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 participant lines are in a listen-only mode. After today's presentation, you will have the opportunity to ask questions and you may do so over the phone, by pressing star then 1 at that time. Today's conference call is being recorded. If you have any objections to this, please disconnect. And now, I would like to turn the call over to your host for today, Ms. Irene Aihie. Ms. 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 9th 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, Sara Brenner, Associate Director for Medical Affairs; and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, all in CDRH, will provide a brief update. Following opening remarks, we will open the line for your questions related to today's discussion. Now I give you Timothy.

Timothy Stenzel: Welcome back to our virtual town hall meeting today. We will continue these calls through June and you will receive information about that in the very near future. I did want to take this opportunity to correct some of my remarks that I made last week. This has to do with the notification list for any notified (tests), but especially about the serology tests. So enforcement discretion and policies in our guidance do not make notified tests legally marketed. Enforcement discretion means that we do not intend to enforce the requirement. It does not waive the requirement.

So I perhaps should have correctly said tests on the notification list may market their device under the policy in the FDA policy for Coronavirus Disease 2019 test. So I hope that is helpful in clarifying my remarks from last week. There are several updates and then we have a number of chat questions that we didn't get to last week that I'd like to go through. First up, on the FAQ page updates, it said 29 notified serology tip developers were removed from our notification list for pathway (D).

There is a new list that's been added and it's under the question what test should no longer be distributed for COVID-19. Commercial or manufacturers listed below this question did provide notification to the FDA that they had validated and intended to distribute their serology tests for infection as set forth in section 4.D of our policy. The FDA had previously included them on the Web site notification list of commercial manufacturers distributing through all of these test kids under their pharmacy, but they have now been removed from the notification list and placed on this list.

As noted in the guidance, if the EUA request is not submitted by a commercial manufacturer of serology tests within a reasonable period of time or if significant problems are identified with such a test that cannot be - had not been addressed in a timely manner, FDA intends to remove the manufacturer and test

from the notifications list. Some commercial manufacturers have voluntarily withdrawn their tests from notification and such tests are noted by an asterisk on this list.

All right. With that, I wanted to move into a couple of other brief FAQ updates. One is we added a new extraction option and that is the Beckman Extraction Reagent. Also, we've provided a notice on the RADx program. There is significant funding for developers of a rapid antigen, as well as molecular diagnostic tests. This applies to all developers and to just a new start-up developer. So even established companies who want to develop on the line that are noted in the (RADx) notification, we do want to make that widely available to all developers.

And with that, I will move onto the chat questions that we didn't get to last week. There was a question about are there any current saliva test applications under review? And is there any expectation that new saliva tests will be offered? Unfortunately, I cannot share any information on submissions under review. We can however, share that on May 21st we authorized the second test home specimencollection and this can be found on the EUA authorization Web page.

Can we develop a rapid detection assay use another rapid assay as a comparator method to demonstrate equivalence? At this time we are recommending that the developers use a high sensitivity molecular assay as a comparator. This is noted on a rapid antigen template on our Web site, as a recommendation.

So is there any role for point of care tests in asymptomatic pre-surgical patients? We are open to receiving data that we provide education on appropriateness for a test that can be promoted for this type of application. We have noted very clearly on our FAQ page that with an order for a test labs are

allowed to perform tests that EUA authorized tests for asymptomatic patients.

Another question is are the (NCI) panel samples available for manufacturers or developers to test their platforms? And at the moment, the testing is being performed at (NCI), but we are looking into how would you make the panel available for developers at their sites. For home collection kits, new questions, does the kit need to receive an EUA approval prior to using the kit or can an EUA be submitted and the kits used in parallel with EUA in the field? The notification policies in the guidance that permit clinical use prior to receiving EUA do not apply to that home collection kit, which must be authorized prior to use.

Next question - how long does it take to validate a lateral flow serology test? It depends on the data; validation is datadependent and not time dependent. Next question. With so many serology tests that we're required to submit now for EUA approval you can expect some notifications of these tests that start to be published on the FDA? EUAs will be posted once granted, which will happen as soon as possible. And so stay tuned and keep an eye on it.

