**FDA Virtual Town Hall Series –
Immediately in Effect Guidance on
Coronavirus (COVID-19) Diagnostic Tests**

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's conference. At that time to ask a question from the phone lines please press Star 1 and record your name when prompted. This conference is being recorded. If you have any objections please disconnect at this time. I would now like to turn the call over to your host. Irene Aihie. You may begin

Irene Aihie: Thank you. Hello, I am Irene Aihie, of CDRH's Office of Communication and Education. Welcome to the FDA's 20th in a series of Virtual Town Hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the Public Health Emergency.

Today, Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, both from CDRH, will provide a brief update. Following

opening remarks, we will open the line for your questions related to today's discussion. Please remember that we are not able to respond to questions about specific submissions that might be under review.

Now, I give you Timothy…

Dr. Timothy Stenzel: Thank you Irene and hello again everyone and thank you for joining us. And we greatly appreciate everything you're doing to help out in this pandemic. We passed a new milestone recently. We have authorized now over 200 tests in the EUA pathway. And thanks to many of you for that accomplishment. Without developers like yourselves doing this, we could not have achieved that goal.

We are going to have many many more. We have hundreds of EUA applications in house. And the vast majority of these have come through the notification pathway so that they are able to if they do that if that's allowed to them you are all able to go out and market your test prior to EUA authorization. It is the honor system. We expect that the validations have been done well, the performance is acceptable and we thank you for that.

We allowed this pathway in this pandemic because of the absolute huge need to provide testing in abundance as soon as possible. And so please do bear with us as we go through these applications for EUA authorization. We obviously have to have a prioritizing so that we make the best decisions possible in all cases. So everyone's EUA is important and we will get to them.

Please work closely with the contact that we've provided. Again for EUAs, not pre-EUAs, for EUAs direct to the office make sure that every EUA applicant has a contact within two weeks of submission hopefully less time now. And that's important that you have a contact that you can get at least weekly updates from.

And those that do require an EUA prior to launch they obviously get triaged. For those new submissions new technologies that require an EUA, they do get higher priority because they are waiting EUA authorization to be able to get to the market versus those who come through the notification pathway.

The second update has to do with pooling. Of course there are, there's a greater need for tests than available tests and turnaround times at labs have increased. One of the potential solutions to this is that we find a way to pool. Pooling in all cases appears to decrease the percent positive rate that is low positives are going to be missed. And that's just a given if you start pooling.

We want to limit those misses to an acceptable level. And our updated templates call for a PPA relative to single tests on the platform of 85%. You can pool up to as many as you want as long as you hit that number. We are asking for an even distribution of levels of positivity so a good range of low positive and high positives, up to high positives.

So there's not an overabundance of either, an overabundance of low positives if it doesn't match your distribution in your lab which is the ideal thing is to match the distribution your lab sees then, you know, it's not as helpful. So we'll work closely with you to make sure that that distribution is good.

The pathway for pooling additions both for kit developers as well as labs to alter kits and/or alter their own LDTs is through the notification pathways. So validate whatever pool scheme you want to use. Make sure the performance is good. On the honor system, you can notify us and submit your data within 15 days. All the while, 15 business days, all the while continuing the test pools unless you hear any concerns from us.

And we'll get to those applications as soon as possible. They are a priority now so that we understand the variables that go into developing a pool scheme. There are multiple schemes. We have seen tremendous variability between labs that have tried to validate pooling even with the same kit.

So for example somebody might fail the bar at a lower sample pool where another lab seems to pass and so we are gaining more and more information about why that might be. It seems to be driven by two different things at least but these are probably the major drivers of pooling success. And that is the LOD of the assay. Obviously a more sensitive assay will be less likely to miss the average low positive than a test that is pooled that has not as great a sensitivity.

And then second is the distribution of low positives in a given labs menu and experience. So it's important to understand historically what your low positive rate is. We like to see CTs historically for the labs to help them guide them to the right pool scheme. It will give them great performance with pooling and balance the need to increase throughput with getting an acceptable performance and not missing a lot of positives.

