

Clinical Laboratory COVID-19 Response Call

November 30, 2020

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JASMINE CHAITRAM: Hi, everyone and thank you for joining the Clinical Laboratory COVID- 19 response call. I'm Jasmine Chaitram, I'm with the Division of Laboratory Systems at CDC. And the Division of Laboratory Systems at CDC hosts these calls, and we've been doing that since March of this year.

First, I want to wish everyone a late happy Thanksgiving, and I hope that all of you on the call today had some time to rest, and take a breather from all of the craziness and activities that are going on right now to support the response. Showing today's agenda we've got a list of really great speakers. Before we get into our speakers though, I do have a few announcements, and before I even do the announcements I want to remind everybody that the CDC Division of Laboratory Systems has been working with clinical and public health laboratories for years now. And we're supporting them on issues like quality and safety, workforce and training, informatics, biorepository, and data science.

We've also been supporting them for public health emergency response, and we've been doing that throughout the COVID response. We were doing it in preparation for a pandemic like this or other outbreaks. We're serving as a liaison between the clinical laboratory community and the CDC Emergency Operations Center, and that's why we host these calls to provide this communication to you, and hopefully it is relevant and timely. And on to some announcements, so the first thing is and I've said this before, we have our CDC Preparedness Portal, this is a DLS hosted website, and this is where you can find information about our clinical laboratory COVID-19 response calls. That includes transcripts and audio recordings.

All the information is usually posted within a week of our call, so if you missed the call for some reason, or you want to share the information with a colleague, just send them to this website.

Asking a question it's important that you use the Q&A button in the Zoom webinar system and type your question into that Q&A box. We will do our best to answer the questions during the call, unfortunately because of the number of questions, and the amount of time we have for these calls we don't always get to answer all of the questions. But we do try to provide a response if not live then shortly thereafter. And if not then we usually bump the question to the next call, or use it to help us form an agenda topic for a future call.

So please submit your questions this way. And also as a reminder, because we can't answer all of these questions on the call, please submit your email with your question if you want us to respond to you. And if you're the media, please send your questions to CDC Media Relations, media@cdc.gov. And if you're a patient, please direct your questions to your health care provider. The next call will be on Monday, December 14.

We are doing these calls every other week at this point in time. Here I am showing a list of CLIA approved proficiency testing programs for SARS-CoV-2. We've showed this list before, but this is an updated list. And we also wanted you to be aware that some of these PT providers are going to be – if not already, in the very near future –providing PT for antigen tests as well. And as usual, here's are link to COVID-19 resources for laboratories.

We put these links in the slides. The slides are on the Preparedness Portal so if you want to go back to the slides to find a link to information we put them here. Easy access for you, one stop shopping by going to our Preparedness Portal and our slides. We also like to get feedback from you on training and workforce development needs. Please email those needs to LabTrainingNeeds@cdc.gov. And we will try to address those in various ways, whether that's a presentation, or the development of an actual online training, or other mechanism.

And then I wanted to also make an announcement about a recent LOCS message, that's LOCS-- Laboratory Outreach Communication System, that's how we communicate with all of our clinical laboratories and provide information by email when we're not having these calls. We also use LOCS to announce these calls, so if you're not signed up for LOCS, please do that by sending an email to locs@cdc.gov. So L- O- C- S- at cdc.gov. We had a [recent message](#) that went out about waste management guidance for SARS-CoV-2 point-of-care testing. And we did get a question and we thought that it may be a question on the minds of many of you. So we've actually asked Bill Arndt from the Division of Laboratory Systems to join us today to give us a little bit more information. Bill, are you there?

BILL ARNDT: Yes, I'm here.

JASMINE CHAITRAM: OK. Go ahead and take it away.

BILL ARNDT: Yeah, thanks Jasmine. So the question we got was related to disposing of home collection kits in the general home waste. And should that waste be treated as a biohazardous waste that would typically come out of a laboratory? From the CDC's perspective, this is a risk

assessment question. After a testing at home you will have one used-- potentially one used test that is discarded in a general trash.