What approval steps are necessary to begin selling nasal pharyngeal swabs? NP swabs are class 1 exempt and manufacturers should be aware of other requirements for class 1 exempt devices, such as adverse events reporting. For those manufacturers who have unconventional or alternative manufacturing needs, we encourage you to collaborate and validate your NP swabs through engagement with the NIH 3D Print exchange.

Next question. What's the position from FDA on use of current EUA (PCR) based test in asymptomatic and pre-symptomatic patients or for use to screen patients undergoing elective procedures? I did address this question earlier and as long as their healthcare professional is ordering the test and no plans are

being made for asymptomatic testing the FDA asks that a manufacturer using the EUA authorized test can go ahead and test those samples and report out those results. Let's see.

There's a question about when an EUA designation may end and when to move into the 510(k) pathway. And so the emergency declarations for public health are made by the secretary and are unlikely to be terminated any time soon. We always do encourage developers to work towards a routine application. In the first case, this will be a de novo and then the second case will follow that. So we encourage these applications as soon as developers are ready and we're willing to work with them right now to convert these over to routine applications and routine authorizations.

We do have considerable discretion. Once tests begin to be authorized under this pathway to keep other EUA tests on the market, we look for the importance of those tests remaining on the market. And we do not foresee that need from going away anytime soon. Can the FDA address requirements for pooling samples from EUA? Have any EUAs been granted for approval samples? So we have not authorized EUA's approved samples. We know that there's a lot of interest in this as both reagents may be sometimes limited. And also as we ramp up testing as part of the get back to work and get back to school program.

And so we are very open to pooling approaches. We would invite you to come in to discuss validation of these with us by emailing us at the template email address. One of the - a couple of the real critical functions here or - for consideration is what is the impact on detection on even low positive samples and what is the impact on the limited detection when you perform pooled testing?

So we do have thoughts that we can readily share with developers. Please reach

out. And we will be looking for opportunities to update our Web site with some information as soon as possible. Here's another question. Wasn't the FDA required to provide approval within 45 days of submission? Somebody has been waiting a while since studies have shown success. Why is there such a delay when other companies get authorized?

We cannot comment on specific submissions. We encourage the sponsor of this submission to reach out to a lead reviewer if they have any concerns. We do make it a priority to review applications that require EUA authorization prior to marketing or prior to offering that kit or that service. And so as long as somebody can offer something through one of the notified lists, that allows us to focus our resources on those that clearly require our EUA authorization.

I think that pretty much addresses the questions from last week that we didn't get to. So we can open it up for Q&A now. Thank you.

Coordinator: Thank you. If you would like to ask a question over the phone at this time, please unmute your phone and press star 1. You will be prompted to record your name and your name is needed to introduce your question. If at any time your question has been answered while waiting in the queue, you can remove your request by pressing star 2. Once again, that is star 1 for questions over the phone. And we do have our first question over the phone, from (Mark). Your line is open.

(Mark): Thank you. (ZOG) by (EYT) they were on the regulatory status submission pending a few weeks ago. Now if it's not in there now does that mean they're still pending or not pending? Where do they stand right now?

Timothy Stenzel: So are you talking about a test that was on a notified list and is no longer on that notified list?

(Mark): Correct. It was submission pending two weeks ago and now it's not. But it's still on your list.

Timothy Stenzel: Can you check the new list for tests that can no longer be marketed and do you have a name for that?

(Mark): It was (ZOG) by (EYT). Yes.

Woman: Can you clarify which list you're looking at because we don't have a list that says pending submission. So I want to make sure that we know which list you're referring to.

(Mark): It's off the (360BX) dot com, the Coronavirus testing tracker.

Woman: Okay. That's not maintained by us and I think that is based on - probably based on self-reporting by the companies. The only lists that we maintain are on our Web site.

(Mark): Okay. Well, thank you.

Woman: Sure.

Coordinator: Thank you. The next question comes from (Ventak). Your line is open.