And then finally I wanted to mention that recently we did authorize the first semi-quant serology test in fact there were two of them that we authorized semi-quant, quant and neutralizing antibody serology tests will be a priority going forward. There is a lot of interest relative to vaccines as you might guess. So we are working closely with any party that any developer that wants to advance development of these tests. And we look forward to more and more authorizations.

It is a bit more complicated to semi-quant, a bit more complicated to do a neutralizing essay or to correlate a given serology test to a neutralizing assay.

So we look forward to working with you. And with that, that ends our introductory remarks today and we can turn it over to questions. Thank you.

Irene Aihie: Operator, we'll now take questions. Hello, operator are you there?

Coordinator: Yes I'm here. My apologies. We will now begin a Q&A session. To ask a question over the phone lines please press Star 1 and ensure your phone is unmuted and record your name at the prompt. Your name is required to introduce your question.

To withdraw your question press Star 2. One moment please for incoming questions. We do have a few questions in queue. One moment, please. Our first question comes from (Elisa Maldonado-Colbert). Your line is open.

(Elisa Maldonado-Colbert): Yes. Thank you. Question regarding readers, after receiving EUA approval for an antigen test with a reader. If we validate a new reader after our internal validation do we need to submit a new EUA. Thank you

Dr. Timothy Stenzel: That would probably be a supplement to your existing EUA. And the validation requirements would depend on how closely the second reader performs relative to the first reader. Without knowing those differences and how you do that it's hard to predict and give you feedback in the short time we have on this call. That would, if the antigen test itself is the same just different readers that will be more straightforward and can be a supplement to your existing application

(Elisa Maldonado-Colbert): Thank you so much

Coordinator: Once again as a reminder to ask a question from the phone lines please press Star 1, unmute your phone and record your name at the prompt. Please limit to

one question per caller. Our next question comes from (Shannon Clark). Your line is open.

Shannon Clark: Hi. This is Shannon Clark with UserWise Consulting. We conduct human factors testing for medical products and I did email you Timothy about this. For viral sample collections using swabs, the template includes 30 unchanged subjects using the swabs all are negative for SARS-CoV-2. And we directly observed these as uncovering use errors.

My question is about the lateral flow test kit because for those it only requires five health care providers ten less than the FDA minimum number of human factors, no direct observation and it requires 30 antibody-positive finger stick samples.

So I was just wondering if the purpose of this point of care testing to uncover use problems and if so why doesn't it include and require observations? And why does it require positive finger stick samples? But if the purpose of the testing is for clinical agreement or test accuracy can you confirm that it is not considered human factors testing?

Dr. Timothy Stenzel: So there's a lot of questions in there I'd like to unpack things one by one quickly. One is why do we require 30 finger sticks that's because that sample type is physiologically different than other serology sample types. And we want to observe performance particularly on the lateral flow device that is equivalent to serum plasma or venipuncture whole blood. And so we do need to see the full 30 positives and that's a much lower level than we would normally require for a submission and that's because this is a EUA.

There were a number of other questions and I am not sure that I caught all of them. I think one of them is why for point of care. do we only require four or

five or so users. It's because they are health care workers and they are experienced in many cases with running point of care devices.

So we don't feel like the training, the users that have previous experience with various potential point of care devices we don't under the pandemic we don't feel like we need to for EUA we don't need to see quite as many as for non-healthcare worker situations where because we require so much less of a validation relative to a non-EUA situation we want to see more users who are unskilled and are not health care workers to make sure that they get accurate results. And there might have been some more questions in there and just want to pause and see if there's any clarification.

Shannon Clark: Yes can we just confirm that the point of care testing that is required by the template is not human factors testing and that you can just send a follow-up questionnaire to these health care providers you're not required to observe for use errors as you would in traditional human factors testing?

Dr. Timothy Stenzel: So for health care workers in health care settings performing the point of care testing we do not typically recommend for authorization for observation. Now a developer may want to do that to make sure, you know, that everything's working fine, that the workflow is great that users don't have difficulty, you know, more commercial marketing purposes.

Shannon Clark: Thank you so much. So we'll just proceed with advising our clients that the purpose is a point of care testing is for clinical agreement and/or test accuracy not for uncovering use errors.

Dr. Timothy Stenzel: That's true. I mean in performance in experienced hands such as health care workers sort of factors some of those things in already okay? All right thank you.

