Clinical Laboratory COVID-19 Response Call

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Panelists

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JASMINE CHAITRAM: Hello, everyone. Thank you for joining the Clinical Laboratory COVID-19 Response Call. I am Jasmine Chaitram. I'm the Associate Director for laboratory preparedness in the Division of Laboratory Systems at CDC. The Division of Laboratory Systems at CDC has been hosting these calls since March. We hope you find them informative. The Division of Laboratory Systems works with public health and clinical laboratories on a number of issues talking about quality and safety, biorepository science, informatics, data science, and workforce competency.

On these calls in particular, we were working on preparedness and response issues, which we were doing previously before COVID, and will continue during this COVID response, and will after. We also work with the CDC Emergency Operations Center to serve as a liaison between public health and clinical laboratories and the CDC.

Today's agenda is showing. We've got a number of topics. Most of them are focused on laboratory reporting. So we hope that this will be good information for all of you. I'm going to go through a couple of housekeeping items before we get started. OK.

All right. So the first housekeeping item is our next call is scheduled for Monday, September 28 from 3:00 to 4:00 PM. We are hosting these calls every other week. This started in June. During today's call, we will open up a survey. We do the survey now once a month, and the survey will close on Thursday, September 17 at 8:00 AM. We have added a number of questions to this month's survey. It's related to the fact sheets that we had done a poll on during the last call. So two weeks ago we asked two questions, or four questions really, about the fact sheets that are provided with emergency use authorized assays, and we have additional questions related to that, and we are very interested in getting your feedback. So please complete the survey at your earliest convenience.

We also want to hear from you on your training and workforce development needs. You can send those needs to LabTrainingNeeds@cdc.gov. We also have resources that we provide to all of our participants through these slides. The links are provided. The slides will be available after

the call, and all the slides from previous calls are available. So if you need to go back and check any one of these links, you can do that by going to the slides that are posted on our website.

And I've got two pages of resources. You'll notice information here about the recently posted antigen testing guidance and some recently posted frequently asked questions. Also wanted to announce, very exciting, that we have a new Preparedness Portal. This is hosted by the Division of Laboratory Systems. And you can go here for any information that the Division of Laboratory Systems has been leading on, in particular the information about our calls, the clinical laboratory calls, our transcript, which was posted previously on cdc.gov/safelabs, has now been moved to this portal. And so you can find the transcript for these calls. Everything is in one place. So it's like a one-stop shop for all of our preparedness activities. Please visit our new portal.

Finally, last housekeeping thing that I want to mention is how to ask a question. Please use the Q&A button in the Zoom webinar system, and don't submit your questions through the chat mailbox. We'd really like to have it in the Q&A box. We also like to have your email when you ask those questions. We try our best to answer all the questions during the call. A lot of times, though, there's a lot of questions coming through or we've got multiple topics on the agenda. We can't always get all of the questions answered during the call, but we do try our best to answer the questions before the next call. So please include your email address if you want to get an answer.

We also use the questions to help us determine what topics are of interest, where your questions are. So that helps us formulate the agenda for future calls. So please submit your questions, submit your ideas and suggestions. You also have the opportunity this month to submit those ideas for future calls during our survey.

And two last minute things-- and if you are the media, please send your questions to media@CDC.gov. This is not the forum to ask those questions. And if you're a patient, please direct your questions to your health care provider.

And with that, I think we are ready to start off with our first topic on the agenda, which is an update from CMS, the Centers for Medicare and Medicaid Services. We did have an update on our last call on the interim final rule specifically about laboratory reporting. There were a number of questions. And so CMS folks Regina Van Brakle and Amy Zale are back to give us some more information based on the questions that you asked, and also give a another opportunity for you to ask questions. And so with that, I'm going to ask Regina or Amy to go ahead.

AMY ZALE: Hi, Jasmine. It will be Amy today. Regina is luckily on leave. So I will be presenting on behalf of CMS. What I would like to do is, last time we talked about our interim final rule, there were a number of questions that we were unable to answer on the call. And so CDC forwarded those questions to us, and I thought that I would read those questions and give you our responses just so that you have a little bit more information, you're getting your answer

directly. A lot of them, as Jasmine talked about, did not have email addresses attached with them so that we could reply directly to you. So we thought that we would just take the opportunity that everybody could hear the question and everybody could hear the answer and benefit from that information.

So I'll start at the top of the spreadsheet, and the first question was, "How can CMS require reporting of SARS-CoV-2 for nursing homes including civil money penalties, and then create an FAQ that allows universities to test for SARS-CoV-2 without CLIA or reporting requirements?" CMS is requiring that all CLIA-certified facilities report all positive and negative results to their state and local health departments. The university frequently asked question states that universities can perform surveillance testing without CLIA certification. If a lab is CLIA certified, they are required to meet the laboratory reporting requirements. If the laboratory is performing surveillance testing and they are doing surveillance testing, they are not covered by CLIA and therefore not required to report those results.