(Ventak): Hi. Good afternoon. Thanks for taking my question and thanks for all of the information that you have been giving. It's very useful. My question again is do we have a timeline when we can get the panel of samples that will be available for serology (update) developers? Because you have over 190 tests that are there and they - all of them are submitted to your (NCA) interagency panel.

It is going to be really pushing so much pressure on - again in our resources on the particular team. Is it not really required to send the panel so that the developers can perform the test and give you the results for comparison? The test panel is really, really an essential thing. Can you please expedite and provide the panels to the developers? Thank you.

Timothy Stenzel: Okay. Yes, we're doing our best. So we'll continue to work hard and try to make that available. In the meantime, if a developer has notified us and has submitted an EUA, they can continue to offer that kit.

(Ventak): Thank you.

Coordinator: Thank you. The next question comes from (Daniel). Your line is open.

(Daniel): Hello? Hello? Can you hear me?

Timothy Stenzel: Hi, (Daniel). Yes.

(Daniel): Hey. How is it going? So I'm calling in regards to A2 viral science. So it's a serology test. So at first we have the EUA pending just like the other guy said. My question is where - our percentage for the (ZOG) test is about 93% how do you say, like the - what is the rating? When you take the test it's 93% positive, the serology test.

Timothy Stenzel: Okay.

(Daniel): So what is the - how do you guys go about that? What are you guys looking for in the ratings?

Timothy Stenzel: I'm not exactly sure what you mean by ratings. But our expectation on performance, and you're talking about a serology test?

(Daniel): Yes.

Timothy Stenzel: So our expectations are that overall combined sensitivity of 90% is achieved or a positive percent agreement. And that for specificity or negative percent agreement that overall specificity is 95%. And then if there are reported out for isotypes for IGG we expect 90% sensitivity and for (IDM) we expect 70%. So...

(Daniel): Okay. So for the IGG and both IGM is 92% and 93%? So just going back to what you said a little bit earlier that if we had any information that could expedite, you know, you guys looking into a specific test, I would encourage you to please look at A2 bio science because we have a really good test study for it.

Timothy Stenzel: Okay. So our team of experts is working very hard. There are a lot of tests submitted and because of our guidance and the application list. And the requirements in that as far as submitting an EUA package. We do take quick looks at those packages. If there are any potential risks to - from the tests that may still be on the market, we will be addressing those with the developers as quickly as possible.

Otherwise, our reviewers are working hard and working through all of those. And as I said, as long as you're set up and met our conditions of the guidance including submission of the EUA package, you can continue to offer on that for you.

(Daniel): Okay. Then I also have one more question. The company is also working with Cedars-Sinai to - on a product named (Serolite). That's for (UAV) entry through

a catheter. Any updates on that? Any - have you guys looked at it or is that...

Timothy Stenzel: So I would urge you to contact us offline with your very specific question. And to address your question to one of our emails, , you can address that to our template email address. So any sort of specific - that kind of specific question we'll take offline. I'll just - when appropriate, I can talk generally about what our expectations are and what our processes are now for - leading to EUA authorization or another certain decision.

(Daniel): Thank you. Once again that's A2 bio science.

Coordinator: Thank you. The next question comes from (Vash Ladani). Your line is open.

(Vash Ladani): Hi Timothy. This is (Vash). Thank you so much, for taking my question and everything you and everyone at the agency is doing. My question is in regards to a model test that the company I work for are developing. And it's (unintelligible). We're wondering if, for development and validation we could use (then) blood samples from early 2019 for either negative control or cross-reactivity. Would that be an appropriate approach?

Timothy Stenzel: Yes. Potentially. We want to make those as streamlined and efficient as possible. However, I would really - we would really need to know the specifics of your technology - what markers you're looking at; what the purpose of it is; whether it's qualitative or quantitative. So what the stability of a bad sample is. So I would urge you rather than getting into specific details here, to reach out to our template address. If you haven't - if there isn't a timely response and timely means within 48 hours of sending that email, go ahead and ask them to connect you up with me.

