Agenda
Clinical Laboratory COVID-19 Response Call
Monday, December 27, 2021 at 3:00 PM ET

Agenda

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  - MariBeth Gagnon, CDC Division of Laboratory Systems (DLS)

JASMINE CHAITRAM: Hello, everyone, and good afternoon. Thank you for joining the Clinical Laboratory COVID-19 response call. I'm Jasmine Chaitram. I'm the Associate Director for Laboratory Preparedness in the Division of Laboratory Systems. And if you've been joining us for a while, you know that the Division of Laboratory Systems at CDC has been hosting these calls since March 2020.

Before we get into our topics for today's call, I do have a few reminders and announcements. Just a reminder that the Division of Laboratory Systems, we're here to support clinical and public health laboratories. And we've been doing this in a number of areas before COVID-19. That includes quality and safety, laboratory training and workforce development, preparedness, and response, just like we're doing now for the COVID-19, and informatics, and helping make laboratory data accessible and usable.

We have a Preparedness Portal, which is our one-stop-shop for all the information and support that DLS provides as a liaison during this response to the clinical lab community. On this web page, we have an archive of all of these calls, transcripts, and audio. Obviously, transcript is audio – slides are not transcripts. All of the agendas can be found on this web page with all of our LOCS messages - that's the Laboratory Outreach Communication System - and their links to COVID-19 web pages can also be found.

I did want to make one announcement about the CDC OneLab Network. This is a collaborative network of clinical public health and CDC laboratory education and training professionals. And it was launched in February 2021. And the purpose is to meet COVID-19 education and training [needs] with peer support, rapid, large scale emergency responses in general, and the training needs around that.

After a survey, we identified some priority topics related to COVID-19, as well as resources, free job aids, and trainings. And all of this can be available if you join this network. Some of the topics that we've most recently added was “COVID-19: Leading in Times of Crisis”, as well as “Supply Chain Lessons Learned”.

And so if you're interested in receiving any of those, or having access to it, all you need to do is click the link that says Join the Network. And you can do that by visiting the Preparedness Portal and the archive of this call where the slides are. And it should be easy, it links right there to it. Also, we have staff on the line that are going to be putting these links in the chat as well.

The next call will be on Monday, January 10 from 3:00 to 4:00. So we look forward to you joining us then. Also, for training and workforce development needs, please continue to send those to labtrainingneeds@cdc.gov.

Reminder about asking questions, we want you to have questions placed in the Q&A box on the Zoom feature. But not in the chat box. We suggest you record your questions. It also will be helpful if you included your name in an email, in case we cannot answer your question on the call today.

As a reminder, these calls are intended for clinical public health laboratories, and our topics are focused on laboratory testing issues. If you ask a question that's not related to laboratory testing, we may not have the right subject matter experts available to answer your questions. We will try to get them answered for you, but it may not happen on this call. We also have a number of people dialing in, and sometimes because of the time allotted, we don't always get to answer those questions on the call. But please be patient with us. We will either address your issue on a following call, future call, or get back to you by email.

One last thing, just a reminder that the slide decks may not necessarily represent CDC's opinion, official position. And all of our presenters are associated with CDC. OK. Ready for our first speaker, Dr. Henry Walke, from the Centers for Preparedness and Response. So serving in the response right now, talking about a potential increase in testing demand. I'm going to go ahead and turn it over to Henry Walke.

HENRY WALKE: Yeah, thank you, Jasmine. And welcome. Good afternoon, everyone. As you know, we were seeing an increase in cases throughout the country. And we expect a continued need for laboratory testing due to the Omicron variant, the transmissibility that we're seeing, and on top of holiday related gatherings and travel.

With the increase in demand, we're really reaching out to all the partners on the laboratory side to encourage, and in this call, encouraging clinical laboratories with testing capacity to contact state and local health departments to coordinate surge testing support. Certainly, local jurisdictions, state jurisdictions have surge testing plans. And if the clinical laboratories have testing capacity and are already included in those state and local health department surge testing plans, we encourage you to contact your jurisdictions, local jurisdictions.