The next question is we don't have an interface with our state health department. Consequently, they indicated that they don't have the resources to track manual negative test results. Do we still have to report even though they will be discarded? Laboratories are required to report all positive and negative SARS-CoV-2 test results to state and local health departments. As long as laboratories have documentation that they are meeting that requirement, they are in compliance with the new laboratory reporting requirements rule.

The next question is, Last week, when reporting results to the health department, they sent an email stating that the laboratory no longer had to report negative tests. Per the new CMS CLIA laboratory reporting requirements rule, all CLIA certified laboratories are required to report all positive and negative test results to their state and local health departments.

The next question-- Can you clarify if the CMS rule means that we must report to our state only, or if we must report to resident states as well? We currently report our results to our state health department. The new CMS CLIA rule states that laboratories must report all positive and negative SARS-CoV-2 test results to their state and local health departments. We are not prescriptive on the number of health departments that you must report to. You must show documentation that you are reporting to your state or local health department to be in compliance with our new rule.

The next question states, Will the CMS CLIA web 116 be updated to include COVID testing for Certificate of Waiver applications as it was added for nursing home COVID testing? Yes. States entering new CLIA applications, regardless of whether it's a Certificate of Waiver, Compliance, or Accreditation, are going to have the option to select COVID testing at the time of application so that CMS CLIA can better capture who is performing testing.

The next question was, extensive reporting requirements for many data elements, including those required by CMS, were already mandated by state public health departments. Can you clarify how CMS reporting is different? Is there a separate centralized site to report to CMS?

SARS-CoV-2 results are not being reported directly to CMS. They are being reported to state or local health departments. CMS is just enforcing the requirement to report, not adding additional reporting requirements.

The next question-- Could you comment on using LDTs instead of an EUA PCR test for SARS-CoV-2? Are there any special compliance and/or billing issues with LDTs for SARS-CoV-2? CMS CLIA cannot comment on reimbursement issues. They are handled by a different division within CMS. However, there are not any special requirements different from the normal CLIA requirements for LDTs.

ZALE: The next question is, is it retroactive back to the date that the laboratory started testing? For example, if a laboratory hasn't reported anything yet, and they started to test on July 1 for antigen and antibody testing. The new CMS CLIA laboratory reporting requirements are not retroactive. So they do not go back-- laboratories were required to start on August 1, and if your laboratory has started reporting requirements from August 1 on, you are in compliance with the reporting regulations.

The next question was, if a lab is only testing for COVID 19 RNA in surveillance mode, in wastewater, is there any reason to report other than to local county authorities? Surveillance testing is not covered by CLIA, and therefore not applicable to our new laboratory reporting rule.

The next question is, is there a better way to report results when we process patients from multiple states? CLIA is not prescriptive about how to report results, just that all SARS-CoV-2 test results are required to reported to be reported to state or local health departments.

The next question is, the reporting of positive negatives, are they to be reported in aggregate? And the answer is no, that individual positive and negative results are required to be reported.

The next question is, are the data elements that need to be reported under the CARES Act consistent with what needs to be on a CLIA compliant test report? And we are saying that CLIA requirements for this new interim final rule only require that CLIA certified facilities report all positive and negative test result to state and local health departments. While CMS is only enforcing the reporting of those test results, laboratories are still required to report the data elements as detailed in the HHS June 4 guidance.

The next question is, if your facility is sending results directly to HHS under the HHS protect system for tests being performed, do they still need to also send it to the state? And we say that as long as the laboratory has documentation of reporting positive and negative SARS-CoV-2 test results, they are in compliance with the new requirements.

The next question is, will you be clarifying the point about CMPs only applying to the reporting of results and not to the June 4 guidance? CMS has put out surveyor guidance in a memo entitled QSO-20-37-CLIA that speaks to laboratories being required to report all positive and

negative results to state or local health departments. More detailed guidance will be forthcoming that will reinforce the positive and negative result reporting requirements. While CMS is only enforcing reporting of SARS-CoV-2 test results, laboratories are still required to report the data elements as detailed in the HHS June 4 guidance.

If reporting to HHS, must the results still be reported to state and local health departments? As long as the laboratory has documentation of the reporting of positive and negative SARS-CoV-2 test results, they are in compliance with the new reporting requirements.

The next question talks about-- it's very long, but I'll shorten it by saying they're asking if even serology tests for SARS-CoV-2 would need the results to be reported. And the answer is that all CLIA certified laboratories that report the results of any test that is intended to detect SARS-CoV-2 or to diagnose a case of SARS-CoV-2 or COVID-19 are required to report results regardless of the type of laboratory performing the testing. All negative and positive SARS-CoV-2 results must be reported, irrespective of the method used, whether it's molecular, antigen, or antibody tests.

The next question is, point-of-care testing is done in the emergency department. Does it still need to be reported? And the answer is yes.

The next question is, what if a state health department is unable or unwilling to accept data elements that HHS is requiring laboratories to report? A laboratory just needs to show documentation that they have tried to submit all positive and negative results to state or local health departments to be in compliance with the new laboratory reporting requirements.