But the team is working very hard. We're getting thousands and thousands of

emails and they're trying to do their best to address all questions in a timely manner.

(Vash Ladani): Understood. Thank you so much. I appreciate it. This helped very much.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question is from (Sai Maje). Your line is open.

(Sai Maje): Thanks again and thank you to all of the organizers for these town halls. I work at National Travel Health Institute and I was just wondering if there's any effort to expand access for - or availability and testing this platform for children and pregnant women?

Timothy Stenzel: So what kind of testing are you looking to expand into?

(Sai Maje): So both antigen as well as iron testing, specifically focusing on developmentally disordered children and children with intellectually disabilities. Both availability as well as commercial testing platform approval technically.

Timothy Stenzel: Right. So I don't know of any limitations in any of our assays with regards to patient age or demographic or other COVID related condition. So can you tell me a little bit more about essential access issues that you're experiencing so that we perhaps can better address your concern?

(Sai Maje): They haven't heard specifically about access issues, but this goes out for summer and potential reopening plans in discussion. I've been attending town halls and have not heard any questions in this regard. So I was wondering if there were any. That's why I called in.

Timothy Stenzel: Yes. I mean get back to work and get back to school as potential efforts by their very nature, involve testing of a lot of people and of asymptomatic people, potentially what those entities employers and/or schools and other organizations decide to employ. As long as they're currently EUA authorized tests, as long as there's a healthcare provider order for such a test and is being monitored under their care, then that can apply broadly to institutions. I would just direct, you know, folks to their individual state's laws, rules and regulations to make sure they're complying with those.

But as long as an EUA authorized test is ordered by healthcare provider, the lab can definitely accept in our thoughts, these samples and tests and have those results. I mentioned earlier, pooling schemes are two things that in order to test the volume is needed. In some situations perhaps that pooling is a strategy. So you're really combining pooling testing and asymptomatic testing which we don't really have good understanding yet of what the asymptomatic carrier rate is and whether or not the virus is expressed at the same levels as in those with symptoms.

And then we also expressed that for pooling we'd really like to chat with developers who use pooling to ensure that the performance is still going to be accurate in those situations. So this certainly is something on our minds and that we're having conversations about. So don't need to inquire if it's not important. I'm glad you brought this up. Hopefully, that addressed some of your questions.

(Sai Maje): Absolutely. Thank you so much.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. Before I introduce the next question, please as a reminder, please

only ask one question and then you may queue up for another question if you wish. The next question is from (Mitch Andria). Your line is open.

(Mitch Andria): Hi there. Thanks for taking my call. Just to be clear, on the FDA.gov site what test should no longer be distributed, you went over that there's a list of 29 manufacturers, correct, that are on that list?

Timothy Stenzel: Currently. Yes.

(Mitch Andria): Okay. So my direct question is this, and again I'm going to bring up the company's log, if they are not on this list then that's a positive thing meaning they can continue to distribute their test kits. Is that correct?

Timothy Stenzel: So any company that's on this, you know, no longer to be distributed list, should not be distributing.

(Mitch Andria): Right. But if they're not on the list then they can continue to distribute?

Toby Lowe: Are they on the notification list?

(Mitch Andria): No. They are not on the list.

Toby Lowe: So they're...

(Mitch Andria): I'm sorry.

Toby Lowe: ...list and that's where the manufacturers have notified us that they have validated their test and they're offering it under the policy outlined in Section 4.D of this item.

(Mitch Andria): Okay.

Toby Lowe: And tests that are listed on that list may be offered under those policies. If they were previously on that list and have now been moved to the new no longer to be distributed list, then they should not be distributed.

Mitch Andria: Okay. So if they're not on the do not disturb list, they still have to be on the original list -- which I'm sure they are. So that puts them in good standing. And that would also mean that they're still under pending submission for EAU.

Toby Lowe: So if they're on the notification list, then they may distribute under that policy. I don't, I'm not sure what you're referring to.

Mitch: ZOG Z-O-G. Are you allowed to comment on the list?