Coordinator: Our next question comes from (Dana Hummel). Your line is open.

(Dana Hummel): Hi. Thank you for taking my question. It's kind of a follow-up to the last question. For the section regarding point of care studies for the robustness of the test, you know, testing different volume samples, different lighting, is that required to use finger stick whole blood samples or could we use other sample types such as venous whole blood, plasma or serum or even controls with recombinant antibodies?

Dr. Timothy Stenzel: Yes. So I think you're talking about a serology test. And I do believe it does give you options on how to do that. Primarily we want to understand how does the test perform, if they are available that aren't controlled by the test themselves that are user-dependent time, volume observations. And even if you have a, you know, like a smartphone reader the lighting conditions matter.

So for those Toby, you know, might have this more at your fingertips than me but those things can be tested more analytically in the lab rather than with actual finger sticks. And I'm just going to that section but I don't think I have time to go to it right now.

But any additional questions that aren't clear from the template, the serology template for commercial manufacturers please just ask our team. But I believe there is advice for how to do that without having to use actual patient, direct patient material.

(Dana Hummel): Okay. Can we perform these tests outside of the US or are they required to be in the US?

Dr. Timothy Stenzel: There's no requirement to perform those tests within the US...

(Dana Hummel): Perfect. Thank you so much.

Dr. Timothy Stenzel: ...for those for those questions. Thanks.

(Dana Hummel): Thank you.

Coordinator: Our next question comes from (Neil Armstrong). Your line is open.

(Neil Armstrong): Thank you. Hi Tim and Toby. Thanks as always for doing this and really helping us out. Our product is a general diagnostic device. It's not specifically to detect the COVID-19 disease but because it detects changes in the body we believe it's got an application in staging the progression or recovery from COVID-19.

We got a lot of help early on in getting through this sort of template process and getting them into the right sort of format to put our information in. But recently we seem to have ground to a halt. We now believe we're in a position where we could put in a 510(k) for a general indication. And we appreciate you guys are just really busy on all the EUAs for the same sort of normal testing.

Should we put in a 510(k) for a general indication knowing that people may be using it off label for staging COVID-19 progression? Should we pursue the EUA route? Should we do both? If we put in 510(k) should we asked for an accelerated or expedited review? Really what's the best way of us moving forward on something that probably isn't your first priority and may take a bit of review time?

Dr. Timothy Stenzel: So yes things that are not targeting SAR-CoV-2 or antibody response to SAR-CoV-2 we have been bringing in non-microbiology review staff -- even

though there may be a microbiology component to it right -- because the desire to appropriately assess these technologies that can potentially assist in the care for COVID patients. So I without knowing the details of the process and your specific situation it's hard for me to advise.

Where possible we do want to follow the EUA route. We do follow closely the regs and guidance obviously for determination of what qualifies for an EUA. And we've been in some cases in many cases very flexible in adopting those things into the EUA process.

For example, multi-virus or multianalyte panel testing isn't something that was too clearly, you know, something that's a EUA because it detects viruses and other respiratory pathogens that aren't directly COVID related. So if you've gone to the halt and I hate to suggest this because my e-mail box is crazy but if you send it to me and you copy Toby so send it to the templates email address ask Toby and Tim. or Dr. Stenzel copied I'll get to it as soon as we can and help unblock this and make some specific suggestions for you to help your out.

(Neil Armstrong): Thank you. Thank you very much. Really appreciate that. Great of you.

Coordinator: Our next question comes from (Sarah). Your line is open.

(Sarah): Hi. And we're looking for some clarification on the stance for university student testing. The updated FAQs indicate broad screening requires a EUA but that healthcare ordered tests can be completed under the current authorized EUAs.

If our student testing is completed under a health care provider order as suggested was acceptable on our previous call from their high-risk status do we still need to submit a EUA for this screening and if so can the data be retrospective or should it be collected prospectively?

Dr. Timothy Stenzel: So our - when it comes to molecular diagnostics tests and use in screening, if the test that you're using is a EUA authorized and/or notified a test and it doesn't have any particular limitations, maybe due to some sensitivity or some issues that we've seen, then they can be used in the screening slash asymptomatic population when there is a health care worker prescription order.