And the last question that I have here is, does reporting to your local health department count as reporting to CMS? And the answer is yes.

So we tried to capture all of the questions that were asked during the last meeting. So if anybody has any other questions, or Jasmine if you're seeing things in the Q&A, I'm happy to try and answer them now.

JASMINE CHAITRAM: Thank you so much, Amy. That was really good information. A lot of information from questions that were asked during the last call. I appreciate that. And as you were talking, people were submitting questions. And I think some of the questions have been answered through what you said, but just for the record, and to make sure we're all clear, I will ask you a few questions again. And so it could maybe be a shorter answer.

This first question, I'm not sure if you covered is, this reporting is only for the duration of the public health emergency, right?

AMY ZALE: That's correct.

JASMINE CHAITRAM: OK. The next question is-- there's several questions, and maybe I can just roll it up into one. There's a lot of questions being asked about laboratories performing testing for individuals that reside in another state, and where are they supposed to report those results. The CDC guidance that we have on our web page, is that they're supposed to be reporting to wherever the individual resides. So wherever that sample came from, that individual sample, those results should go back to that respective state health department. Do you have any comments on that?

AMY ZALE: I don't have any comments past what you said. So the CMS rule isn't as prescriptive as that. We just say that those positive and negative results need to be reported to state and local health departments. We don't get into the detail that the CDC guidance does.

JASMINE CHAITRAM: OK. And then there's a question, does the final rule-- and this one I know you answered, but let's do it again. Does the final rule apply to antibody testing?

AMY ZALE: It does. Yes.

JASMINE CHAITRAM: What happens if you came into compliance on August 2? Do we go back and report out on the August 1 results?

AMY ZALE: No.

JASMINE CHAITRAM: OK. And a question was, is it possible our state passes the results onto the county so we don't have to. Would that be acceptable? Because you said state or local.

AMY ZALE: The laboratory needs to show documentation that they have reported to state or local health departments. As long as they have that documentation, then they're in compliance.

JASMINE CHAITRAM: OK. If a hospital infection control nurse is reporting the results for COVID to the state, do the labs have to report it again? We just want to prevent duplicate reporting. So there's reporting going on, but it's being-- the hospital infection control nurse is reporting it to the state. And the lab is asking if they also have to report it.

AMY ZALE: As long as the laboratory has documentation to show that those results have been reported, then they are in compliance. But if a surveyor was to go into a laboratory, and they said, well someone else is reporting it. And they don't have documentation of that, then they would be out of compliance.

JASMINE CHAITRAM: OK. OK this question is, there are some test result reporting elements in the requirements that are optional. Can you please clarify what elements are optional? And I will go ahead and answer this one since it's very specific to the HHS guidance that was issued on June 4.There are required data elements, and we did send out a Laboratory Outreach Communication System message (LOCS) email on July 31, which hopefully provided some information to all of you about what is required to be reported versus what is requested to be

reported and what is optional. And when our next speaker comes on, Mike Waters, who is part of the implementation guidance team, he can probably clarify a little bit more on the optional data elements.

But I encourage all of you to go back to the LOCS message from July 31. And as I mentioned, you can go back to all of our archived messages through that website to find any of the previous LOCS messages. And you can also send a message to the DLS Inquiries mailbox, and we can forward the message to you. But the emphasis was on the 18 required data elements. That is what CDC is recommending that everybody focuses on right now as far as trying to report to your health department.

OK the next question is, are the ask on order questions required for antibody tests? So this goes back to what I was just saying. There are 18 required data elements. The ask on order questions are actually requested. So I wouldn't use the word required, but we are highly encouraging laboratories for the sake of this response to implement the ask on order questions so that the state health departments can do the appropriate case investigation. So please do your best in trying to collect that information as well.

For more information about laboratory data reporting, visit https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html.

OK let's see if we have any other questions for you. If a sample is sent to the reference lab, and the reference lab is the testing site. Do the labs sending the sample also need to report the results again?

AMY ZALE: No. It's just the laboratory performing the test.

JASMINE CHAITRAM: OK. Thank you. All right let's see-- OK here's one. If a CLIA lab is doing testing for an IRB approved study on de-identified specimens, does the IRB hold the report, or does the lab report de-identified results?

AMY ZALE: So if you're saying de-identified, I guess my first question would be, is that actually surveillance testing? And if it's surveillance testing, those results don't get reported. So I'm not quite sure how to answer that without knowing if that's actually surveillance testing, which is what it sounds like.

JASMINE CHAITRAM: Yeah, I would agree with you, and I would have said the same thing. So I think that that is a good answer. Thank you. Give me one second. Let me look for some other ones. Here's another one. I think we've answered this already, but I'm going to do it again for the record. The lab performing the test is required to report, not the lab collecting the specimens, correct?

AMY ZALE: Correct.

JASMINE CHAITRAM: OK. Our positives and negatives are being reported to the state, but several local counties only want positives, and some do not want antibody. As long as all is being reported to the state, it is OK that only the partial results are going to the county.

AMY ZALE: Correct. As long as the laboratory can show documentation that all those results are being sent, then they are in compliance with the new rule.