Toby Lowe: Yes. I mean it's a public list. I have it up right now. I did not see them on the list.

Mitch: Of which one?

((Crosstalk))

Mitch: On the notification list. They're not on actually either of the lists.

Toby Lowe: Correct.

Mitch: So however sometimes names are a little bit different and we do our best to get the names correct. So it could be listed under another name.

Toby Lowe: Yes.

Mitch: Orient, how about orient gene like oriental orient gene?

Toby Lowe: I don't see them at first glance. I think if you want to email us at the EUA mailbox if you have questions about whether a certain test is listed or what name that might be listed under, we would be able to help you through there.

((Crosstalk))

Mitch: Okay.

Tim Stenzel: You can also contact the developer and ask them if they are on the list and have them show you whether they're on the list. So there's two lists that we're allowing serology kit developers to offer their tech. They're either on the EUA authorized list or they're on the notification list. And we have one list where if they're on that list they should no longer be distributed. If they're not on the notified list, and they're not on the EUA authorized list they should not be distributed either.

Mitch: Okay. I appreciate all your time. Thank you.

Tim Stenzel: Yes.

Coordinator: Thank you. The next question comes from (Shawn Nevas). Your line is open.

(Shawn Nevas): Thank you Dr. (Timothy) and the team there. I'm sure you know, you guys are overworked and under-resourced just like everybody else. And we really appreciate it. I have a question on virus transport media. We have developed one and we want to commercialize it. But I want to know if it is not for home collection, are we still required to get an EUA authorization?

Tim Stenzel: So (Toby) is that a question addressed on the FAQs? If not I can address it.

Toby Lowe: Sorry, what was the specific situation?

(Shawn Nevas): The specific situation - go ahead, sorry.

((Crosstalk))

Tim Stenzel: I was going to say the developer of a VTM -- and I don't know if it's on our FAQ about what VTM manufacturers are required or recommended to do if they want to...

Toby Lowe: No. That is not on the FAQ. If you can send us an email to the EUA mailbox then we can get some more information to you that way.

(Shawn Nevas): Thank you.

Tim Stenzel: Yes, just email us a template. We do have advice that we can give to developers such as you. And we are looking at different ways that we can make information more publicly available. Thank you.

(Shawn Nevas): Okay. Thank you so much. Another question, if I may ask only one more question for saliva samples and protecting symptomatic and asymptomatic or pre-symptomatic people, what are your views on comparison of saliva sample collection to these (unintelligible) -- saliva being an easier way of collecting samples.

Tim Stenzel: Yes. I'm going to refer you to our template for molecular and/or direct antigens. We have updated the template with recommendations for saliva validation. If you're a manufacturer...

(Shawn Nevas): Yes.

Tim Stenzel: ...you can notify us of an update, submit your validation and then be on the market while we review your submission. If you're a lab, you're not required to submit a EUA or saliva. Both of these are in circumstances where saliva is collected by a healthcare worker. If you're a lab, we have recommendations for saliva validation on our template. You can follow that. You're not required to submit an EUA.

If you want to offer this for home collection...

(Shawn Nevas): Yes.

Tim Stenzel: ... we do require an EUA authorization prior to offering that whether you are a lab or whether you are a kit manufacturer.

(Shawn Nevas): Okay. So if it is for home collection and you know, an EUA is needed, do we have to be connected if we only have the saliva collection part of it. Do we have to be connected to a lab that does the processing and have the whole line of custody work out before we submit for an EUA authorization? I was looking at (Everlywell) as an example.

Tim Stenzel: Yes. They're a great example.

(Shawn Nevas): Yes.

Tim Stenzel: So we do only authorize when an EUA authorized test is also authorized for use for that collection kit. And then each new assay will require a validation study to be added for that collection kit to be added to their authorization. So at a

minimum, developers of home collection kits do need to link up with at least one assay that's already EUA authorized or can be EUA authorized in parallel. And then we can give an EUA authorization to a home collection kit in concert with a specific assay.

(Shawn Nevas): Yes.