And we're allowing that very clearly on our FAQ site. FAQs we encourage labs to accept these samples even though they may be screening or asymptomatic patients if they have valid orders and to report those results.

And for that purpose, there's no necessary change to a EUA unless that EUA wants to claims, you know, that they have a certain level of performance in the screening population. And then we will want to see data in the screening population that would support that claim that their test has a certain level of performance in the asymptomatic or screening population. And our templates go into a lot of different details about, you know, how to go about getting that.

So for example, if you're, if you already have a EUA authorized test, you know, there's a pathway to add that screening asymptomatic claim. If you're, have an entirely new test and you want to go directly for that asymptomatic pathway if you want to have an OTC test there's a different pathway, et cetera, et cetera.

So the details have gotten such that it's hard for me to keep them all straight but it's all laid out in the templates if you have any questions about that. But if you're not going for, you know, wanting to advertise that you're testing has a certain performance in the screening asymptomatic population you're fine. Just accepting the health care worker orders slash prescription, doing the testing and reporting it. Hopefully, that helps.

(Sarah): Okay yes. Thank you so much.

Coordinator: Our next question comes from Martha Casassa. Your line is open.

Martha Casassa: Hi. Thank you for taking my call. I am calling on behalf of the Clinical Lab Management Association. We are looking way in the future and wondering what is the plan once EUAs are lifted? What will be the status of all these assays and what will be required of laboratories to be compliant? Can you answer those questions, please?

Dr. Timothy Stenzel: Yes. So I think what you're saying is once we begin to authorize regular submissions and potentially if the emergency should come to an end what is the status of all these EUAs and what would be the plan for them at that point, correct?

Martha Casassa: Correct.

Dr. Timothy Stenzel: Yes so obviously this is very important. I will say that many of the previous emergencies are still declared and most of them have not been converted to regular submission. Some of them do and we certainly wish them to be able to do that. And we work with them to achieve that. And we've achieved that. I think for an Ebola test and the Zika test for example.

And so we don't know what decisions are going to may, be made regarding this emergency. I certainly don't foresee it coming to an end but I'm not the one making the decision. And you can rest assured that we will have, you know, a plan that will work for most everybody taking all these considerations into place.

So the thinking, a lot of thinking has already gone into this. So the other thing

that you say, as soon as we can make those plans public we will do so. So we're already thinking about that. So I don't know that it should be a concern. I certainly don't personally think that it's a concern for any of the developers out there right now.

Martha Casassa: Excellent. Thank you so very much. Have a great day

Dr. Timothy Stenzel: Thanks. You too.

Coordinator: Our next question comes from (Pamela Turbeville). Your line is open.

(Pamela Turbeville): We purchase qualitative serology tests IgG, IgM that only have an EUA. We read the results visually positive or negative. And then our app digitizes the person's data, saves a picture of the cassette and then reads the test results and sends a photo and the qualitative result to the person's phone

However in parallel, we have a reader with an app that also quantifies the antibody scores from the serology test. We're not sharing the data with the individual but we are using it to build validation data for the EUA application in the future. So our question is can we proceed to test individuals, provide them qualitative data per the third parties IFU and then capture the data, the validation data, and then compile it into a EUA application in parallel?

Dr. Timothy Stenzel: So I just want to check a few things. So you are taking somebody else's test probably not your own?

(Pamela Turbeville): Right.

Dr. Timothy Stenzel: And you've developed a smartphone app that takes a picture of the visually read lateral flow device. The data isn't, the data that's input, you know, and it,

and this potentially would go to the health care provider medical record and/or or a patient even. The test is visually read by the appropriate person who is authorized to do that.

(Pamela Turbeville): Right.

Dr. Timothy Stenzel: Most cases that would at the moment I don't think we have any point of care but for serology. But in which we're very interested in and we'll work with developers to achieve that. But, you know, they're - then they're moderately into high complexity lab situations now.

So those workers would read that test. They would record that result in your software package along with a photo capture of the results. Are, is your device currently reading the strip itself and making a determination of either qualitative results and/or semi-quant results?