JASMINE CHAITRAM: OK, here's another one. What would be considered acceptable documentation for labs sending results electronically? If a lab faxes results, and there's a successful fax transaction printout, that's generally not part of an electronic system, but would that be acceptable?

AMY ZALE: It would. We are very aware that these results are being reported in a plethora of ways, fax included. And so as long as there is some kind of documentation to show that those results were reported, whether it's fax, whether it's email, then the laboratory is in compliance.

JASMINE CHAITRAM: OK, Amy, thank you so much. In the interest of time, I'm going to move to our next speaker. I do appreciate you being on the call and answering all these questions. I'm sure the labs appreciate it as well.

AMY ZALE: Sure. Happy to be here. Thanks for having me.

JASMINE CHAITRAM: Our next speaker today is going to be Mike Waters. He's currently serving on the Testing and Diagnostics Task Force in the Health and Human Services. He is going to talk about technical guidance for implementation of laboratory data reporting. We've had previously Sara Brenner on these calls. Mike Waters works with her and is representing their team. Mike, go ahead.

MIKE WATERS: Thank you, Jasmine. And it's a great privilege to be able to talk with you guys. I do like to try to stay in the background as much as humanly possible, but it is a nice opportunity to actually provide some clarification here. So thank you for that. There actually has been some updates to the technical specifications that are associated with the implementation for laboratory data reporting. Next slide.

And to just focus on these and bring it a little more into a consolidated vision, there are really three primary aspects that you could bucket these into between test orders, test results, and patient demographics. And as the iterative improvement processes has unfolded over the course of the release of the June 4 guidance to right now, there has been some added back and forth conversations to help improve the way we can all work together to ultimately get this information.

So within this presentation here are actually links to the updated HHS COVID-19 implementation guide. And also note that every week our teams work together to actively

make sure that every single test that is getting launched-- as it gets authorized through FDA, it has specific mapping that can be provided for it.

But with respect to the questions that have truly been categorized in the frequently asked category-- Next slide. What we have there are questions that can ultimately be consolidated primarily-- if we're moving from left to right here on the slide and focusing on the red dotted boxes, we've added some clarifications as to where to find some of these things.

So what has been in the June 4 requirements was a link to the mapping file for all SARS-CoV-2 tests and COVID 19 tests that says specifically what codes to be used. But some people were having trouble navigating those files. We are working right now on providing additional information, but just for clarification, directly in this technical specifications guide you'll now find exactly what column each one of these critical data elements are in.

So if you have a particular test, you can actually just use the filter that is inside that Excel file, and filter it down to get exactly the information that you would need for reporting. This further clarification-- there's been a lot of questions around the pulled specimens and how that information is to be reported.

We're very grateful for everyone in communicating with us, and we have made sure to highlight that because there's I think rather obvious nuances. What happens when you're testing multiple asymptomatic patients as a potential that for an interesting nuance associated with results that are coming around in pulled specimens that ultimately comes out in the back end. And this is really just a note that we get the data that we get on the front end with premarket review. And that's fantastic to help qualify how well the test is. And then we're trying to help monitor in the back end to make sure test performance is happening well and to try to utilize this information in the most appropriate possible way.

And then if we move over to the last part here with a link, there's actually now a link to the HL7 version 2 guidance, which has a lot more detail. We acknowledge that there are a lot of different ways that information is being reported, and there are highly automated ways that are happening through HL7 messaging. And there is also flat files and all these different ways that people come in. And we're just trying to work with stakeholders as much as humanly possible so we can get harmonized data that comes in, and we can help return the value of all these efforts. Because we're always just very grateful. Next slide.

And we're always very grateful to have that information come in, which enables us to get ultimately-- to do the job that we have to do. And when now we're talking about what's required to be reported. There was a lot of questions on what's required to be reported where, and some clarifications around that. And as Jasmine said, and as Amy said, which are the required data elements are. Now a little bit of a clarification has been provided at the bottom of this implementation specification, which the link is provided here. And we're also answering these questions through direct emails when people have nuances to these questions.

And I also just like to highlight and note that APHL has worked hard to help provide a national flat file, which will also help in the provision of this information to your local and state reporting authorities. And to the next slide.

So just so you can see what we're seeing on the back end, if you look actually at the reporting that's happened from January 1 to June 3, what you see in the bars is the degree of LOINC codes that are used to represent the question. So this is the harmonized data scanner that's used represent the question a diagnostic test asked of the specimen.

The number of LOINC codes have actually increased dramatically. So that sounds quite nice to us. If we look from June 4 to September 11, we can see that a much greater diversity of use of the harmonized standard has been applied. Now if we think about PCR tests, right now there is about 78.4 million PCR test results that are individual line elements have been reported. And if we think in-- an add on antigen test of that, that's about 84 point-- I forgot whatever million. And that is great to actually see the appropriate way to represent those, the test system, has been utilized.