Which is compared to such as a nursing home, or a hospital, or laboratory, which generates thousands of tests and discards those in large volumes, the risk of disposing of a single test in your general trash, the risk of exposure is considered relatively low. And low in that it's going to contaminate-- less of a chance to contaminate other materials, as well as less chance for potential exposure. So at this time, CDC does not see the waste generated from the at-home collections as a biohazard, such as it does with normal waste that you would see generated in larger volumes from laboratories, or nursing homes, or hospitals. Thanks, Jasmine. We're happy to take any more questions if they're on.

JASMINE CHAITRAM: OK great. Well thanks. And Bill will be on for this call so I'm going to move to our first agenda item. But if you do have biosafety questions, I will try to slip them in as we have time. The first topic on our agenda today is CMS reimbursement update. We've had this topic on the call before. There were a lot of questions that we were not able to get through, and as I mentioned, we do try to answer those questions, or bring them back as an agenda item so that we can provide more information to you. Today we've got two individuals from CMS to speak about this. Sarah Harding and Sarah Shirey-Losso. OK, so Sarah Harding, I think you're up first.

SARAH HARDING: OK, great. Thank you. And thank you for having us back, I did bring Sarah Shirey-Losso with me to perhaps help with any questions or certainly backup if I misspeak. With the planners of the call, I don't have anything new to present today. There hasn't been a lot that has changed as far as payments around lab tests since the last time I spoke on this call. But as Jasmine mentioned, there were some outstanding questions that I thought I would try to walk through relatively quickly.

And so certainly if there are follow ups, we can answer them either during this call, or after. But the list I have I'll just read them out if that's OK and try to give brief answers. The first was whether we were aware of the status of recently requested CPT codes for a combination test of SARS-CoV-2 and Influenza A and B? The answer is yes, we are aware of recently requested CPT codes. There are several actually that have come in, both from category one CPT codes, as well as proprietary laboratory analysis codes.

All of these codes you will see with coverage and payment decisions made at the local MAC level. Since our timing at the national level occurs during the summer for new codes to come through a public meeting, anything that is new this time of year will be dealt with on the local level. So if there are questions about payment rates or coverage, I would recommend that you refer to your local MAC. This relates to the next outstanding question, which is, whether if an organization has multiple MACs, who governs the rate assignment?

I believe that the MAC overseeing a given test has to do with where the test is performed. So there may be a lab that would have multiple MAC rates depending on if they have multiple

locations. And so depending on where-- both where the sample is collected, and then ultimately the test is performed, would be the local MAC to contact. But they would also be able to help you with that.

Can providers refuse samples because it will lengthen their turnaround time? I believe this had to do with the Administrative ruling that was released in the last month or so, establishing an add on code for high throughput COVID tests performed within two days. So can providers refuse samples? It's an interesting question. I don't think we have a particular payment policy that precludes a lab from doing that.

I feel like that would have more to do with labs being known they're not taking samples. But again I don't know that CMS necessarily has rules against refusing samples. The Administrative ruling speaks to the turnaround time from the data specimen collection to the date of the results completion. So that's the extent to which the Administrative ruling speaks to. If you're simply not bringing samples in the door, the Administrative ruling really doesn't speak to that specifically.

The next question is, whether there are any blackout dates between rapid testing? They're asking about I believe maybe a homeless shelter or homeless entity wanting to test residents and staff weekly. Is this reimbursable under HRSA? So I can't speak to reimbursement under HRSA, so if that was meant to be reimbursable under CMS, certainly you could ask. But again, if that's specifically to HRSA, I cannot speak to that.

There's a question about other payers, speaking about having issues with patients not getting preauthorized to be tested. So much like the prior question, I can't speak to the decisions that other payers are making. If we are not able to bill under the CARES Act, is it OK to bill the patient? Can they file for reimbursement? So to the extent of Medicare-- Medicare has an agreement for laboratory tests under the clinical laboratory fee schedule with the laboratory itself. So I believe if you're working with Medicare as the payer, the lab would be the entity to bill, and not the patient. But again, if this question really was to a different payer, I can't quite speak to that.