(Pamela Turbeville): Okay the strip itself provides the qualitative results. So we tell it care, tell the person right away yes or no. So that is just the operating procedure that's done. But what we're doing, in addition, is we take the test cassette. We're putting it into our device that sits on a smartphone, insert it, press a button and it quantifies it. We record that data. We're using that data for our own future submission for EUA.

Dr. Timothy Stenzel: Yes. So that would be considered a device because you're actually doing analysis of the results of the test and coming up with a new output...

(Pamela Turbeville): Right.

Dr. Timothy Stenzel: ...based on the - that device's analysis. So there are two pathways. There's an easier pathway and there's probably a very difficult pathway. One is to work

with a given developer who already has a task and do the performance measurements and validation on that test for use with that test.

And that can be - there are various pathways for that. If you're, you know, test developers themselves can submit everything, you know, and update their EUA potentially or you can stay independent. We can figure out how to do that basically which team writes better reference letters.

And we would probably update both, you know, give the - your smartphone application that's on EUA and then we would also update the package insert of the test to say that it can be used with this device. If you wanted to have a more broad claim that would work on multiple platforms, multiple tests could be a little bit more challenging because there's obviously variability in those tests.

And that would be fairly challenging given, you know, sometimes the reads are different, locations are different, colors are different, intensities are different, et cetera, et cetera. et cetera okay?

(Pamela Turbeville): Got it. Thank you so much.

Coordinator: Our next question comes from (Gabe Olin). Your line is open

(Gabe Olin): Hi Tim. Hi Toby. Thank you for everything that you and others are doing. I'm working with a university-based lab that's developing a NexGen sequencing platform for massive diagnosis for students who are coming back to campus on the order of about 100,000 tests in a single day using saliva.

In the molecular diagnostics template, there's a requirement for alternative respiratory specimens to each 95% PPA with an NP swab sample. And I'm just wondering, knowing that our specimens in different areas in the respiratory

tract have different concentrations of virus, if you think that this is going to be a pretty rigid rule to maintain 95% PPA in this kind of setting?

Dr. Timothy Stenzel: Also are you going to try to pool to get a pool actual saliva samples before you begin testing or you're going to just do a massively parallel and test saliva samples individually and use bar codes to convolute and de-convolute?

(Gabe Olin): The latter, so massively parallel and they'd be unpurified saliva specimen which is what allows it to be so scalable.

Dr. Timothy Stenzel: Okay so we've found saliva to be an incredibly unpredictable when challenging substrate. I mean and we've really not ever considered testing saliva for a respiratory virus and authorized it before to my knowledge. This is incredibly unique, you know, and we're open and flexible and adaptable to different approaches.

But we've seen and denied some saliva submissions because of performance. And we are aware of multiple developers who have just decided that saliva's too tough. Obviously there are advantages to saliva right, easy to collect. You don't need - you may not need transport media or if you do it’s in a device that's easily used. And we've authorized tests with some devices already.

And you don't need, you know, swabs. You don't need VTM per se. And so there are huge advantages to being able to use saliva. So we just ask the developers and if they want to - and saliva can be added to a EUA test without an FDA submission if it's an LDT. Obviously kit manufacturers they can - it's a notified pathway they can validate saliva, notify the FDA and in 15 business days submit their saliva EUA package.

But for labs that want to either alter a kit or alter their own LDT, we don't

require a EUA submission for that. And but we do ask that you validate it well. And we have come to believe that a comparison to NP swab is critical to understanding the performance and the performance limitations of saliva. And we don't - I don't think we acquire that much. I mean it's basically 30 positives. And we understand that nasal pharyngeal swabs are sometimes hard to obtain.

A good second choice for an NP to saliva comparison would be a mid-terminate sample, mid-terminate swab sample. I think most students patients would much prefer to have a mid-terminate to an end - to a nasal phrayngeal swab. So that is also acceptable to us right now.

We are trying to discourage nasal swab to saliva because there is the potential for additional loss of sensitivity in the nasal swab. And we have found in many cases now that that comparison is not the best comparison to use going forward. So hopefully that helps.

(Gabe Olin): Got you. It does. Yes, I think, you know, we have a pretty strong limit of detection with our assay. And so I think maybe some of the loss in sensitivity can be made up for by frequent testing on a more regular basis. So just curious if that would come into consideration when comparing to the NP swab but great. Thank you.