That being said, the line there is the number of ultimate tests that have been provided. And the bar there represents the number of LOINC codes. There are 78 LOINC codes that are to be used for test reporting, and so the application of the appropriate code every single time is something we're still trying to help partner with folks and work on. So if we can actually utilize the appropriate LOINC code every single time, that would probably help get more and more utility and bang for the buck out of this post market generated information.

And there's also a keynote that there's still about 12.4% of the test results that don't have a standardized code set system associated with it, and the top three of those are listed right here. COVID-19, Corona PCR, and COVID-19 and null. Those are the top codes that are used if a LOINC code is not used.

And that just means that this is a sign that we are constantly in the process of improving and partnering together to really work together and get data that will help us better provide service to this country. And so I see this as a very positive message. That people are constantly working together to iterate and provide ultimately better and better value to address this pandemic. And with that I just want to say thank you all very much for all your hard work. This is a really good sign. And I'm done. Thank you.

JASMINE CHAITRAM: Thanks, Mike. OK, before we move to the next presentation, a couple of questions real quick. First I wanted to thank Keith Higginbotham from the Alabama State Public Health lab for his comment, which is correct. And I'm going to say it out loud, which is he wanted us to clarify that although CDC and CMS is saying report any which way that you want, just get it into your state health department, there are reporting requirements that are specific to state and local health departments. So please check with your state and local health department on how you should be reporting.

OK the next question, and this one's for you, Mike. There's two questions related to device identifier. Is there a resource to help correctly define the standard device identifier? And can you provide an example of a device identifier?

MIKE WATERS: Yeah, absolutely. Actually, there's examples in that HHS laboratory data reporting guidance implementation specification, which is what I showed in that presentation. And it's also within the HHS FAQs. And you can also reach out to SHIELD-LabCodes@fda.hhs.gov

And the note is that the two primary ways to do this is, the optimal way to do this is with a device identifier, which is part of the Unique Device Identifier. That is actually an alphanumeric or numeric bar code which will fit really nicely into any current messaging system. But those aren't always available. They are being provided by some manufacturers but not by all, and those are usually provided by manufacturers for a specific test.

The alternative surrogate way to do that, which everybody should have access to, is the test name, which is like the trade name, and that is on the package insert usually at the top and the center. And then underscore the manufacturer name. And for every single authorized test, what you'll find if you download the file that is on the CDC website, you'll see a representation of that. And if that is able to be copied and pasted into a system, it will really help a whole lot in being able to identify a very specific device. But that is-- those are the two examples, and I hope that answers the question.

JASMINE CHAITRAM: Thanks so much, Mike. I'm going to move us forward in our agenda today and go to the next speaker, who is going to be Jordan Olson from the Geisinger Health System, Department of Laboratory Medicine. And this is a good presentation for you all to hear. They're going to talk about the experience they had with meeting the laboratory data reporting requirements. Jordan?

JORDAN OLSON: Yeah, hi. This is Jordan Olson. Thanks for allowing me to speak. I'm the Medical Director of Clinical Pathology Informatics and the CLIA director of two of our hospital laboratories in the Geisinger System. And I want to talk today about-- not the resulting or the basic demographic type things that we've been asked to report to, in our case we're reporting to the State Department of Health, who then forward those on. But the answer on order questions, which are in our implementation guide, are in the implementation guidelines really numbers 27 through 33. They're called out with green in the guidelines, so that's very helpful. Next slide, please.

So a little bit about us, Geisinger Health System. We're a nine-hospital system with 80-plus outpatient clinics. We're an integrated health care system in north central Pennsylvania. And the Geisinger laboratory is a cohesive entity throughout the system. We begin COVID testing in April, and we now have four different platforms up for PCR-based testing with rapid testing available at every hospital, centralized testing for non-STAT needs, and antibody testing available.

In August of 2020, we performed approximately 32,000 PCR tests, and about 1,500 antibody tests for our system patients, our external clients, local colleges, nursing homes, a lot of different entities. Next slide.

So just in terms of timeline, again we began testing in March. In April, we began electronically reporting results to the PA DOH. In June, when different guidance came out, we expanded our interface messaging to include some additional what I would call demographic or identification type things, like the patient address, provider address, provider phone number, things like that to our state. And then we started working on those answer on order questions at that time. And at that time, we reached out to the state, and the state said, no don't send it to us. We can't accept those right now. Don't even think about it. And so we put all that work on hold. And then on August 3, the DOH said, OK we can now accept that answer on entry content. And I'll talk a little bit more about that later.

And then so between September 3 and September 9, we rushed to comply with this, with these mandates. Like the mandate says, or the implementation guidance says, every reasonable effort should be made to achieve reporting. So we made every reasonable effort, and spent about 300 hours of IT analyst time in that time to implement those answer on order questions. And that's not counting the initial test build, the interface setup build, the things that we had already in progress. This was all new build on top of it starting on the third. So next slide.

So also to understand our experience, you've got to understand a little bit about how we receive orders for COVID testing, and we receive them in a variety of ways. Our system's EMR provides a slight majority of the total orders that we do, but we also receive orders electronically from outside laboratory clients routed through our health information exchange, for outside laboratory clients routed through two different outside client interface systems, and then we receive a large number of orders on paper requisitions from outside health entities.