The lab may often not receive the specimen until the day after has been collected, can the two day time frame start when the laboratory actually receives the specimen? So this is a good question that we have been getting frequently and we are working on a set of frequently asked questions to be published. Unfortunately, the process of getting these out in the world has traditionally taken some time. And so unfortunately, we haven't gotten those out as fast as we'd like. Generally speaking, what we're saying about the time frame is, the day the specimen collection occurs is your day zero. So if you collect a specimen at any time on a Tuesday, whether it's at 1 AM, 9 AM, 7 PM-- whatever it is on that Tuesday, that's your day zero. To get the add-on code benefit, the test needs to be performed by the end of day two. So Wednesday would be day one, Thursday would be day two, you have until the end of day two to complete that test. So hopefully that gives a little bit of wiggle room. But the goal of the Administrative ruling, was to encourage that two-day time turnaround.

Any idea of the reimbursement for COVID neutralization tests? I will admit I don't know what the COVID neutralization test is. So if anybody is on the call who asked that and wants to clarify, they would be more than welcome. But I would just say, generally speaking, if it is a test that has a CPT code, then it is up to the local MAC to make a coverage or payment decision.

The last question I had related to, once again, the two-day calendar time frame. So that's the same answer as I gave earlier. But like I said, we are working on some FAQs to clarify and make sure it's consistent across all labs. So those were the outstanding questions.

JASMINE CHAITRAM: Thanks, Sarah. I do have a few more for you. The first thing, I just wanted to comment on your last statement about the neutralization test. So that's an antibody or serology test. So I don't know if that helps to clarify anything. I'm not sure if it has a CPT code.

SARAH HARDING: So there are a couple codes that cover antibody testing. I don't know if that specifically described. If it is then again, it's under the same sort of characteristic that it's likely a test that you'd have to work with your local MAC with.

JASMINE CHAITRAM: OK. So you keep mentioning the term or acronym, MAC. Could you just say what that is?

SARAH HARDING: I'm so sorry, yes. I've definitely started to take that one for granted. Your MAC is your Medicare Administrative Contractor. There are, I believe, 56 or so different jurisdictions across the country. Those are managed by various contractors that essentially administer payments for Medicare on a local level.

So I think there are six or seven overall MACs that each of those jurisdictions gets grouped into. So if you have a question about who your local MAC is, M-A-C, you can look online on the CMS eb page and there's a whole map. You would be looking for lab tests, you would be looking for your Part B MAC, and they do differ depending on what area of Medicare you're in. But that is what you'd be looking for.

JASMINE CHAITRAM: And here's another one-- another question for you. Has CMS relaxed regulations for physicians to bill for COVID Molecular tests if they're CLIA is the lowest level? And I guess what they mean by lowest level, they're talking about a [waived test](#)

SARAH HARDING: So it looks like another group who is on this call would like to answer that question. At least there was a comment and then it looks like it disappeared.

JASMINE CHAITRAM: Yeah, it's the-- question. Well that's us just clicking them off so that we can keep track of which questions we're answering.

SARAH HARDING: I thought somebody was reserving it for themselves. But I do you think Amy Zale might be the better person to answer that question, just because it is CLIA-- it is CLIA related. Generally speaking, from our perspective there have been tests that are CLIA waived.

So that some entities, such as nursing homes and whatnot, don't have to get a full CLIA certification in order to run the tests. But specific to physician labs I don't know, Amy, I don't know if you have comments on that specifically.

AMY ZALE: I have to apologize. I didn't hear the initial question. Can you give me the question again, Jasmine?

JASMINE CHAITRAM: Yeah I will. It's not so much about the CLIA level for physicians, it's about whether or not there is relaxed regulations for physicians to bill for a COVID test, and I don't know that it has anything at all to do with the CLIA certification. And maybe it does, maybe it doesn't. But if you'd like to provide some clarification around that, that would be helpful. Do you want me to ask it again?

AMY ZALE: No. So there isn't any relaxed regulation from a [CLIA](#) standpoint. It sounds like maybe the inquirer is asking if there's relaxed regulation around billing. But I don't believe that from a CLIA perspective-- obviously you need to have a CLIA certificate, whether it is CLIA Certificate of Waiver, or any of the higher level CLIA Certificates of Compliance and Accreditation. But I don't know from a reimbursement perspective, how those CLIA certificates change reimbursement, I just know that you have to have them.