Also, we're experiencing some long lines at drive-thru and specimen collection sites. And if there are laboratories with the ability to help with specimen collection, or stand up, drive-thru testing, also please contact your state public health labs. We know there's still a lot of capacity within the terms of laboratory

testing. We certainly expect to see some longer turnaround times in some parts of the country versus others.

But overall, there still is in talking with a number of you, there still is in the commercial labs, there still is a lot of testing capacity out there. But I think that the demand will only increase. And so we want to make sure that this afternoon, that we reached out to you and just encourage you really to work with state and local jurisdictions, and if there is an opportunity to provide more testing capacity. Hard for us to coordinate this at the federal level. But certainly, you have the connections at the state and local level.

We'd also like to know-- I co-lead the testing diagnostic working group in HHS as well. And within that team, there is an industry engagement team. And we'd like to know about any supply chain issues that you're having. We're monitoring this on a regular basis, whether it's pipette tips, or plates, or whatever it is, reagents, we'd like to know if there's any supply chain issues.

And so I'm going to put-- I assume Jasmine will put the contacts in the chat here. If there are any issues related to supply chain issues, you can reach us at testing diagnostic - tdwginfo@hhs.gov, and we'll reply. That's really all I wanted to say, just to put in a plug for again, connecting with local and state jurisdictions if there's an opportunity for the clinical laboratories to provide additional surge testing capacity. So thank you, Jasmine. That's all. But happy to take any questions.

JASMINE CHAITRAM: Thank you, Dr. Walke. I'm not showing any questions for you at this time. If you're able to stay on with us, I'll let if we do have any that come up.

HENRY WALKE: Great, thank you.

JASMINE CHAITRAM: And I forgot to mention that we didn't have slides for that particular update. Our next speaker is Dr. John Barnes. And he's going to give us an update on the SARS-CoV-2 variants. And I believe John is going to share his own screen.

JOHN BARNES: That is right, yes. Let's see. Here we go. OK. So I thought I would just go through the portions on the COVID data tracker for the latest week, and kind of walk you through some of this. There's a lot have been made about the last prediction interval. But I thought I would give you some context as we go through.

So over the last couple of weeks, the confidence interval for the date that we have for Nowcast projections on the week ending 12/18 was 73.2% for Omicron. But you can see there's a very, very wide confidence interval with 95% confidence interval in this region for the national forecast. We have done our very best to try to get and make sure that our laboratories that are feeding us data, contract labs, as well as surveillance labs, as well as other labs submitting samples aren't prioritizing specimens. But we can't predict that has not happened.

So I will give you that caveat. This has been a very, very hard virus to predict. And so this is the estimate that we have now. But I would really like to stress that those confidence intervals are very, very wide, and this is the reason for some of the wide intervals that we're dealing with in this projection.

Delta has been predicted to decrease down. Again, you can see very, very wide confidence intervals on that. The reason is when we're predicting a proportion of variants, the one affects the other. Our ability to predict one affects the other.

So if we look at Omicron prevalence in the regional data, we can see that it is predicted to be the predominant variant in a region-- excuse me-- region 10, region six, region four, the overwhelming predominant in five as well. They are just a few regions actually in region one and seven that were not predicted to be-- the Omicron was not predicted to be the predominant variant. Again, those confidence intervals for this though, are very, very, very wide, and should be understood in that context.

If we look at the weighted proportions of variants by jurisdiction, this includes data that is empiric data from each jurisdiction, as well as some estimated data that we would add into this based on the rate that we see for those variants. This data takes quite a while to backfill. And so this does not yet contain any Omicron in this estimation.

If you look at B11529, which is Omicron right here, there's nothing presented. And that's because during that time frame for the weeks ending at 11/27, there were no cases that had been reported by that time. So I'm sure that the news had already been out about some of these proportions, but I thought I would give some updates about the intervals, and just how wide they are. Thank you, Jasmine.