Screening-- or not screening, but college testing events, nursing homes, and so on. And what's important to know about this is that these questions, when we said, OK now we've got to implement them, they not only had to be implemented in our electronic medical record, which is one area, they had to be implemented in our health information exchange, our client interface systems, obviously in our LIS, and then also with our outside clients who are sending paper requisitions.

When we talk about our outside laboratory clients who are sending electronic things, if they want to send us electronic orders for it, we've asked them to build these questions on their side. And I'll be very blunt, very few of our outside clients have gone and built these questions to capture this data electronically and send it to us.

Same thing, when we say to an outside client that sends their requisitions in on paper, the requisitions on paper, can you please fill out these questions, very few of them fill out any of the questions. And when they do fill out the questions, then it becomes a burden on our quite frankly overburdened receiving and processing staff to transcribe those paper orders into our

system. So when we ask about this, we say it's a huge effort to coordinate these type of changes, and these questions are often not filled out. Next slide for me.

So when we look at our EMR, I will have to call out that we've been extremely lucky that our EMR vendor, Epic, has provided some pre-built packages to speed the implementation of these answer on order questions in their system. These pre-built packages also help to pull data from other areas of the chart to improve compliance with answering. But I want to give a little bit of the insight into the philosophy of our physician informaticians. So our physician informaticians dislike any answer on order question that slows down the provider while they're doing their job. And they really abhor any hard stop or required AOE question.

So in the past, they've set guidelines that require AOEs with hard stops to really meet the following guidelines of only asking for information the provider has at their fingertips at the time of order, which is sometimes difficult, knowing that providers may be ordering these tests for patients who are beginning presurgical testing or may be ordering these tests for patients who they're seeing via telephone encounter or another type of encounter. Second thing is that the information should be required to act on the order and will improve or change the treatment of the patient. And when you look at this, none of these questions, the AOE questions, actually are required to process a test. You can process a test without this.

And they also want any hard stop to not be transcription of information that is available elsewhere in the chart. And when you look at a lot of this, you've got to put yourself in the provider's shoes to say, well is this the first COVID test? Well, that information is in the chart. Is this patient pregnant? Well, that information is either in the chart, or in many cases it's a male prep patient. Same thing. Are they hospitalized? Are they admitted to the ICU? When the provider's placing those orders, they generally know that information. And asking this is felt to be a undue burden on the providers, and really contribute very little, if anything, to the care of that patient that they're ordering this test on.

So these were not made hard stops, although I again I want to commend our EMR vendor for providing these packages, because what some of these packages did is not only a, greatly reduced the amount of build time we had and IT analyst time we had to put into this, but it allowed them to have some logic to put into default answers. Such as for hospitalized for COVID-19, the EMR was able to look at where the patient is currently located. If they're an outpatient, it goes to No. If they're an inpatient, well then it looks on the problem list. However, that obviously gives you questions and data provenance and data quality issues with you relying on the problem list. So next slide.

So when we look at what kind of data we're getting from the answer on entry questions, you can guess that we're getting a lot of data that's a lot of unknowns. And one of this, is that we found that both the internal Geisinger providers and the external providers, and especially external providers, are unwilling or unable to provide accurate answers. Now, when I talked to our physician informaticians, this is due to a lack of perceived benefit to the patient who is undergoing these testing.

So we're collecting this data. We're passing it on to the state. But I'll be honest, I wouldn't rely on this data for a lot of decision making. When we look at the EMR, or when we look at our laboratory, a lot of these answers are unavailable to the laboratory, or if they would be available but not answered, it would take a tremendous amount of chart review that we just don't have the manpower to answer. So the fact that the implementation guidelines specify that unknown is an acceptable answer for pretty much every one of these answer on order questions, that's really our saving grace. But what happens is it becomes the most commonly reported answer. So next slide, please.

So when we talk about reporting to the state, that's kind of our final hurdle to the answer on order questions. And quite frankly, our Department of State has been great to work with in terms of getting the basic positives, negatives, reported, and even great to work with in terms of getting that like, OK let's make sure that they have a phone number. Let's make sure that they have an address. Let's make sure that they can identify, do contact tracing, do that sort of work.

But when it comes to these answer on order questions, they've pushed back on us quite frankly. And although they do accept this data, so we feel comfortable that we're meeting the mandates for reporting, they've been-- they've told us that they're not officially onboarding those questions, quite frankly.

So when we say we're meeting the guidelines, but then you go how good is the data? Is this really helpful? And it's a huge burden. When I think about some of the questions we've onboarded, like is this patient a resident of a congregate care setting, or is this patient an employee in health care? Well, we've added questions via our EMR's packages to put those questions in a registration workflow. Well, that's two questions added to a registration workflow that happens in our system about six million times. That's 12 million additional questions. As you can see, they're not being answered regularly. And when they are, we're not sure. So we're not sure how useful they are.

