into production for ELR to ease the strain of reporting. The team would be happy to work with states as soon as both parties have available resources. And so feel free to reach out to our ELR distribution list noted here if you have any questions.

As you can see on the chart, here, the pandemic has significantly increased the number of transmissions our system has reported, from an average about 50,000 per month to nearly 400,000 reports in April. We report each result, including negatives, to the appropriate state per further transmission type, and we're also reporting each result to the CDC for federal government tracing.

From my standpoint in the process, maintenance requirements in our reporting system is an ongoing challenge. Future goals for laboratory reporting may include collaboration for standardization of reporting across states, and improved communication of changes, and making the requirements easier to discover.

Our team has worked closely with many of the state health agencies, and I'm humbled by the collaboration. I'm impressed with all the amazing teamwork that has come from this unfortunate and ongoing situation. Many team members have moved mountains to make all this happen as seamlessly as it has, and we've learned many things as a team, and it will only strengthen our organization as we move forward into the future.

And my final slide, I just want to say thank you for listening. And please reach out to your team if you have any questions.

JASMINE CHAITRAM: Thank you, Corrisa, very much for presenting that information. And we have had a lot of questions about reporting. And there are several laboratories that are coming online that are not familiar with reporting to multiple states. So this was helpful.

But there was one question that came through on your last slide that I'm showing now about COVID-19 opportunities. Somebody asked, what are the numbers on the x-axis?

CORRISA MILIANDER: Those were the dates-- or the month and year, starting with, I think it was, like, May of last year, and through April. The two raised ones are March and April of this year. I don't know why that formatted funny.

JASMINE CHAITRAM: OK. All right, thank you. OK, we are going to move to our next speaker, Janet Hamilton from the Council of State and Territorial Epidemiologists. And she's going to talk about state reporting requirements for COVID-19.

And just to let you all know, Janet does not have slides. She will just be speaking. So if you're looking for slides, there won't be any. Janet?

JANET HAMILTON: Thank you so much. And thank you all for listening to today's call. And thank you to CDC for hosting these calls.

My name is Janet Hamilton, and I am the Executive Director of the Council of State and territorial. Epidemiologists, or CSTE. And for those of you who are not familiar with CSTE, we represent those epidemiologists at the state, local, tribal, and territorial levels that are doing the disease investigation work. We're the disease detectives and receiving those electronic laboratory reports, and then initiating the case investigation process.

And what I wanted to highlight for folks, and I think you just heard a great presentation from Mayo, that it is state law that governs reportable disease surveillance. So reporting is a specific state police power, and it allows the states to gather the identifiable information-- the patient's name, address, telephone number, et cetera-- in order to locate that individual. And then it's de-identified data that is passed on to CDC.

State reporting requirements generally encompass three different groups. It encompasses reporting requirements by physicians, reporting requirements from laboratories-- all of you-- and reporting requirements from hospitals. So many times, hospitals are allowed to designate single reporters or reporting activities so that each physician that practices in those hospitals is not responsible for individual reporting.

And I just want to highlight that I think it is a challenge that different states have varying reporting requirements for reportable diseases. For COVID-19, what I would say is that states

are very interested and have reporting requirements that include getting both positive and negative results. That is different than how most reportable diseases are handled.

So that is one activity. Reporting is via HL7 messaging. We do understand that as new labs are coming on board who have never done reporting before, that sometimes HL7 messaging is not achievable quickly, and so many states are offering an alternate or CSV file format. And that is really to be used as an interim or stopgap until that HL7 reporting can occur.

I would also say that it's been a real challenge for states to act upon the laboratory results that they receive because there is a large amount of missing information. So missing address and phone number, as well as race and ethnicity information. So as much as we can find ways to partner to close those gaps, we are very interested in doing that.

Additionally, we are working to partner with CDC so that we can think through how we can make improvements over time. So we recognize that we're not fully streamlined, but we are very much interested in how we can close those gaps and work as collaboratively with you all as possible.

I think one last challenge that I will just highlight for folks is that state reporting for COVID-19 and reportable diseases is probably something that you all realize, but it is HIPAA-exempt. And so that reporting activity, the results should go to public health at the same time as those results are provided back to providers.