JASMINE CHAITRAM: Thank you. There is one question for you. And that question is, how does CDC account for the variation across laboratories for the sequencing platforms, and the sequencing depth in coverage when aggregating information nationally on circulating variants?

JOHN BARNES: So that's a great question. And it has been very difficult. The depth in coverage and the different platforms have led to various issues that we see for individual based calls. But for something as large as general variant calls, they're less problematic. And so the variants are a little bit lower bar, if you will.

And so they're easier on a variant call level than they are on a per base level. But we have done a lot of work in our strain surveillance and emerging variants group, and looking at the individual platforms that our partners are using, and the individual lab methods that they're using to look at the validity of those calls. But it has been a long-protracted process, and one that we're still going through.

JASMINE CHAITRAM: Just checking to see if there's more. Will there be updated Nowcast estimates for this week?

JOHN BARNES: Yes, the newest Nowcast estimates will be out tomorrow morning. And so we're hoping that the confidence intervals, and we get a more resolution in those Nowcast estimates for the latest couple of weeks.

JASMINE CHAITRAM: And we're not showing any other questions for you right now. Thank you so much, Dr. John Barnes, for joining us.

JOHN BARNES: You're welcome.

JASMINE CHAITRAM: OK. Before we go to our next speaker, there was one question in the chat box that I think we can answer. I saw that Dr. Henry Walke had to drop, but I think Dr. Ren Salerno, who is also in the same task force, has joined, and can possibly provide an answer. The comment is, Omicron is less severe with lesser hospitalizations. So how will it increase the demand for testing? Ren, do you think you can answer that one?

REN SALERNO: Hi, Jasmine. So I just want to make sure I understand the question. It is, if we assume that Omicron is less virulent than previous variants, why will that increase the demand for testing?

JASMINE CHAITRAM: Yes.

REN SALERNO: Right, OK. Well, I think the issue is the rapid transmissibility of Omicron. And that it seems to be moving very efficiently and effectively definitely through unvaccinated, but also seems to be infecting vaccinated individuals, which is why the government is urging those who are qualified to receive booster shots to increase their protection against Omicron.

But that high level of transmissibility is leading many people to become sick, or to have symptoms that can be associated with COVID-19. And so a large number of those people who are getting those symptoms, or who know people who are having those symptoms, or know close contacts who have tested positive, are deciding that they need to get tested as well. So it's fairly common. And we've seen it throughout this pandemic that as we experience a variant with better transmissibility, we also see a corresponding increase in the demand for testing.

What we're seeing now too I think it's quite interesting, is that the demand is much heavier, much higher for tests that return results quickly. So there's a high demand for the over-the-counter test that can be taken at home, or outside of a traditional testing environment. There's a high demand for the point of care rapid tests that return results quickly. But as Henry Walke said earlier, we are being told by many of our clinical and commercial lab partners that there remains significant capacity in the laboratory testing environment that is not necessarily being completely used up by the existing testing demand.

So I think that's also part of the problem, is that the demand could be primarily for these rapid result tests, whether it's point of care or over-the-counter. And that we haven't been able to adequately at a national

level distribute testing across all of our available testing resources. So I hope that answers the question, Jasmine.

JASMINE CHAITRAM: Thanks very much, Ren. OK. John, I've actually got another question for you, if that's OK. The question is, what percentage or range of isolates are currently being sequenced for variants? How much regional variation in sequencing?

JOHN BARNES: How much regional variation in sequencing?

JASMINE CHAITRAM: Yeah, but I think the first part of that was what percentage of isolates are currently being sequenced for variants?

JOHN BARNES: So the percentage seems to bounce around quite a bit. So the estimates that we utilize are based on kind of a three-tiered model that we produce across the United States. And that includes data from three different sources. One is, we at CDC have what we call an S3 that we sequence here. And it varies, but how many we get a week, but we ask for a certain percentage of those to be sent in.

And then we have contract data that we do through our Office of Advanced Molecular Detection Program, in which we have paid clinical labs to give sequence data that they have produced. And we utilize that. And then we also take in data that is from our partners, jurisdictional partners, that tag sequences for baseline surveillance. And in all of that, we average more than 35,000 sequences a week that are being processed through our data system.