So we wanted to give that opinion, and give that experience to say, hey we worked really hard. So next slide, please. Because we worked really hard to make sure that the required data elements are present. And quite frankly, we felt that those were very straightforward to report. Positive, negative. And although it's complicated to identify the device, or the LOINC code you should be using sometimes, once you get through that it's fairly straightforward and you can get that data sent electronically.

However, those answer on order questions pose a significant difficulty. Clinicians feel it's a burden without a tangible benefit to that patient in front of them. They're unwilling to answer them. It's a significant build effort. Our EMR vendor gave us tangible support to build them in our EMR, but as you'll remember that's only a fraction of the total orders we get in. When they come in on paper, these questions are rarely answered. And when they are answered, it's additional work in a laboratory to transcribe them into our electronic system. And for our outside clients that send us electronic orders, it's additional work on their systems to build

these questions, to interface them to us, and to make sure they work. That quite frankly they're very hesitant to do.

The fact that unknown is an acceptable answer has been, quite frankly, a godsend to our attempts to report this data. And as you see, unknowns make up, in many cases, the majority of the answers that we send. So that has been our experience. Next slide, please.

I want to thank you for allowing me to come here and explain our experience. I know that there's a lot of great work going in on this, and quite frankly I think that being able to report the basics has been a great experience. And I think it's the right thing to do. So thank you very much.

JASMINE CHAITRAM: Thank you, Jordan. Appreciate the presentation. I guess I could say that as a person who's working on the laboratory reporting pieces of this response, that we do acknowledge the burden of the information that we're asking. I think that seeing your data is very helpful, and we will definitely share this with our partners that are interested in this data, at the state health departments, and at the Council of State and Territorial Epidemiologists so they can see what it looks like, at least from your experience. And maybe there are opportunities to make improvements along the way as we all learn more throughout this response.

There was only one question that came in during your presentation, and it was about the AOE questions, and whether or not these were being implemented at the Geisinger Health System for COVID only, or are you using them in other ways?

JORDAN OLSON: So we've implemented these questions for our standalone COVID test, for our COVID tests that are part of respiratory virus panel, panels, or panel and soon to be panels that have COVID in them, and we've implemented them for our antibody testing. But our experience has been that the data that we get out of them-- I wouldn't rely on it for anything, quite frankly. So I think it's skewed, and that's only a fraction of the orders that we're getting.

So no, we've tried not to implement these questions or this type of data collection for anything else. We find the answer on order questions to be a-- it's not an effective way of getting information from clinicians.

JASMINE CHAITRAM: OK, thank you for those comments. I'm going to keep us moving so that our last speaker will have some time on the agenda. And that is Tim Stenzel from the Food and Drug Administration. Tim is usually on our calls every week to answer questions, and I'm sure he has a few already lined up for us. Tim?

TIM STENZEL: I do. Thanks, Jasmine. It's a pleasure to be on the call again this week. Lots of topics to run through, so I'll get right into it. You may have seen our article in the New England Journal of Medicine last week on lessons learned to date in this pandemic. You may be interested in that. Also, you may have seen our op-ed in The Hill on home testing. I'll go into a

little bit more detail about that. Just suffice to say that we're very supportive of seeing home testing come onto the market. And then finally, you may have seen the op-ed by the FDA Center directors in the USA Today last week.

We just wanted to note that, to date, the most recent numbers I have for EUA authorizations is that we have authorized 247 tests. That includes 197 molecular tests, 46 antibody tests, and 4 antigen tests. Plus hundreds of more have allowed to reach the market through the notification pathways that are available. I did want to talk briefly about home testing updates. So there has been a lot of interest in having home tests where patients and individuals can perform testing at home and know whether or not they're positive. And we're very supportive of that. There are some tests in development already through the RADx program and others that will allow home testing. And we'd like to see them reach the market as soon as possible.

There's been questions around what does the sensitivity need to be? What does the LoD need to be? We're focused on what's the most important thing for public health. And an absolute LoD being very, very sensitive for a home test is probably not what's needed. What's needed is to be able to identify patients who have infective levels of virus in any of their saliva or in their nasal swab sample. So that's kind of what we're focused on right now.

In all of our template having to do with the development of these kinds of tests, in those templates are our recommendation. So if a test developer has something that's other than what we recommend, we urge them to come forward, talk to us about other opportunities to validate their test. The other thing I'd like to say about home testing is that to date, we have not received a single EUA for a home test. Not one. And this is despite having our template on for home tests available for a long time now.

We've had a lot of good dialogue around this, and we've expressed our openness that we do welcome those submissions. And we believe they'll be coming in in the not too distant future. As far as point-of-care updates go, we are trying to be flexible in point-of-care studies. I just wanted to point out that in device point of care studies we will be allowing banked samples. There may be some post-market requirements if you do that prior to authorization, but please interact with our team members to find the best way for you to get to the market with a good test as soon as possible.