JASMINE CHAITRAM: Sarah, anything else that's on that one?

SARAH HARDING: Not really. I think related to physicians and COVID tests, I know that you and Amy mentioned this, there's certainly been the waiver for the initial order for the test. But in terms of regulations for billing I don't know of specific relaxations around that.

JASMINE CHAITRAM: OK. Just in the interest of time, I'm going to ask only one more question. There are two questions that are very similar, and it says, is reimbursement for an isothermal molecular test the same as a real time PCR test?

SARAH HARDING: Yes, I saw that. So that does relate back to the CPT codes. And basically whatever coding descriptor best describes the test whether it's isothermal, whether it's molecular, whether it's antigen, the CPT codes are now getting more granular in terms of optical rebility. So wherever the most descriptive-- the most accurate description from a CPT code is the correct representation as far as billing goes.

JASMINE CHAITRAM: Great. Thank you, Sarah-- both Sarah's for joining us today to answer questions about billing. I'm going to move to our next speaker from CMS, the Centers for Medicare & Medicaid Services. And it will be Amy Zale and she's going to be talking about the Individualized Quality Control Plan. We sent out a [LOCS message](#) recently about this, and received a lot of questions, so Amy is going to also provide some additional information on that. Go ahead.

AMY ZALE: Thank you, Jasmine. And thanks for inviting me to talk today. I just wanted to just share with everybody that CMS has a lot of feedback from the laboratory professional organizations, as well as from laboratories themselves about supply chain issues. And we're hearing that there are continued reagents shortages, and test kits shortages, and that our policy that came out about IQCP and EUAs really exacerbates that. We don't want to be part of the problem and want to be sensitive to the shortages that laboratories are dealing with.

And in light of that, we are reviewing our policy regarding IQCP and EUAs. We are asking for everyone's patience as we re-evaluate our policy and work to get further guidance out to you as soon as possible. So I saw after the last meeting that there were quite a number of questions about IQCP, and it's not the best thing for me to answer those questions as the policy states today, in light of the fact that we are re-evaluating that policy. The other thing-- there was another question that came from the last meeting that was talking about the Quidel Sofia. And it was saying the question was-- I'm trying to get to the question now, but the question was about the Quidel Sofia and that the test is waived.

And so did that mean that the laboratory was not responsible for quality control? And I just wanted to make sure that it was clear that the Quidel Sofia test is authorized to be used in a [Certificate of Waiver](#) laboratory. That does not mean that quality control is not required. Certificate of Waiver laboratories are required to follow any and all manufacturer's instructions as such, if quality control is required in the Quidel Sofia manufacturer's instructions, laboratories are required to perform quality control as outlined. And so Jasmine, I don't know if there are other questions that I can try to answer? But I would just reiterate that the IQCP and EUA policy is under review, and probably not good for me to be answering questions about that today.

JASMINE CHAITRAM: Well, thanks Amy. And I'm sure you can see the Q&A box and you can see that we are still getting a few questions about the IQCP. So once CMS has finalized their policy, we would be happy to send out a LOCS message with that clarification on the policy, and hopefully that will address a lot of these questions.

AMY ZALE: Definitely, we'll be trying to disseminate that far and wide as well.

JASMINE CHAITRAM: OK, great. Thank you. All right, so we will go ahead and keep moving forward on our agenda. Our next speaker, I think you've heard from him before, is Ren Salerno. He is the Director of the Division of Laboratory Systems. And he's going to give an update on the COVID-19 antigen test and some lessons learned that CDC has developed. Ren?

REN SALERNO: Thanks, Jasmine. Yes, we at CDC have been actively following debates around the use of antigen tests ever since they were authorized for use by FDA. We've conducted a tremendous amount of outreach with users of these tests as well as a lot of work with the manufacturers of the tests. And what has become clear to us is that, a number of brand-new testers have been introduced to testing for the first time, often with these antigen tests. And the perception perhaps has been that these are very easy to use.