And when we look at that, really, our prediction intervals on that is that with very high confidence, over 99%, we can find a variant at 0.1% of circulation within the population. So we don't really use percentages per se, because that's based on the amount of testing going on at any one time. But we rather have used these prediction intervals.

And really, our sensitivity is a lot more sensitive than that. That's when we look at 95%. I think for the MMWR that we recently did, it was down at 0.03%. So we have very good sensitivity of the system.

JASMINE CHAITRAM: Thank you very much. We are going to go ahead and move to our next speaker from the FDA, the Food and Drug Administration, Dr. Tim Stenzel. Tim, are you on?

TIM STENZEL: Yes, thanks, Jasmine. So I had received some questions ahead of time. I'm going to go through and try to answer those. First question is, we have some indications from individuals that have purchased home testing kits from pharmacies that the pharmacies may not be controlling access to kits with respect to their FDA, EUA approval that is allowing access to buy prescription home testing kits without a prescription. In parentheses, are purchased really off the shelf, end parentheses. Also, some of the buy prescription home testing kits are not FDA, EUA authorized for screening testing, which is how they are likely being used. How is the FDA monitoring access within pharmacy chains by prescription versus over-the-counter home testing kits?

And going on to an answer here. You know, so some COVID-19 tests do require prescription, and others do not. COVID-19 tests authorized for use without a prescription include the attribute DTC, which stands for Direct to Consumer. We apply this term for COVID solely to home collection kits. So this is not a home test. It's a collection kit you can take home and take a sample, and then send it in. Or over-the-counter, OTC. And these are listed in the FDA In Vitro Diagnostics EUA page.

Why prescription tests should not be sold without a prescription. Thank you for this information. The FDA does not object with regard to tests that haven't been authorized for screening if there is an ordering clinical order for that test, even if it's in asymptomatic patients, we do encourage labs to do that testing and report the results.

However, clinicians and laboratorians should know that that should be done with caution, as we don't know the performance of these tests in particular in the asymptomatic population. The FDA does use a wide variety of methods to closely monitor the safety of all tests, including EUA authorized devices via the voluntary reporting of adverse events, methods, performance issues, reports of off label use. The FDA does use this data, and as well as other identified so-called signals to maintain our safety surveillance of these and all medical products.

If reports and/or complaints are received, the FDA will investigate, and follow-up actions would be based upon the outcome of those investigations. The risk associated determine potential actions. And if there are activities that are in violation of statutes and regulations, there may be consequences.

If you are aware of any concerning situations regarding the distribution of COVID-19 tests, please report to FDA, so that we can investigate. You can submit these allegations of misconduct through the [CDRH] allegations mailbox. I'll put that into the chat and put that through right now. And then or either that, email, or you can send it to the COVID-- and that one is called CDRHDeviceAllegations@fda.hhs.gov. Or you can send it to covid19dx@fda.hhs.gov. I will also put that email address in the chat, which I just did.

Moving on to the next question, regarding the use of OTC home testing serial screening kits for the Safer Federal Workforce requirement for at least weekly testing of unvaccinated individuals, has the FDA addressed, or is the FDA planning to address agency attempts to use the test kits to fill the at least weekly testing requirement when compliance, or with the serial screening aspect of the FDA, EUA approval is not enforced? So FDA would direct questions about this to the Safer Federal Workforce Program about the program to the Safer Federal Workforce Task Force. Of course, we will do what we can to support any efforts the US government puts forward in any way we can, and of course, encourage beyond label use of tests.

The next question, we have a lab that has an EUA approved quantity-- this says quantitative. But I think RT, PCR NAAT test for NP swabs where some are expired. Are we able to extend the expired kits with bridging validation studies to use these expired kits? The FDA does not recommend using kits beyond their expiration date.