We are seeing some situations where labs are bundling results, and it can be days and sometimes weeks before those are submitted to public health. And that obviously really delays our contact tracing processes as well as our initiation of case investigations. Thank you all so much.

JASMINE CHAITRAM: Thank you, Janet. While you were talking, we did get a couple of questions. And I was wondering if you could comment on state reporting requirements for serology testing?

JANET HAMILTON: Yeah, thanks, Jasmine. That's a really good question, as serology testing is something relatively new on the market, in general. That is another area where states are currently reviewing how that information should and should not be utilized.

Serology testing right now is part of the probable case definition. But the type of test, as well as the type of antibodies that are identified in those tests, are clearly different. And some are for identification of past infection, while others are related to more acute infection, the IgM antibodies. So states are currently working to determine how that information can best be used and consumed.

There's also a lot of concern in the state health departments about the sensitivity and specificity of those tests. And I think you all are probably experiencing some of the frustrations

there. So at this point in time, we definitely recommend that you do reach out to your state health department to enable reporting. And we are currently working to provide additional guidance about how those results should or should not be handled.

JASMINE CHAITRAM: Thank you so much for answering that question, because there were a few that came through related to that. OK, we're going to move to our next speaker. It's Jason Hall from the CDC Division of Preparedness and Emerging Infections. And Jason is also serving in the Emergency Operations Center at CDC on the data analytics task force. And he's going to talk about laboratory reporting requirements. Jason?

JASON HALL: Thanks, Jasmine. And thank you, everybody, for the opportunity to speak today. If you go to the next slide, Jasmine. So I'm going to point out a few things that I think are obvious, first. Your laboratories are critical to the COVID-19 response. And everyone recognizes that you and everyone else is operating at a very high capacity since the COVID-19 pandemic started.

I mean, we just saw some slides from Mayo that shows their huge magnitude of increase that they've had with the reporting. So we're well aware of it, and we know this is a challenging time.

But going onto reporting, on March 29, Vice President Pence sent all US hospitals a letter requesting assistance in reporting data that are critical in public health decision-making around COVID-19. On April the 10th, Secretary Azar, HHS Secretary Azar provided additional information to hospital administrators that included details about lab reporting to HHS Protect system. So that's reported directly to HHS.

Both CDC and HHS recognize that requirements to report laboratory result data, although vital for the nation's pandemic response, place an additional burden and additional needs on you and your staff in the laboratories. We want to make this reporting-- this reporting is critical-- it's critical for us to make this reporting easier to report on everyone, but the data need to flow in the most efficient way possible.

So in an effort to ensure that state and local health departments have the data they need for local decision-making and the streamlined reporting requirements on all the US hospital laboratories, CDC is going to begin handling reporting into HHS Protect system using the de-identified data that Janet Hamilton just mentioned states receive-- or states send to CDC from state health departments.

So all US hospital laboratories sits and should submit COVID-19 testing information via electronic messages or file uploads. Janet was just mentioning there's some that are new. States are working on other ways to accommodate data transmission. HL7 is not always a target you can meet in near-term, but they should submit them, electronic files preferred, to state and large local health departments, which will, in turn, send de-identified reports to CDC on your behalf, and we'll be able to report those to the Department of Health and Human Services, HHS

Protect system. So this will obviate the need for US hospital laboratories to report directly into HHS.

Next slide, Jasmine. So in an effort to ensure your reporting is complete, laboratories should reach out to the state health department and ensure that reporting results are there and that there aren't any problems with the transmissions. And if you're not currently reporting, technical assistance may be available to you.

Also, Mayo mentioned that ensuring that the labs collect all the critical information. We know that it's not always in the laboratories' scope or responsibility to get at some of these data elements that are more problematic right now during COVID response. But trying your best within what's under your control to get these vitally important data for the public health response collected and transmitted along from point-to-point. And that includes patient street address, phone numbers, zip code, race, and ethnicity. Once again, we understand it's not always under your control.