And they are relatively easy to use from a laboratory testing point of view, but they're not simple tests, and there are some complexities to these tests that are important for users to understand. And so the first thing that I will say, which is hopefully obvious to everybody on this call, is that every test must be used according to the manufacturer's Instructions for Use in the package insert. And that every test is unique, and every test may have its own specific way that it needs to be executed and performed for it to be used accurately. So next slide, please. What we've done at CDC, is that we have collected some specific lessons learned on how to avoid process errors associated with the three major antigen tests that are currently on the market. The Quidel Sofia, the BD Veritor, and the BinaxNOW.

And on this first slide, we've listed a few of the specific process-- potential process errors that can be associated with both the Quidel Sofia and the BD Veritor. Yes, these are different tests. Yes, they have their own Instructions for Use in package inserts, and they should not be operated in exactly the same way. But for the sake of this presentation, these particular process errors are common-- or potentially common to both of these specific devices. It's really important that you users change gloves before-- sorry between the tests to avoid any cross-contamination.

Viral Transport Media should not be used with the specimen, before the specimen is tested. Expired reagents or damaged test cassettes and devices should not be used. The timing of the reading of the results of these tests are extremely important. And so it's critical that users keep track of, and follow the proper timing. When we send out groups to do large scale studies of these antigen tests, they all have a large number of timers that go with those studies. And so the timers, and the effectiveness of the timing, is really important for these antigen tests.

The test cassette and device has to be used for each of these tests, within a specified period of time after they are opened, and exposed to ambient air. We have seen mistakes made or false results occur, because the test cassettes have been opened from their package, left unopened on a table or counter for a period of time, and then used. But that lengthy exposure to ambient air can cause false results. The device itself must be kept in a horizontal position when in use, and kept steady, and still. So it can't be on an unlevel surface.

And as I said before, the results must be interpreted within specific time frames. And this is where reading the instructions is really critical. You must read and interpret the results within very specific frames, otherwise the results could change, or be false. Next slide, please. This next slide focuses on the BinaxNOW COVID-19 Ag Card, which is also an antigen test but it's a little bit different than this Quidel Sofia, or the BD Veritor, in that there is no separate test device. The card itself is the reader and the test.

And so some potential process errors are somewhat different, and some of them are similar. Again, it's really important to change gloves between tests to avoid cross contamination. The specimens have to be tested within no more than one hour of collection. We recommend that the specimens are tested as soon as possible after a collection. These tests must only use the correct volume of extraction reagent for each test, no more, no less.

So it's very specific in terms of number of drops, please read the instructions. Use of the kit reagents and cards should only be at room temperature. So where we've seen a couple of problems is they've been-- these cards have been stored in cold storage and been used immediately before they've been brought to room temperature. So that's another example of an error that has happened with these particular cards. Again, just like the devices on the previous slide, the cards must be used in a horizontal position on a flat surface-- when they're used, when they're the test is performed.

Again, when the test is performed is extremely critical. The test results should be read promptly at 15 minutes after the swab is inserted. You need that timer, and you need to set the timer the instant you place the swab into the card, and start the test. You should not read the results before 15 minutes. And you can't read the results after 30 minutes. And so these are fairly specific to this particular test.

But again, these are examples of errors that we've seen already with this particular test. Next slide, please. So in the interest of time, I will pretty much stop there, other than to say that these lessons learned for these three particular antigen tests-- and we realize that there are more antigen tests now with emergency use re-authorization-- than just these three. Although, these three are I think currently in largest supply in the marketplace. We do intend to share these lessons learned documents that we have developed with anyone at CDC who is involved in antigen test studies or antigen testing work.

We are sharing them with specific partners including FDA and the manufacturers. As I said, we've developed these lessons learned with the manufacturers to ensure that we understand their instructions and that we're properly representing them. We are in the process now of converting these lesson learned documents for each of these three tests into infographics, and once those are approved and cleared at CDC, we will post those infographics on our Point-of-Care Testing website, which we have talked about on this call before. But the link is there. And we will continue-- once we do all of these things, especially when we publish them on our website, we will definitely send out a LOCS message letting you know that.

And the other thing I will add just to say is that we've also revised our [antigen testing guidance](#). It is still in clearance. We believe it's very close to being fully cleared. We hope that it will be published within the next week or so. And you will see some of this information, a whole new section in that guidance on processing of antigen tests that take into account the various lessons learned that we've been able to acquire over the last few months, and you'll hear about that through a LOCS message as well. Thanks, Jasmine. Over.