If there is data to support extending the expiration date, the EUA test authorized holder should submit a supplemental EUA request to the FDA, including real time stability data to support extending the expiration date for FDA review and authorization. We've been doing this on an ongoing basis for any test developer that wants to extend their dating. You can also please check with the specific test developer to see if the FDA has in fact extended the dating for that specific test, and/or lot in your possession. So we have when requested by EUA test authorization holders to allow tests to be used in the field that have had their dating extended, but the box contains a short date to allow that developer to communicate with their customers and use that material.

I'm moving on to the next question. Is there a difference in COVID test sensitivity between nasal mid-turbinate and NP, nasopharyngeal samples? There may be, but it may be small, if any difference. The easier access of nasal swabs and mid-turbinate swabs compared to nasopharyngeal swabs allows perhaps for more frequent and easier testing over the use of the more difficult perhaps, more sensitive nasopharyngeal swab.

There's also a reduced risk to health care workers, less sneezing and coughing with a nasal swab, or a mid-turbinate swab. Many tests have been authorized for both nasopharyngeal mid-turbinate and/or nasal swabs. For some, there is data in the authorization documents demonstrating performance for each sample type. But that's not always there.

Moving to the next question, if a kit that is EUA cleared says that it should have confirmatory PCR testing for all negative results, would it be considered modifying use if we do not perform a PCR confirmation? In short, yes, that would be a modification. And it would no longer be considered an EUA authorized test, because it's not being used as authorized. The FDA does recommend performing EUA tests according to the instructions for use that are listed with the kit and test, and also available on the FDA website.

In cases where a test has been authorized to provide, "Presumptive negative results," results. Give me one second. The authorization typically indicate whether all negative results should be confirmed, or whether negative results should be confirmed if clinically indicated. The EUA authorized tests should be used in accordance with its authorization when the test is not performed as described in the labeling, such as not performing a confirmatory PCR test, there is a greater risk that those results of the test may not be accurate in total.

Such labeling as presumptive negative, or encouraging use when needed of confirmatory testing is there for a reason. Because there is the greater possibility that a negative may be a false negative. Next question, has FDA identified any sensitivity or specificity differences on approved assays on fully vaccinated individuals versus non-vaccinated? This is a question that we've had front of mind for some time now, certainly, in greater consideration for serology tests.

But as far as diagnostic tests to date, the antigen molecular test, we have not received data that suggests there's any difference at this point that would behoove the FDA to make any additional recommendations

at this point. FDA does recommend to test developers that they note in their clinical study data whether or not a test subject has been vaccinated. It is through this process that we can look at performance by subtype, by category. Does the performance differ in the vaccinated versus unvaccinated population, or whether they previously had a viral infection?

Next question, we are a high complexity clinical lab located in California accredited through CAP, and we have developed an LDT molecular COVID test, and it is only used within a single laboratory. Our daily volume is around 600 to 1,000 tests. Do we need to submit an EUA to the FDA before January 15, 2022? I think this is concerning the recent guidance update on November 15, 2021. You can go to that guidance, which I'll put into the chat when I get a chance, so people can pull that particular guidance up. The short answer is, yes. But if you have any specific questions, you can reach out to the covid19dx@fda.hhs.gov email to ask specifics about your test.

The FDA generally expects newly offered COVID-19 tests, including LDTs to have an EUA, or a traditional marketing authorization. That's a full authorization, which are granted de novo or cleared 510(k) prior to clinical use. For tests currently being offered without the submission of an EUA request that were developed before the 15 of November 2021, the FDA has noted in that guidance that they can continue to offer that test, but expects the submission to occur within 60 days of November 15, that I believe puts it at by January 14, 2021, as described in the revised guidance.

So I just want to make it clear that any LDTs that were on the market as of November 15, 2021, can remain if they wish to pursue the EUA authorization pathway, and look to the guidance, which I will put into the chat function here as I'm speaking. There it goes. For any specifics, come to us if you have any specific questions that you have addressed in the guidance.

Really, this is a pretty straightforward process. In fact, you can simply photocopy or scan your validation documents as you have done it for your CLIA validation, and submit those as your EUA submission. You do not have to put it into the FDA template. You can if you want, not required to. We're trying to make this as easy as possible.