If your laboratory is not currently reporting electronically to your state or local, large local health department, CDC can provide technical assistance to help you report electronically. And you can contact the Emergency Operations Center laboratory reporting working group, of which I'm the lead. And our email address is shown on this slide. It's eocevent405@cdc.gov.

Next slide, Jasmine. All right, and as of Friday May 8, so this past Friday, CDC began reporting laboratory testing data publicly based on what the states are sending to us through our CDC COVID-19 data tracker website. The website includes a number of-- there's multiple tabs there, but there is a tab there for testing data now.

It includes the number of tests reported nationally by state, and by state, the number of positive tests nationally and by state, and the number of-- then the percent of laboratory tests that are positive nationally and by state. So right now these data are aggregated at the state level. We're receiving them from states right now, and a few territorial jurisdictions as well.

We're receiving them on the county level. So in future updates, we're going to be showing county-level maps, and having those made available publicly as well. And once again, these are also data that we're going to be sharing with HHS Protect as well for their internal use and visualization.

So that's it for my updates, Jasmine. So if anybody has any additional questions, or want to talk about technical assistance, or anything related to what I just presented, you can reach out again at that email address, it's eocevent405@cdc.gov. Thanks, Jasmine. Back to you.

JASMINE CHAITRAM: Thank you so much. So just want to let everybody know-- you should have seen it if you receive messages from our LOCS, Laboratory Outreach Communication System. We did send an email out on Saturday with a link to the CDC COVID data tracker. So that should make it easy for you to see the information that's posted on the website.

Jason, we did get a couple of questions. And I think it's important to provide some clarification. So the first question is, does just the testing lab have to report? My lab sends out these tests. Do we still need to report?

JASON HALL: So is this a question related to HHS Protect or to states? If it's to states, the performing lab is the one that reports, but there are a number of states that require dual reporting, what's called dual reporting. And that would be the ordering labs also, would then report those findings as well. Not every state has that requirement in place, but there are a number of them that do.

JASMINE CHAITRAM: OK, great. Thank you. And there are some laboratories-- commercial laboratories-- that are directly reporting to CDC right now. And I think the question is, do they need to continue reporting to CDC directly if they are already doing that?

JASON HALL: So right now, we just went public with these data, and we are continuing to transition with states online-level data. These are aggregates right now that are being reported.

As we move along with transitioning to using your line-level data for everything, that's when we will probably start discussions about whether or not some of those can be turned off. A few of those predated the response. So I mean, those are a little different. But the four of them that were brought on just for the COVID response, I think we'll have those discussions after we transition to the line-level data.

JASMINE CHAITRAM: OK, thank you, Jason. In the interest of time, we're going to move to our next speaker. And that is going to be Karen Dyer from the Centers for Medicare & Medicaid Services. And Karen is going to be giving a CLIA update.

We were not able to allow her to finish her update on the last call because we ran out of time. So hopefully, she'll be able to provide all the information from last week's call and this week's call in the time we have. Go ahead, Karen.

KAREN DYER: OK, great. Thank you all. Just a couple of questions that we keep seeing, or keep getting after the presentations and everything. We get a lot of calls or questions about the coding for the CPT numbers and when they're going to be available.

Obviously, CLIA does not deal with the reimbursement aspect of the test itself. And the best recommendation right now is that you reach out and contact your Medicare Administrative Contractor (MAC)or your other providers of benefits to see what they have. I think there has been some information put out from CMS just recently. So those would be the best people to get in touch with as far as the updated codes and so forth.

We have a question about the requirement under CLIA for a research lab planning to do COVID-19 screening. If a research lab is performing testing and reporting their results in the aggregate, they're not going to need a CLIA certificate if those results are in the aggregate.

However, if a research lab is performing the COVID testing and returning individual participant results, it would definitely need to become CLIA certified before testing, or have a lab director of an existing CLIA lab willing to partner with it as a temporary location under that lab director's CLIA site.

OK, for enforcement right now, due to the limits of our surveys, what we are doing-- and we're beginning to do this now-- is to send a cease and desist letter for labs that we find testing either without a CLIA certificate, or they're testing with a waived certificate and doing a high-complexity test for that certificate. So we let them know to give them the opportunity to make those adjustments and make the changes that they need to do.