((Crosstalk))

Dr. Timothy Stenzel: We do allow in a performance of a molecular test and also a direct antigen test down to an 80% sensitivity or PPA for almost anything. We do request that anything that generally falls below a 95% sensitivity compared to a good swab sample or another good test be labeled with the negatives being presumed negative rather than actually negative.

Because if you're missing up to 20% of positives we think that the clinicians should know that and make sure that the situation that they're getting that results on doesn't warrant a follow-up swab test, for example, to make sure the patient is absolutely negative.

(Gabe Olin): Okay. That's good to know. That's actually what we're intending, is to then if they get a negative they'd be - they would then get an NP swab. So thank you very much, Tim. I appreciate it.

Coordinator: Our next question comes from (Daniel Marcus). Your line is open.

(Daniel Marcus): Hey so my question is related to the notification pathway. Specifically in the May 11 guidance, you guys use the term distribution and that it's okay for commercial manufacturers to distribute the tests. And in this conversation, you mentioned the term market.

I'm just wondering what that looks like with respect to commercialization and what developers and manufacturers are capable of doing as far as being able to see any sort of financial reimbursement for their tests? That's question one.

And question two is you guys specify two, basically two entities that can - where these tests can be distributed which is high complexity CLIA labs and healthcare workers at the point of care. Is - so I'm wondering what, you know, what that definition of healthcare worker at the point of care looks like and whether those have to be high complexity CLIA lab personnel or they could be any healthcare worker at the point of care? But I'd love to get the first question answered first and the second one is just icing on the cake.

Dr. Timothy Stenzel: I'm going to actually reverse them because I'm going to hand the second the first one over to Toby for her thoughts after I first try to address it just to make

sure she doesn't have anything else or any corrections on what I say.

Toby Lowe: Sure, happy to.

Dr. Timothy Stenzel: But we authorize tests under EUA and we give clear indication on whether that test, where it should be performed, whether it's a high complexity lab, moderate complexity lab point of care which are healthcare settings with non-laboratory personnel, non-lab collection including home collection, non-lab testing including home testing and whether that that non - and whether that non-lab testing is by prescription or it's over-the-counter without a prescription.

So there are all these various scenarios. And if we have said that either a test is moderately complex or highly complex then it should not be used in a point of care setting except as is allowed under a moderately or high complexity lab's CLIA certificate. So it cannot be performed only under a waived certificate. Now hopefully that provides some clarification.

(Daniel Marcus): Okay.

Dr. Timothy Stenzel: Regarding...

(Daniel Marcus): That's in the E - that's within the context of the EUA but I'm asking vis-a-vis the notification pathway what's acceptable in addition to a high - in terms of distribution of the test in addition to high complexity CLIA labs.

Toby Lowe: Yes, so...

Dr. Timothy Stenzel: And let me...

Toby Lowe: ...on their notification...

Dr. Timothy Stenzel: Toby let me...

Toby Lowe: Oh, go ahead Tim.

Dr. Timothy Stenzel: Yes let me start that question or that answer. So under notification, the test can be performed at high complexity lab. For those entities that are labs and have an LDT and they want to have their notification posted, we'll post it on the FDA Web site.

All kit manufacturers via the notification pathway do go on that list. It is my understanding that - but we would have to refer you to CMS on reimbursement but tests that show up on the notification list that perhaps aren't yet EUA authorized can still get reimbursed. And with that, I'll turn it over to Toby for filling in more details and/or correcting me.

Toby Lowe: No, thanks. So right so under notification as noted in the guidance there are - all of the tests that are being offered without or prior to EUA default to high complexity. And that's under the CLIA regulation. So because they're high complexity the only way that they can be used at the point of care is if that point of care site is covered by the laboratory's high complexity or by a high complexity laboratory's CLIA certificate, sorry about that.

So I think that gets to your second question of what the setting is where these tests can be performed while they're being offered under this policy. Does that - is that correct? Is that what you're asking there?

(Daniel Marcus): That is what I'm asking. That does clear it up. One still question...

Toby Lowe: Okay.