And all the while as long as you submitted it by January 14, 2022, you can stay on the market while we review it. If we have any questions, we'll reach out. That was the intention of this updated guidance that any LDTs that were on the market as of that date could remain on the market. Next question, will the Cepheid GeneXpert 4 Plus, that's a flu A, B, COVID and RSV test miss the Omicron variant? No, not to our knowledge. The FDA has not identified the Cepheid test to be impacted by the Omicron variant.

Our FDA website, we keep as up-to-date as we can. Once data comes in, and there were only three tests as of prior to today that were molecular that were missing Omicron, one of those has been updated, the Tide's Laboratories test. They recently revised their assay, submitted the validation information to the FDA. The FDA authorized the update. We now think those tests can detect Omicron due to the revision of their test. And so the FDA website was updated with that information a little bit earlier today.

The FDA will continue to investigate tests for potential Omicron issues, especially antigen tests, and an update to the website will occur as needed. And I will put the link to the variant mutation, which covers all variants, not just Omicron into the chat function as well shortly. Moving I think to the last question, any discussion on the need for validation of EUA approved assays after the national emergency is listed?

So I'm going to just make some assumption about the question is all about. We cannot anticipate, the FDA cannot anticipate when a public health emergency will end. However, the FDA is committed to helping ensure the public access to a wide variety of test options for COVID-19. And for the time being, we're continuing to review EUA requests that address public health needs according to the most recent guidance, which states our priority for review.

Test developers who wish to keep their tests on the market after the national emergency declaration is removed, should validate their tests for full authorization, and submit that validation to the FDA. The FDA has recently posted draft transition plans for test developers. So you can go to those drafts and review them. And the FDA is inviting comment on these. There's two drafts.

And so you have an opportunity to comment now if you want. We'll receive those comments. We'll then make any needed revisions to the guidance documents, submit them for clearance within the government. And then it may result in a final guidance with those. But again, don't know exactly the timing for all of that. And with that, I'm going to post the last couple of links that I mentioned, and turn it back over to you, Jasmine.

JASMINE CHAITRAM: Thanks so much, Tim. A couple of questions did come through for you, new ones. The first one is, how sensitive are the rapid tests? Isn't it possible for the low sensitivity, the rapid test to cause false negative, and therefore, it causes people to easily infect others? So it's just a general question about the sensitivity of rapid tests?

TIM STENZEL: Yeah, so we've known since the very beginning that rapid tests for COVID, in fact, for any respiratory disease, there's going to be less sensitive than the molecular test. The advantages of a quick result on the spot result that it's positive can result in, and hopefully, the appropriate triage of that patient into therapy, or whatever the clinicians think is best for that patient.

So as a rule in test, they can be very effective. Every test has a false positive rate. We've been expecting antigen tests for COVID, and for any respiratory virus to be as specific as possible. Typically, the tests that we've authorized are at least 98% to 99% specific. So you know they're fairly specific.

However, the sensitivity is known across all variants to be less than molecular tests. We are currently examining antigen tests for Omicron sensitivity. There have been some publicly made documents, especially in other territories of the world, that have noted at least analytically, the antigen tests when tested, say, with live virus diluted into some sort of matrix doesn't appear for the tests that those entities looked at to be any less sensitive for Omicron than previous variants, or original virus.

So that's good news. The FDA is always interested in actual clinical performance. So our investigations do continue, and we're in contact with all the antigen test developers. And as soon as we can, or as soon we need to update anyone about performance, we will do our best to do that.

JASMINE CHAITRAM: Great. Thank you, Tim. Here's another one. Is an assay automatically EUA approved for updates for different extraction analyzers with the same methodology and reagents?

TIM STENZEL: Yeah, that's a very specific question. So we work with any test developer, and any updates to their tests we'll entertain. And we do get regular submissions for supplements and updates. If a lab wants to validate a different platform that's not included in the label, it's important to validate it properly, make sure it works. But that it wouldn't then be an EUA authorized test.