OK, let's see here. We know a little bit about the company called "CLIAwaived." We know that they are out there. We've had some conversations with FDA and CDC about what we can do. Right now, we have no real guidance for that company.

They're a legal business entity and made use of that name. As you work with labs or you go to try to order tests or anything, you can let people know to really be careful when they order to make sure not just to go by the name of the company, but to actually look at the tests that they're ordering, the package insert, to make sure they see what the proper FDA classification is for that particular test.

The other questions we've gotten. What do we do if we find labs that are testing and they don't have a CLIA certificate, or they're using wrong test kit, any kind of issues in that particular genre? The best way to deal with them is to reach out to the state health department that oversees the CLIA program and let them know your concerns. There's a process for filing a complaint with the state. And they will take that information and process it from there.

OK. Let me see here. OK, if you come across some rapid serological tests that have not been approved by the FDA and do not have an EUA, please report them also to FDA-COVID-19-Fraudulent-Products@fda.hhs.gov. We currently do not have any plans to help with-- we had a question, basically, that was, do we have any plans to issue guidance to CMS-approved regulatory or accrediting agencies to allow rerouting of non-COVID-19 specimens in the event that a lab either closes or shifts focus of temporary testing in order to ensure safety of staff?

We don't have any plans to issue any guidance of that. We do recommend that labs have contingency plans in place in the event of those kinds of emergencies. I think we've obviously found that this was really important right now, that, kind of, this has all come across unexpectedly here.

And I think the last question I have, is there an update on CLIA assignment of specialty and subspecialty for COVID-19 testing or the COVID antibody test? At this point in time, we have not changed. We have not listed a specialty or subspecialty for the COVID-19 testing. If you have questions regarding the EUA and the timeframes for that classification with the FDA, those questions should be referred back to the FDA. And Jasmine, that's all I have. So thank you.

JASMINE CHAITRAM: Thank you. Our next speaker is Tim Stenzel from the Food and Drug Administration. And he's going to talk about an updated policy for serology testing and probably touch on a couple of other topics. Tim, are you ready?

TIM STENZEL: Yes. Thanks, Jasmine. Hello, everyone. Yeah, I'd just like to update everybody on the May 4 update to the EUA guidance. Primarily, the changes were directed towards serology kit developers. And that we are now requiring all serology kits to submit an EUA application.

And they have 10 days from the date of the new guidance, if they had previously notified us, to submit an EUA application. We also have established templates that have performance expectations in that update. We expect that overall specificity should be at least 95% and overall sensitivity should be at least 90%. We do allow a lower sensitivity if IgM is reported out separately. However, it still must be at least 70% sensitive.

We also are continuing the NCI testing program. This falls under a number of different categories, but largely it's still for the umbrella issued a couple of weeks ago for serology that allows a pathway to go through the NCI where testing is performed. But where we have performed testing at NCI, when we make our regulatory decision about a serology test that has been tested at NCI, we will make the testing information public.

And if you go to a web page that we have now established on EUA-authorized serology test performance, and you can scroll down to EUROIMMUN test, and you'll see the NCI report there for that test. And that data from NCI was used in determination of authorization for that test, and it will be used going forward as well.

And as I mentioned earlier, we now have established templates for both kit manufacturers as well as lab developers. Lab developers, it is still a voluntary program to come in for an EUA authorization, though we do encourage it. Again, all serology kit manufacturers now must submit an EUA for application for authorization. And that is the major update to the policy.

As I mentioned also, earlier, we do have an EUA authorized serology test performance website. So all tests that have been authorized by the agency under the EUA, now is individually listed along with key performance metrics, including sensitivity or positive percent agreement, specificity or negative percent agreement, as well as positive predictive value for the prevalence of 5%. That 5% is just listed because it was relatively middle ground, perhaps. And the negative NPV for 5% prevalence as well.