JASMINE CHAITRAM: Thanks so much, Ren. We did get a couple of comments in the Q&A box while you're talking. And the first one is about the reach audience-- reaching the right audience for these "Lessons Learned." The comment is the folks on this call are laboratorians that are most likely not the ones that are using these particular waived tests, or need these types of lessons learned documents because they are aware of the instructions through use and following them.

So the question is, will the CDC be sending out these tips to CLIA-waived locations, where these types of issues are more likely to come up? And I know you've mentioned already the [point-of-care testing Web page](#) that we have and the Laboratory Outreach Communication System messages that we send out. I will also comment that for those folks on the phone, we also reach out to our professional organizations that are partners to CDC, and help with promoting messages. And just like them, I guess we could also ask those that are on the call, that if you're aware of facilities that are using these types of tests, to please forward these messages and communicate them broadly. We also work with another task force in the Emergency Operations Center that is predominantly providing support to nursing homes, and they are also promoting this information, and messaging around the availability of this information. Ren, did you have anything else you wanted to add?

REN SALERNO: No, I mean other than that this call is one of many, many different calls that we are on trying to spread this word around the importance of following the Instructions for Use. And the challenges with performing these particular tests. And so we hear you, and we're doing the best we can to get this information out as widely as we can.

JASMINE CHAITRAM: OK, great. All right, the next question is related to the Antigen Guidance, Antigen Testing Guidance. And the question is, can we use antigen testing, like the BD Veritor for screening asymptomatic? I've seen this done all over, but it's technically against the EUA. In light of the warnings that FDA sent earlier this month on false positives for antigen testing, can we use it to screen for asymptomatics?

REN SALERNO: Yeah, so this is-- I think I know the answer to that question. But I think I'll let Tim Stenzel answer that question, because they've put out some messaging on testing of asymptomatics. CMA has also put out an FAQ on this issue, but I'll stop there.

JASMINE CHAITRAM: OK. Tim, you want to jump in?

TIM STENZEL: Sure, it's one of the questions that I was prepared to respond to. Hopefully you can hear me OK. While there is a growing number of devices, IVD tests, that have been authorized for use with asymptomatic patients, most have not been authorized for that. In only extremely rare cases have we limited testing-- it's very clear from the language in the authorization-- to only patients with symptoms. The FDA has made clear-- and supported by HHS, the CDC too, and CMS, that off-label use is just fine for these tests.

We are only beginning obviously to see, performance of these tests, so we can't authorize them without data to support-- known performance data. But what we've said very clearly on our FAQ page, is that these tests can be used off label. They just need a valid user prescription license, or just need a valid prescription. And users that understand that the sensitivity in asymptomatic population may be less. We've seen some accumulating data, although very early, to that effect.

And how less sensitive, don't know, and is that tied to how we validate these tests? Because it's really hard to tell with asymptomatic patients when they might begin shedding without symptoms, obviously. Or is there a different biology, is there a lower level of virus? And truly it is more difficult to detect. So all that is left to be seen.

Some early data for one of the rapid tests that I've now seen in the last days, has been real world evidence that these devices are meeting our performance expectations, when it comes to the symptomatic population. But it might be lower than what is in the package insert. So in real world situations, for whatever reason, the sensitivity seems to be at or slightly above 80% sensitivity. We set the bar for these without mitigation, other than-- other than it be by prescription at 80%. So they seem to be upholding that in real world situations and that's good.

But they're obviously not as sensitive as molecular tests are, nor do I think they need to be, given the situation. Very clearly, I think if you're truly positive with an antigen test, you have a virus around that could be transmissible. It is, however, difficult to imagine-- just to put it out there-- less sensitive antigen tests being useful in a less sensitive, in a symptomatic population. But in the asymptomatic population, some of these data seem to show relatively low sensitivity. Whether that's true or not, I don't know, too early to tell.