We also want to express some flexibility having to do with the validation of asymptomatic individuals. So we have required usually about 20 asymptomatic individuals be tested who are positive. In the validation, we're going to allow 10 of those done prior to authorization at a minimum, depending on their requirements. And then to fill in the rest of the pre-market requirements with a matched set of symptomatic patients. And then of course there would be a post-market commitment to collect the rest of the asymptomatics.

So with that, I want to move on to the questions that we received in the interim regarding a number of issues. The first question is, can you recommend the best rapid test for CLIA labs? And I'm going to say that no is the short answer, and we would urge you to look into your

individual needs. And check out the performance of these assays as evidenced in their instructions for use that have been posted as links with each of those authorizations on the FDA website.

Next, we got a question about a certain point-of-care test and test manufacturer who was requiring a contract and a minimum dollar amount for that contract. Just wanted to say that the FDA is not involved in the distribution of tests nor on the contracts related to test purchases or distribution. So we're happy to take questions about that and do our best to help out, but that's not in our purview.

Next question was, my child's school is testing all of their students without a prescription. No direction by a health care provider, but only at the direction of the school. Is this appropriate? We would recommend that you reach out to the person in charge of the school testing program. It's possible that they have arranged for oversight by a health care provider who has issued a blanket or a standing order for testing at that school. If it is not the case, please feel free to reach out to the FDA through the CDRH-EUA-templates@fda.hhs.gov email address, and we will get involved as is required.

Next question has to do with SalivaDirect has a kit creating a lot of misleading publicity that makes our job in the lab a lot more difficult. Can the FDA take steps to make such approvals more clear about what is actually involved? This test isn't low cost. There are a lot of highly skilled labor and complex equipment involved. The FDA recognizes the complexity of this test, which is why it is only authorized for use in high complexity laboratories. We do try to communicate key new authorization through press releases. And of course, one can always go to the letter of authorization posted on the FDA website next to the test that's authorized for additional information, including the EUA summary or IFU.

The SalivaDirect test was authorized under the EUA issued to Yale. And in order to perform the test under the Yale EUA laboratories should contact Yale to request designation. Designated laboratories must acquire all components specified in the authorized instructions for use and perform the tests according to the authorized instructions for use provided by Yale. If you'd like more information, you can reach Yale at SalivaDirect – that’s one word – @gmail.com.

Next question is, so is that a no related to screening asymptomatics, or a yes that we can use the Binax. The Abbott Binax to screen asymptomatic, or for that matter any other rapid antigen test. Is that yes only if the doctor orders it? What about nurses in New York? The use in asymptomatics would be off-label, and the FDA does not regulate the practice of medicine. If the clinician prescriber orders the test on an asymptomatic individual, they are responsible for interpreting the results and determining the clinical management plan for those who test negative and are positive. Performance in asymptomatic individuals is still under some investigation for some devices. We have authorized some tests already, and we expect to authorize many more in near future.

Next question is, rapid antigen results are considered presumptive. Are rapid antigen positives also considered presumptive? It seems some states do not count antigen positives as new cases. No, positives are not considered presumptive, and antigen testing has generally demonstrated high specificity with regard to positives. Although there are known cases of cross reactivity issues, especially with transport media that we alert you to and recommend to use whatever is specified in the kit, or where possible to use the direct test extraction buffer and reagent to avoid these issues. It does seem that some states do not consider antigen test to be laboratory confirmed cases. However, FDA was not involved in that decision making and cannot comment on that rationale.

Next question is, what about Sofia SARS antigen negative results? Should all of those patients greater than five days of symptoms or all negatives be sent for PCR confirmation? The short answer is it depends on the patient and the clinical situation. It is not required that results are confirmed. However, antigen tests are generally less sensitive than PCR tests. Clinical judgment should always be used in interpreting results, and if necessary order another test. This even applies within the five days of authorization if clinical suspicion is high.

Last two questions. Hopefully I can go through these quickly. Will you be elaborating on HHS changes to asymptomatic testing and LDT validation requirements for EUA methods? We do refer you to the HHS statement of a few weeks ago. We note that LDT are tests designed, manufactured, and used within a single high complexity CLIA certified laboratory. This does not include, for example, test components such as collection devices, platforms, or reagents. Neither does it include home collection tests, at home tests, direct to consumer tests, over the counter tests, tests distributed or used beyond the single lab in which it was developed, or tests designed in one location but manufactured and/or used in another location.

And finally, Yale will still be responsible for monitoring performance characteristics of SalivaDirect, correct? Yes, but also those that they-- and labs that they designate to be able to do the testing. So I would refer you to the letter of authorization at the FDA website for the SalivaDirect test.

And with that, that's all the questions I had.

JASMINE CHAITRAM: Thank you so much, Tim. I want to thank everybody for participating today. Thank you for submitting great questions. We will do our best to get answers to you. Thank you to all of our speakers for great presentations. Reminder to visit the preparedness portal on the DLS website. That's Division of Laboratory Systems. You can find the slides and the transcript for this call. You can also find previous laboratory outreach and communication system messages there. If you aren't getting messages from us, please sign up at LOCS, LOCS@cdc.gov. And apologies for going over. This concludes today's call. Thank you and be safe.