We have included on that web page, a calculator. And it's just for calculating what an NPV might be, or a PPV might be based on the prevalence. And you can put in the prevalence of your location. It also gives a theoretical calculation if you have both an initial serology test follow-up by a confirmatory test, what the potential ending PPV or NPV might be if you're using the results of, not one, but two tests, and allows you to put in both the sensitivity specificity for each of those two individual tests.

We do recommend that if you want to use a secondary confirmatory serology, that you pick one that uses a different antigen as the target than the first assay. That kind of covers the update to our serology guidance. I did want to follow up with some answers to previously asked questions.

One was, can you clarify what to do if you become aware of a lab that is waived or moderately complex is performing a pathway de-serology testing? Please clarify who to notify if we find claims at someone's website that do not seem accurate, et cetera. And as Karen mentioned earlier, we do have a fraudulent, or potentially fraudulent, email address. You can find that our FDA EUA FAQ page. There is a link there that makes it very easy to report any potential problems, which we will, in all cases, investigate and take action as is warranted.

Next, there is a question about saliva. And particularly, home collection of saliva. So we have authorized last week, our first home collection of saliva. It was using a device that was previously cleared for collection of saliva in the presence of health care providers.

And we based that decision, overall, on actual patient data and performance for the specific test at Rutgers. So we will base our regulatory decisions on this sort of foundation of basing it on review of data.

We are encouraging alternate sample collection, especially the inclusion of home collection. We have been hearing some patients are avoiding the use of NP swabs, and maybe even avoiding testing because NP swabs out there have gained a reputation for being rather painful and/or uncomfortable. And therefore, collection alternatives, including saliva, nasal swabs, and home collection are important considerations in this current pandemic.

There was a question about asymptomatic screening. What is the FDA's position on using current EUA-authorized tests? I would say that our intended use authorizations right now state that these EUA-authorized molecular diagnostics are authorized for use in individuals suspected of COVID-19 by their health care providers. And the FDA now says on our FAQ webpage that testing of asymptomatic individuals who are suspected of COVID-19 is at the discretion of the health care provider ordering the test.

Now, this doesn't necessarily apply to test developers. And if test developers want to appropriately validate for the intended use population of asymptomatic screening in asymptomatic individuals, we recommend that you reach out to us to discuss that validation plan that would support an EUA for such an indication.

Next question has to do with prescription. Currently, most, if not all of the EUA authorizations that we've made-- I believe it's all-- do require a prescription. That is so that we can consider the involvement of a clinician in prescribing and interpreting results to be a mitigation for the risks of both false negatives and false positives. However, we are considering additional options. And if that's important, we request that you reach out to us at our template's email address.

Finally, there was another question about use of the Abbott ID NOW and VTM. And some question about whether positives were missed on using VTM. I would just reiterate that we have now authorized an update to the Abbott ID NOW, and that does remove VTM as a sample type. So we recommend that all users of the Abbott ID NOW use only the direct swab route, not going through VTM. And with that Jasmine, that's my updates. Thank you.

JASMINE CHAITRAM: Thank you very much, Tim. And I want to thank all of our speakers today for the time to be on the call with us, and prepare talking points, and answer questions. Really appreciate it. I also want to-- couple reminders.

Please fill out the survey. The link was in previous slides. We'll also be following up with an email. It should not take very long. We really want your feedback on how these calls are going. We've also included a question about topics for a future call. So please give us your suggestions.

I want to also mention that the transcript is posted online. So if you missed any part of the call or you want to share it with other people, again, it's at cdc.gov/safelabs under resources and tools. We also send out LOCS messages, so please sign up for those. That's LOCS@cdc.gov. And you can get a lot of information that we present on the calls, a lot of information that's late-breaking or it's new information that's coming out each day, we try to send out a LOCS message as quickly as possible. So it's really good to get on that particular email distribution list.

Also, our next call will be on Monday, May 18. And we hope that you will join us. We will not have a call on Monday, May 25, since that is Memorial Day. We will send out an announcement about that. Reminder to submit your questions through the Q&A. Questions and topics where we want to hear from you.

And finally, thank you so much for joining us. And thank you, also, for all of the work that you've been doing to support the response. And that concludes today's call.