(Daniel Marcus): ...that I - not to hog the mic is so you guys are allowing for - maybe this is more of a CMS question or a CLIA question, you guys are allowing a high complexity to CLIA labs to do I guess off-site testing outside of the auspices of their own campus? So if they wanted to - if a high complexity lab wanted to be...

Toby Lowe: So...

(Daniel Marcus); ...able to do testing at a school or just totally outside of your domain?

Toby Lowe: That would be a CMS question. But what we're generally referring to here in the guidance is situations where - and this happens outside of the public health emergency. There may be situations within the hospital with the hospital laboratory does some of the testing at a near-patient site so at their bedside. But it would still fall under the laboratories certificate.

(Daniel Marcus): Okay, got it.

Toby Lowe: And so your - for your reimbursement question that really would be a CMS question.

(Daniel Marcus): Okay so I mean it's not really reimbursement more so than, you know, is it possible for a commercial manufacturer just outright sell a test during the notification pathway or is that a CMS question?

Toby Lowe: Oh yes. The notification policy applies to commercial manufactures distributing their test kits for testing. And that does - that is intended to mean the sale of your test. We're not saying that you should distribute them without...

(Daniel Marcus): Okay that's what I wanted to get clarification on. So you guys answered my questions beautifully. I will stop hogging the mic. I appreciate your time

Dr. Timothy Stenzel: Operator do we have any other questions in the queue? We'll take our next...

Toby Lowe: Operator are you - is our operator still there? Do we have another question?

Irene Aihie: (Victor) are you on the line?

Toby Lowe: Sorry for the technical difficulties on today's call everyone. Thanks for your patience.

Irene Aihie: (Victor) is on the line.

Coordinator: (Un) my apologies. Okay, my mic was being odd. I apologize. We do have a question in queue and that question is from (Nermil Robbie). (Nermil) your line is now open.

(Nermil Robbie): Thank you. Thank you for this really informative session. I work with a clinical diagnostic laboratory that's outside the US that's using a US FDA EUA test, PCR test for COVID-19. So my question is, is the FDA accepting any user data regarding test performance because we are seeing between 10% and 20% invalid test results? And so would the FDA be happy to receive those data and if so how can I do that? Thank you.

Dr. Timothy Stenzel: Yes I'll start off. Toby may have something additional. So I think what you're talking about is if you're seeing subpar performance or issues with a test even though you might be using it outside the US are you allowed to report that to the US FDA? And yes absolutely. You can report that through the

MedWatch program on our FAQ page. You can also email our template e-mail address.

You can also report that to the company. We do require companies to record all complaints due at root cause determination and find out if it's verified. And in situations that require it, reporting those results to the US FDA even though they might occur outside the US as long as that test is also marketed in the US and could impact US healthcare. Toby is that pretty good?

Toby Lowe: Yes that sounds right to me.

(Nermil Robbie): Thank you very much and which template e-mail address should I send it to? CDRH?

Toby Lowe: It's CDRH-EUA-templates and...

((Crosstalk))

Toby Lowe: ...it should be on - I'm sorry @fda.hhs.gov. And it should be on the...

(Nermil Robbie): All right.

Toby Lowe: ...slides that are being displayed with the presentation too.

(Nermil Robbie): Thank you both very much.

Coordinator: Our next question comes from (Liba Sayed). Your line is open.

(Liba Sayed): Hi Tim. Hi Toby. Quick questions for you about the non-lab use template as we are running out of time here. First question is regarding the exclusion of

individuals who have experience with diagnostic home use tests like glucose monitoring tests. I'm assuming that applies only if your test is a finger prick type of non-lab use test as opposed to nasal swab. Is that correct?

Dr. Timothy Stenzel: No. In general, we want to assess untrained patients. And somebody who has routinely been performing testing on themselves at home will have an advantage over an untrained patient or consumer. And we're really trying to understand on the small number of samples that we're requiring in an EUA in that setting that we really understand the performance in a totally untrained user because that's the vast majority of potential users out there would be somebody who's never performed something like this before.

(Liba Sayed): Okay thanks. And then just really quickly I'm wondering in terms of the translation to Spanish of the quick reference information if the software user interface is not translated that that's the quick reference information is utilized in the studies if that is going to be acceptable for OTC claim?