Very clearly, they are detecting positives in the asymptomatic population, which is important, I believe. And so we want to make these useful. So really HHS and CMS have cleared the path for this off-label use. CMS that says, you're not going to have a CLIA inspection issue-- CMS can correct me if they want-- if you're using this quote "off label" at the point of care. And HHS has said, that-- other things, which I would defer to them. So bottom line is, it's my recommendation that you consider using these devices in the asymptomatic population. That unless it's a high-prevalence population, that you do confirm asymptomatic positives with a high-sensitivity molecular test. So that was a long winded-- hopefully it's a good answer for things. Thanks.

JASMINE CHAITRAM: And thanks so much for answering that question. And Ren, thank you for your update on the "Lessons Learned" documents and infographics for antigen tests. We're going to transition to our final update, which is Tim again, Tim Stenzel from the US Food and Drug Administration. And Tim, I'll just turn it over to you.

TIM STENZEL: Thank you, Jasmine. And thank you, Ren, also for those tips. Not surprisingly to people on this call, the Instructions for Use need to be-- need to be followed. There are reasons for that. Not all lateral flow devices are the same. They may act similarly at the basic science level, but they're actually fairly complicated devices to make them work, in timing and other things are very important, of course. Just like any laboratory test.

So the other questions we received, and I'll attempt to answer is, when does the Public Health Emergency end? We don't know. The Secretary would make that determination, Secretary of HHS. In the past, for the most recent Public Health Emergency, they remain open. So Zika, Ebola, for example, remain open.

What happens with EUAs when the Public Health Emergency ends? Well, CDRH, our center, is drafting guidance that we believe will give sufficient time for developers of tests to convert to full authorization. So we realize that this is a huge need for testing, it will remain so for a very long time. But developers across the board labs and kits, have spent a lot of time and effort to make this available. And we have every desire to continue the availability of these tests.

And so we're going to issue a guidance that's currently being drafted. Can't predict when it will be issued. I don't believe there's an urgent rush to do that. I don't think we're in urgent peril of having the Public Health Emergency end. But that's not in our hands, and we'll do our best to meet the need.

But we expect to have a guidance that lays out time frames for conversions to be made that we found to be reasonable. And we'll continue the same access to testing that is currently available, and is still growing, obviously. And then the second related question is, how long will EUA submissions be accepted? I think is the question. And that is, until the public health emergency ends, we will continue to accept EUA submissions.

After it ends then those will be different. And that will be governed by the final guidance that we're drafting so we'll refer to that. So those are the questions, Jasmine, that I had received up front and prepared. I don't know if there's other questions that have come in and you would like me to respond to now.

JASMINE CHAITRAM: OK, great. Thanks, Tim. Actually, we do have a couple of questions for you. First one is, we've been presented with a question from our nursing colleagues asking to use NP swabs as nares swabs, because it's less invasive collection technique for COVID specimen collection. The published [CDC Guidance for Collection](#) doesn't specifically call out the circumstance, so do you have any comment on whether or not it's appropriate to use the NP swabs in replacement of the nares swabs for testing?

TIM STENZEL: That's not the first time that we've received that question. It's a bit odd, because we were-- we obviously had a short supply of NP swabs for a while, but apparently there's a relative abundance now since the FDA has clearly authorized lots of anterior nares, and a growing number of mid- turbinate nares-- assays which are much easier to collect. And patients prefer them obviously. The NP swab is not designed the same as the nasal-- anterior nasal swab. And so we don't know if it will perform the same for sure. It may not.

So we would advise against that unless you certainly have no choice, and then understand that the developers-- the FDA-- have a performance understanding of this swab. I understand their meaning and need, I just urge caution and only when you cannot get the authorized swab. I don't know the other implications for the other agencies, and their view of this would obviously be ideal to validate that. But that obviously involves work as well. But they are not-- to make clear-- they are not designed to be interchangeable.

JASMINE CHAITRAM: OK. The next question is, is there any timeline for COVID- 19 serology LDTs that were submitted for EUA in the summer?

TIM STENZEL: Can you ask that question again? The turnaround time for serology EUA?

JASMINE CHAITRAM: It's-- a timeline for COVID- 19 serology LDTs that were submitted for EUA.