Tim Stenzel: And then we will list, you know, what EUA tests are allowed to use that collection kit...

((Crosstalk))

(Shawn Nevas): Got it. Thank you so much.

Tim Stenzel: Thank you. Great question.

(Shawn Nevas): Thank you so much.

Tim Stenzel: Yes. Next question.

Coordinator: Thank you. The next question is from (Shaling Fan). Your line is open.

(Shaling Fan): Hi. My name is (Shaling). I'm a clinical lab director. Our infectious disease physicians have been pushing the lab to record the (CT) value of the PCR test. They claim it can help them to make clinical decisions. And I reject their request because this is not the standard practice. And also there are many things can affect the collection and CT count. So I would like to know your views on this issue. Thanks.

Tim Stenzel: Yes. Certainly, I've heard about this from others. So I think the context -- and

correct me if I'm wrong -- is that sometimes even when symptoms dissipate for patients, that they can stay in molecular test positive. And clinicians are trying to make decisions during these situations and are hoping that a very high CT which is a very low viral amount -- at least in that particular sample collection -- might help them determine what to do with that patient.

So I would say that you know, we still don't know very much about that. And then there are, you know, very clear challenges when collecting a respiratory specimen of any type. As to whether that sample stays equally well as the next time we sample even the same patient in some uniform way. So what can you really say about what the viral level is with one test used in this manner very unlike other viral load tests like for, you know, HIV, (COV), (HPV) and others that use a blood-based test system where obviously there's great clinical validity in those tests and those patients.

So I understand your concern. It's really challenging to think about how you might validate for that situation. So you know, I think you're an expert. You know your technology and the test that you're using at your lab. And I would certainly support you being comfortable what you do or don't do with the information you have at hand.

Is there something that you that think we could help with, with regard to this?

(Shaling Fan): So if we were going to move this forward, what type of validation do we need to do recommended by you?

Tim Stenzel: Yes. So it's challenging sometimes and we're still learning so much.

(Shaling Fan): Yes.

Tim Stenzel: And we're being asked to do things that are certainly have not been in common practice within other respiratory (sample types). So it's a bit of a challenge. And it almost does need some good data to tell us what it really might mean. Probably a conversation that will not go away -- that will be persistent because of the need to try to figure out what to do with some patients.

So I would urge you to reach out to us at our template email address and do ask for me (Sabim Ball) and let's get on the phone and let's chat a little bit more than we can right now okay?

(Shaling Fan): All right. Thank you so much.

Tim Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Liz Friend). Your line is open.

Tim Stenzel: Hi, (Liz). You may be on mute.

(Liz Friend): Can you hear me?

Tim Stenzel: Now I can hear you.

(Liz Friend): Okay. I (unintelligible). I'm from base 10 genetics. I just have sort of a suggestion. You made a great distinction between the notifications and the (E-ray) the authorizations -- the difference between the two. And in general, one precedes the other.

So I wonder if the FDA might consider helping to in some way educate the public about that distinction because many of us would love to begin distributing tests for which we notify. But the general public -- or at least large

organizations -- are hesitant without that actual authorization.

So I understand that you set it up in a two-step process. But is there any way that the FDA can improve the public education on we're still compliant even prior to issuance of the actual authorization and what your thoughts are on that.

Tim Stenzel: So first thing is we do make these lists public on our website.

(Liz Friend): Yes.

Tim Stenzel: And that can be offered up as evidence. We do have some explanation on the website as well as to what it means. And then prior to you being placed on a notification list all developers receive confirmation from us.

(Liz Friend): Yes.

Tim Stenzel: And that is also a document that can be used.

(Liz Friend): Yes.

Tim Stenzel: I will turn it over to (Toby). If she has any additional thoughts for this discussion.

Toby Lowe: Yes. I think it's also important to be clear that any of these tests that are being offered under the notification policy default to high complexity.

(Liz Friend): Sure.

Toby Lowe: So I think, you know, most you know, general population individuals don't always know what test they're getting when they, you know, they know that

they're getting a lab test but they don't necessarily, you know, pick a specific test from a specific lab. They're going to their health care provider and they're ordering the test for them.