Dr. Timothy Stenzel: I'm not sure I understand your question. You're talking about what language it has to be in because and what population is needed and comprehensive...

(Liba Sayed): Yes I think if you - I think there's...

((Crosstalk))

(Liba Sayed): ...a strong requirement to include your quick reference information in both English and Spanish for over the counterclaim is what the template suggests. And I'm asking if the quick reference information is translated. But, you know, the graphical user interface of the app, the step by step steps are still in English. And those are the tools that are utilized as part of the study if that will be adequate in terms of translation that you don't need to also translate your

graphical user interface in order to obtain that over the counter...

Dr. Timothy Stenzel: Into Spanish yes.

(Liba Sayed): Yes.

Dr. Timothy Stenzel: Yes and bare minimum we want to see things in English for the US population but to the extent you want to include language for other speakers within the US and population then we salute that. But we want to see at a minimum of performance with English language in the instructions and in the app. And it's up to you whether you want to go beyond that.

(Liba Sayed): Okay and then I do have others but I'm going to refrain from hogging the mic. I'll turn it over. Thank you so much.

Coordinator: Our next question comes from (Kodamuti Venkat). Your line is open.

(Kodamuti Venkat): Good afternoon. Can you hear me?

Dr. Timothy Stenzel: Yes.

(Kodamuti Venkat): Thank you for taking the question. My question is you have so many priority EUA things have come for serology, you know, they're semi-quantitative and quantitative tests have come. My question is you have so many pending qualitative serology tests so is there any timeline when the backlogs will be cleared? Are you getting so many additional support so that these pending qualitative serology tests can be looked into and then the decision will be given?

Dr. Timothy Stenzel: We're always looking at adding staff and we are hiring and we are looking

at ways to reduce the time it takes for us to evaluate. And we do appreciate those developers who work closely with us, you know, and as is our desire to see NCI testing to work with us if that's what we ask.

And you know and we are working really, really hard. And that's why we're so appreciative of the opportunity to have the notification pathway so that developers once notified can sell a market distribute their testing to US. So but getting to that EUA decision is also very important.

(Kodamuti Venkat): Actually we have submitted our test to NCI two months ago. We haven't heard anything from them yet. I think they are busy. And also main issue with us is it is in the notification list but many labs they insist it has to be an approved authorized test for them to procure. So they are interested. There is their independent validation but still, they are insisting on a EUA authorization for them to procure. So is there any way you can help?

Dr. Timothy Stenzel: Okay. So we would ask that that NCI is working very very hard. They do have a number of tests to test and they are working very hard and as fast as I think they can. And so you should have a contact at the FDA who can at least on a weekly basis who can give you an update on the status of things and have you direct your questions to that to that contact. And again there's a notified pathway. We understand what you're saying. It's - we're doing the very best we can here.

(Kodamuti Venkat): Thank you.

Dr. Timothy Stenzel: Next question.

Coordinator: Our final question comes from (Steve Skaggs). Your line is open.

(Steve Skaggs): Hi. Thank you for taking my call. I just have a question about the fact sheet that is supposed to accompany the kits. Is there a template available? I haven't seen anything. Or is it just general information from the IFU that we put together for a more layman explanation of how to use the kit?

Dr. Timothy Stenzel: Yes. So we don't typically ask developers to weigh in on those fact sheets. They're pretty standard given a specific technology. They have gone - undergone some revision over time to be more helpful. But that's something that the FDA drafts and provides during the process and then posts with each authorization.

(Steve Skagg): Great. Thank you for your help. I appreciate that.

((Crosstalk))

Dr. Timothy Stenzel: You're welcome. You too.

Coordinator: Now I'll now turn the call over to Irene Aihie for closing remarks.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Tuesday, August 11. If you have additional questions about today's presentation please email cdrh-eua-template@fda.hhs.gov.

As always we appreciate your feedback. Following the conclusion of today's presentation please complete a short 13 question survey about your FDA CDRH Virtual Town Hall experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. Again thank you for participating. This concludes today's

discussion.

Coordinator: Thank you for your participation in today's conference. You may now disconnect.

END