TIM STENZEL: OK. So we are still-- of course the HHS came out with a statement initially that the FDA-- about FDA requirements for EUAs for LDTs. And then more recently has made statements about the FDA revealing LDTs, and at this moment I still have to say that we're in conversation with HHS, and stay tuned. Hopefully, we'll have more information in the near future.

JASMINE CHAITRAM: OK. I've got one more for you. If a product such as a molecular test that has not yet received EUA, and is being sold through the notification pathway, can it be used in a point-of-care settings that are owned by a health care system that has a high complexity laboratory? Or can testing only be performed within the four walls of the actual high complexity clinical laboratory, in the main hospital, for example?

TIM STENZEL: What the FDA has said, and you are probably not the only authority here, is that if-- and it's based obviously on dialogue with other agencies but I defer to them-- CMS and CDC. But it's our view at the FDA that, if that point-of-care facility is covered by the high complexity certificate for the lab-- that it's within the high complexity lab so to speak-- then it should be fine. But these devices that are only by notification have not been authorized for anything other than a high complexity lab situation.

JASMINE CHAITRAM: OK. One more, Tim. For the LIAT combo test-- Flu/ SARS. Since the VPN is in short supply, can any swab VPN be substituted and the test still be waived?

TIM STENZEL: So this is lateral flow? I didn't catch the--

JASMINE CHAITRAM: Yeah, I think so. I'm not familiar either with this acronym says L-I-A-T combo test for flu and SARS. May have to come back to this--

TIM STENZEL: Maybe it's L-I-A-T, rather than L-A-I-T- there's the Roche LIAT--point-of-care test. That's probably what they're referring to. But just to be clear, the first-- the concern, and that is with lateral flow devices we've seen significant numbers of false positives with some devices, with some VTM. And obviously VTM would dilute the sample for a lateral flow device. But I believe this question is about the Roche LIAT, which is a molecular assay. And I would defer to the manufacturer any questions about a suitable VTM with their product.

And I wouldn't want to presume that I know the performance in the different ones. I would say that in general-- well actually, if you send that question to cdrh-eua-templates@fda.hhs.gov, we can look up what's specifically in the Instructions for Use, and we can ask the experts on our

team if we're in the know about the Roche LIAT, to know if there's any theoretical issues. Because the manufacturer, in all likelihood, will probably stick to what's in the IFU and we would like to be at the FDA, at least, as helpful as possible. So that's a great question. In fact, I would try to capture it and try to answer it on the next call. OK? But we can-- whoever's asking the question can send it to our templates email address and get a more rapid response.

JASMINE CHAITRAM: Right, that would be helpful. OK. I've got another one, off-label use has generally been considered on a patient-by-patient basis by the patient's healthcare provider. Can off-label use literally be applied to an entire population or group, as opposed to a traditional patient-by-patient consideration?

TIM STENZEL: So if it's specifically intended for testing asymptomatic individuals with the vast majority of lateral flow antigen tests and molecular tests that we've authorized. I believe-- there may be state law-- state and local law issues, but the FDA at least is fine with a blanket prescription for a population, say a nursing home, a school, or workplace, or other similar venues. Or a blanket clinical order is made for this purpose and it does not need to have an individual script. That's at least from the FDA perspective. I'd defer to other agencies if they have and state and local laws. If they have any other consideration.

JASMINE CHAITRAM: OK, great. And for that last question that you were just answering, and you gave out that email for a more rapid response, and showing it on the slide for the individual who submitted that question, if you want to send it to this email address as Tim mentioned that would be addressed a lot faster than the next call.

TIM STENZEL: And make sure that they make sure that they ask for me to be involved too, so that I can help address the question.

JASMINE CHAITRAM: OK. All right. Well, thank you very much. With that we are at the end of our agenda and pretty much almost out of time. So I do want to thank everybody again for joining us today. A couple reminders, our next call will be on December 14, at 3:00 PM. If you're not receiving announcements for these calls, please send an email to LOCS@cdc.gov.

You will get information about our calls, as well as other information that we send out through that system. We want to thank you all for everything that you've been doing, for what feels like almost a year now, to support the COVID-19 response. And we appreciate all the questions that you've submitted, all of your suggestions for agenda items, again we hope that these calls are helpful to, all of you, and we will talk again in two weeks. Thanks again for joining us.