But I think you know, we've done a fair amount of communication within the healthcare community I need policies. And we do also have some information available on our website for more of the general public. But the...

((Crosstalk))

(Liz Friend): We're looking - okay, we're looking to deal with employers -- helping employers. And serology testing is only one element of the program. So we're not using it in...

Toby Lowe: Right.

(Liz Friend): ... Isolation in any way. But it's large-scale employers you know -- those who have 10,000 plus employees -- and are looking to create, so. And we're a physician-owned company. So we've got a lot of medical backing behind us and all of that. But everybody is worried about if the FDA doesn't authorize it, you know, we can't use it yet.

So you know what? I use all the tools in describing and I really appreciate it and I understand how hard you guys are working. I'm just, you know, specifically for large employers or people looking to incorporate some sort of testing program, you know, just to make that distinction, notification is still compliant, you know. There's a difference between authorization and compliance, that notification is compliant. There's nothing legal about it or as long as they're listed on the list. I just...

((Crosstalk))

Tim Stenzel: Yes.

(Liz Friend): ...a simple (unintelligible). Most of the employers...

Tim Stenzel: Yes.

(Liz Friend): ...dealt with are, we get one paragraph. Anything beyond one paragraph their eyes are rolling in the back of their heads and they're not listening.

((Crosstalk))

Tim Stenzel: So certainly we hear your concern. So a couple thoughts -- yes, we're working very hard to authorize as many as fast as possible as we can. One thing to pay attention to when looking at technology is if you need a point of care application or a moderately complex application, make sure the developer that you've been in contact with has submitted those studies to the agency...

(Liz Friend): Yes.

Tim Stenzel: ... before review. If they haven't done that, then they may get authorized but they may be limited to high or at most moderately complex (unintelligible).

(Liz Friend): We're partnering with a high complexity CLIA lab so.

Tim Stenzel: Okay. That's another option to get that available as soon as possible.

(Liz Friend): Yes.

((Crosstalk))

(Liz Friend): I was just offering a suggestion. Thank you very much.

Tim Stenzel: Yes. We're working hard. Thank you.

Coordinator: Thank you. The next question comes from (Catherine Copley). Your line is open.

(Catherine Copley): Hello. I'm looking to do a finger stick study so that we can use this at point of care facilities. And if we have a clinical validation that's already been done with serums, do we still need to validate the finger stick study with (PCR)?

((Crosstalk))

Tim Stenzel: So if you want point of care, is that what you said?

(Catherine Copley): Yes.

Tim Stenzel: So serum it's not something that's point-of-care. It's either whole blood through a venipuncture or whole blood through a finger stick. So those sample types do require validation and authorization along with some other point of care studies. Let's see. I believe in our serology template -- and (Toby) correct me but -- I believe we do offer up recommendations for those various applications.

(Catherine Copley): Okay.

Tim Stenzel: If you want to use any sort of alternate validation, we do encourage you to reach out to the template address where we can find out more details about your technology and what options you want to consider for alternate validation.

(Catherine Copley): Okay. I was just wondering if since we already validated using a serum for the serology test and we want to move to finger stick if we could use that. (Unintelligible) haven't used the (PTR) test.

Tim Stenzel: Use the serum as the comparator?

(Catherine Copley): Yes.

Tim Stenzel: I would have to defer to our experts. I'm not going to say no it wouldn't be okay. I just would - I'd have to go back to the details of the templates. It should hopefully have some clarity around that. But that's certainly an option that we would entertain. So if that's not clearly stated in the templates, just send us an email to the template email address asking us specific questions.

(Catherine Copley): Okay, thank you.

Tim Stenzel: Yes.

Coordinator: Thank you. The next question is from (Avanti Savage). Your line is open.

(Avanti Savage): Hello. Hi. Thank you for taking my question. And I really appreciate the FDA answering our questions. So I wanted to know, get some guidance on the validation for test collection. And I know that FDA Mentioned in one of the previous town halls that there is be a home collection template and there's something in the works. So could you please give us an update on that or if there is any other requirement or specific guidance for test collection. Thank you.