And do look to the updated November 15, 2021 FDA guidance. I'm not sure if I put that into the chat yet. There are modifications that the FDA will allow to EUA authorized tests for labs to perform. By and large, there are anything that doesn't change the indication for use, doesn't change the components of the actual reaction, you know, primers and probes, and doesn't affect, especially in a negative sense, the performance of the test. So if you make one of these minor modifications, which could be in a different extraction device, and you validate it, and shows equivalent performance, just check the guidance document to make sure that the changes the FDA would consider an allowable change, and not requiring a submission, which in most of the cases, except for the exceptions I said is going to be the case.

JASMINE CHAITRAM: Thanks, Tim. I've got a couple more questions I want to try to squeeze in before the next speaker. The first one is, are there any tests in the pipeline that are CLIA approved for reporting variants to patients or providers, particularly using sequencing?

TIM STENZEL: So there are some sequencing assays that are authorized, and the genotyping is visible. And then of course, it doesn't call out the variant. So the user would have to put two and two together. Those tests are not authorized for reporting of results to clinicians or patients for that purpose. But if a lab gets that genotype data from a sequencing assay, the FDA is not going to object to that going into the report.

Same goes for both the S gene, N gene dropout tests. So there's a number of tests listed on the FDA website on the mutations page that present with Omicron samples, not all of Omicron samples, because not all Omicron have S gene dropout. Not all have N gene dropout. And some non-Omicron samples have S gene drop out.

So neither are perfect surrogates. But these days, when Omicron is so prevalent, and there's an S gene dropout, or there's an N gene dropout, I think there's pretty good certainty that Omicron is present. So the FDA won't object to reporting out the S gene dropout and N gene dropout, knowing that it's not a perfect surrogate. As soon as we can authorize a test that genotypes, we will. And at this moment, that is a priority for us to authorize something like that.

JASMINE CHAITRAM: OK. The last one I'm going to ask you today is, does clinical use of next generation sequencing for variants of concern identification at the patient level require EUA submission? Or is it OK to perform the test as an LDT?

TIM STENZEL: As I covered with LDTs before, this is actually-- we're going through a few questions like this. So any sort of COVID testing done purely for surveillance purposes, and reporting to public health authorities, such as sequencing, sequence information, genotyping, but even plus or minus to the sample have SARS-CoV-2. If it's just for public health reporting, for tracking of disease, for use by the infection control staff within a hospital or system, no EUA authorization is required. However, if you have an LDT or a kit, and you want to have test results reported to patients and clinicians, then yes, an EUA authorization will be required.

JASMINE CHAITRAM: Tim, thanks so much for joining us today. You answered a lot of questions. Appreciate it. Our last speaker for this afternoon is going to be Maribeth Gagnon. She's also with the Division of Laboratory Systems. She's going to be talking about LOINC in vitro diagnostic test code. And this is - we have a mapping tool on one of our DLS websites. And she's going to give you some background on that and some more information. So I'll turn it over to Maribeth.

MARIBETH GAGNON: Thank you, Jasmine. Next slide, please. The Coronavirus Aid Relief and Economic Security Act, or CARES Act, requires that every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2, or to diagnose a possible case of COVID-19 to report the results from each test to the Secretary of the Department of Health and Human Services. In addition, the statute authorizes the secretary to prescribe the format, manner, timing, and frequency of such reporting. The HHS reporting guidance provided this list of the required laboratory data elements and included a link to the LIVD test code mapping for SARS-CoV-2 tests found on the DLS website. Next slide.

I borrowed this slide from my FDA colleagues to describe the origin of this mapping format. LIVD is a product of a public private initiative of 70 plus members called SHIELD. The manufacturers provided the digital format as a common method for transporting the data elements from an IBD platform to the LIS. These early efforts built on many years of work led to the LIVD mapping.

When the pandemic highlighted a significant weakness in the management of health care data, the exposed inconsistencies in reporting laboratory tests when generated by multiple IBD platforms for different laboratories, the data elements were neither defined nor curated for the US health care system. This led HHS to fast track the requirement to use this mapping. FDA is currently in the process of developing a SHIELD strategic plan through the work of many volunteers. This planning is a concerted effort to define, collect, store, distribute, and curate the necessary standardized data elements and metadata generated for any tests on any IBD platform within the US. The plan includes using LAW and LIVD shown in the red circle, LAW is the laboratory analytical workflow, and LIVD is the LOINC In Vitro diagnostic mapping. Next slide.

The catalog is posted on the CDC website, and it contains a lot of helpful information. If you notice the tabs at the bottom of this slide, these are the ones found in the mapping. The LIVD publication tab provides information about the table, as well as the release date to help identify the most recent mapping. The HHS mapping to LIVD provides guidance and screenshots for one-to-one linkage of the data elements in the HHS guidance, and in the LIVD mapping.

Acronyms, it's a government publication. I think they're necessary. The LOINC mapping provides the selected codes for each FDA, EUA approved test. And the Excel spreadsheet is sorted alphabetically by first manufacturer and then the model of the test. The background information provides some historical information, and contains a section called Important Notes.

And this is where we'll add additional information from time to time, such as recently, we added the link to the FDA site on the impact of viral mutations have on COVID-19 testing. The LOINC mapping columns is simply a list of the data elements with descriptions, and then release notes is where we document all the changes that the team has made to the mapping, and the reason for the change. And this table is sorted by the publication version ID when the test was last changed. Next slide.

All of the work is performed by this small team of the members listed on this slide. It meets weekly to discuss the mapping for newly approved tests. And we've developed a system for coding with rules to keep the mapping consistent across similar types of tests. As you can see, this team has a lot of expertise in terminology, SDOs, industry, and government. And I want to thank this team for working with me for the last couple of years to keep the table updated. Next slide.

This is what you see when you go to the DLS website. We've been posting this table since April of 2020. And you can see that we'll list the version date. It's usually updated weekly. Though lately, we haven't had the need to update it that frequently. Next slide.

When a test receives an emergency use authorization, we add the test to the current catalog, and post it with a new publication date. Every effort is made for the test to be added within two weeks of receiving authorization. The test vendors do not have to request that the test be added, but the team always appreciates interest from the vendors in the coding of their test.

Information used to determine which codes are selected for the test, or taken from the instructions for use, or test summary that's submitted to FDA and posted on their website. On rare occasions, we've had to contact the vendor for clarification written in the instructions for use. This slide shows that some tests will have multiple targets. Like, you'll see the Bio-Rad Reliance tests for flu A and B, as well as SARS.

And also the authorization may include that the tests can be run on multiple platforms. And you'll see that in column O we've listed the multiple platforms for this Bio-Rad Reliance test, there were three platforms listed. Thank you for your time. Back to you, Jasmine.

JASMINE CHAITRAM: Thank you so much, Maribeth. There is one question for you. Where will we find the tables that are presented now? I believe that it was placed into the chat the link to the page with the LIVD mapping tool. And then we'll check that. If not, we'll put another link in there.

And one question for you, Maribeth. Who represents the laboratories and the development of LIVD?

MARIBETH GAGNON: Who represents the laboratories?

JASMINE CHAITRAM: Yeah, the laboratory community. How are they represented in this collaboration?

MARIBETH GAGNON: Well, we don't have specific laboratory people on this small team that's developed in the catalog. But there are a number of pathologists and laboratorians on the larger SHIELD team. We've had a lot of participation from CAP and some of the larger labs.

JASMINE CHAITRAM: OK. Well, thank you very much. I want to thank Maribeth and the rest of our speakers for joining us today. Thanks to all of you out there for also joining us today during the holidays. I know it's not a good time. I saw a lot of great questions come through in the Q&A box. And it will help to shape the agenda for future calls.

And want to I guess go ahead and close out this call just a couple of minutes early by wishing you all very happy new year. And we will see you in 2022. Stay safe until then.