Man: So health collection versus home collection are potentially two different things.

So self collection as our nasal, saliva, and in the presence of a healthcare provider is something that for lab-developed tests can be...

(Avanti Savage): Yes.

Tim Stenzel: ...done already. For home collection, I forgot your question original question. Sorry.

(Avanti Savage): Sorry.

Tim Stenzel: Yes.

(Avanti Savage): It was just about a home collection template. Is there...

((Crosstalk))

(Avanti Savage): ...specific.

Tim Stenzel: Yes. Home collection, yes. So yes we understand there's huge interest in home collection. And first of all, sending an email to the template email address today we can get you our thoughts. But we know that there is a desire for this to be made more public. And we're working very hard to make that happen as soon as possible.

(Avanti Savage): Okay. Thank you.

Tim Stenzel: Yes.

Coordinator: Thank you. The next question comes from (Alex Vacilli). Your line is open.

(Alex Vacilli): Hi. Thank you for taking my call. And before I ask you in a Newsweek see a lot of counties, buy these rapid test kits. And they kind of sit on the shelves because they're waiting for approval. So there's a number of tests with a (CE) mark. Can you clarify if, you know, you recommend using tests with a CE mark until you can get the full EUA authorization?

Tim Stenzel: Yes, we wouldn't make that statement. It's my understanding that the CE mark for this kind of test is a self-certification and not by an agency or a notified body or other third-party. So you know, it's not something that for (CE) mark for the contest would be reviewed prior to making those kits commercially available. So you know, our FDA would not.

However, I will say that where there is a review -- a country of origin review -- any other countries that do review these and make horrible decisions we do incorporate those decisions into our review thinking for a given test what it has achieved so.

(Alex Vacilli): Okay.

Tim Stenzel: That's about as satisfying an answer as you could wish for. That's how we handle CE marking.

(Alex Vacilli): Okay. One more quick question.

((Crosstalk))

Toby Lowe: Also important to note that, you know, those tests if they've completed their validation can notify, and then they can offer under the notification policy while their EUA is under review.

(Alex Vacilli): Okay.

Tim Stenzel: That is correct. But I think I heard that from folks who may be purchasing kits out there are waiting for EUA authorization. And again, we're working very hard to make those decisions and make those decisions public.

Coordinator: And our last question for today is from (Jackie Chan). Your line is open.

Jackie Chan Hello and thank you (unintelligible) last question. Thank you. My question is that I notice in all the EUA there is a waiver cost that we've all manufacturer of this (GMP) requirement and the quality system requirements. I'm just wondering why is FDA doing that. Wouldn't it be a risk to waive that requirement?

Tim Stenzel: So under the emergency declaration situation, in order to make as many tests and other devices available, we do make efficient use. We do not waive all requirements. And (Toby) can fill in the details. But we still do require some important elements such as complaint handling and (MDR) reporting that we believe is an important safety element to keep. And there are other provisions that we have or will have made requirements for that are above what we usually consider in an emergency situation.

But practically speaking, if we didn't allow some flexibility when it comes to those regulations and compliance with those regulations, we wouldn't be able to address some of the significant needs in an emergency such as this. (Toby) do you have anything else to add?

Toby Lowe: Yes, that's correct. It's part of the benefit-risk evaluation under the emergency. And as (Tim) said we are not waiving all requirements. We do consider which requirements may be appropriate to waive in this particular setting.

Jackie Chan Okay. Thank you. Thank you again for everything, everyone at your agency does. Thank you.

Tim Stenzel: You're welcome. Thank you.

Coordinator: Now I will turn the call back over to Irene Aihie. Ms. Aihie, please go ahead.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn web page at www.fda.gov/training/cdrhlearn by Tuesday, June 2. 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 the 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 discussion. Again, thank you for participating. This concludes today's discussion.

Coordinator: Thank you. All participants you may disconnect at this time. Speakers, please stand by.

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