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

**Moderator: Irene Aihie
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12:15 pm ET**

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the Q&A session if you'd like to ask a question you may press Star 1 on your phone. Today's call is being recorded if there are any objections, please disconnect at this time. And I like to turn the meeting over to Ms. 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 16th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for the 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 line for your questions related to

today's discussion. Please remember that we are not able to respond to questions about specific submission that might be under review. Now I give you Timothy.

Dr. Timothy Stenzel: Welcome to our call today. We look forward to having great and productive dialogue with each caller. I would just ask that we, you know, continue along those veins and will all be great. You know, and otherwise we'll have to move to the next caller. And with that I will turn it over to Toby.

Toby Lowe: Thanks Tim. Thanks everyone for joining us this afternoon. I have a few updates to share. We've had some recent inquiries so I want to share that we are welcoming certain immediate requests for collection devices that would otherwise need a 510(k) such as saliva collection devices. If you're interested in this please approach us through the templates email address and we can discuss if your device may be appropriate for that approach.

We see this approach as being helpful to developers that want to use these devices and eliminate some of the validations that might otherwise be required for each individual assay. And we're also looking at other ways to ease the path to market for other devices during the emergency.

So for collection device manufacturers who are interested in pursuing this we suggest that you take a look at the EUA template for home collection. It may not be a perfect fit but that template does include a lot of information that we would want to see for standalone collection devices such as stability and usability data. So as we continue to work through this, we'll continue to provide additional information regarding the process.

And then moving on to some updates from last week and earlier this week we have updated FAQs and templates. So late last week we added an FAQ to

clarify the difference between surveillance, screening and diagnostic testing for COVID-19. We previewed that a little bit in the discussion last week on this call. And that last week and again earlier this week we provided updates to the molecular EUA template.

So the first update late last week was to add information about multi-analyte respiratory panels under EUA. As we approach flu season, we're encouraging developers to consider tests that will include SARS CoV-2 along with influenza and potentially other respiratory pathogens. And then the second update earlier this week was to include more detailed recommendations on validations for pooling.

We're encouraging commercial test kit manufacturers to submit EUA amendments to authorize pooling of your assays so that labs can implement this approach. That will be much more streamlined than that each lab having to perform their own validation and submit their own EUA to add pooling.

And then a few other updates, last week we also authorized CDC's combination SARS COV-2 and influenza multiplex test. So that's the third EUA that we've issued for a combination test like this. (Biofire) and Qiagen both previously added SARS COV-2 to their previously cleared respiratory panel.

And last week we also issued an EUA for the second COVID-19 antigen test. That was to Becton Dickinson BD for their BD (Veritor) system for rapid detection of SARS COV-2. And then on Monday this week we issued a letter to clinical laboratory staff and healthcare providers about false positive results with one of the authorized BD molecular tests.

And Tim mentioned that issue on last week's town hall as well so that letter can be found on our Web site as well. And that's all I have as an intro so we can turn

it over to questions.

Coordinator: The phone lines are now open for questions. If you'd like to ask a question over the phone please press Star 1 and record your name. Also please limit yourself to one question. If you'd like to withdraw your question press Star 2. Thank you. First question in the queue is from (Lily Wong). Your line is now open.

(Lily Wong): Thank you very much for taking my question and everything you and everyone at the agency is doing. My name is (Lily Wong) and I am from Boston University. A number of universities across the country are planning for the coming academic year and need to factor in testing.

At Boston University we plan to perform high throughput SARS COVID 2 PCR testing, about 5000 plus tests per day for our students, faculty staff and other members of our community as part of our fall 2020 return to campus plan.

As a testing lab we developed a PCR test for use in our high complexity CLIA lab for that purpose. We submitted a pre-EUA for our PCR test on June 19. It's been two weeks and we have not yet been assigned to a reviewer so it is our understanding that FDA is prioritizing high throughput tests.

Our students, faculty and staff will start to return at the beginning of August so we're on a pretty tight timeline. My question is this - our students' health and occupational health providers plan to issue standing physician orders to test members of our community as part of our screening program. Since our testing will be done under the physician orders does our test still need to have a claim for testing of asymptomatic? Thank you.

Dr. Timothy Stenzel: Well okay did you say you had an EUA or a pre-EUA?

(Lily Wong): We submitted a pre-EUA on June 19.

Dr. Timothy Stenzel: Okay. So it was a question about what the testing plans should be. Is that the what the question - or was there full data in the application?

(Lily Wong): No we had…

Dr. Timothy Stenzel: Validation.

(Lily Wong): …did not include score data in the pre-EUA. We were hoping to have a discussion with our assigned reviewer but we have not yet been assigned.

Dr. Timothy Stenzel: Yes so we are for - in the two week is for applications that have data that we're making those assignments for. But this is an important project so I would be curious and be happy to be involved and get on a call to verify any concerns you might have.

We have provided a lot of templates and the most recent templates on Monday have to do with pooling and since you may be looking at pooling if you do 5000 tests per day. And we hope that those details and the template on Monday really help folks out like you.

To answer your question on the standing order all authorizations are at the moment still prescription only, standing orders by physicians can be made. And yes that physician or that clinician can make that order can say that they would like asymptomatic individuals to be tested. And then the lab it comes to we're asking that they go ahead and test those samples and report out those results.

And as long as the lab isn't making the claim that they have a certain performance on asymptomatic patients then that's all good. If a lab wants a

specific claim then we'll work with them. and our templates have the recommended validation for a lab or a kit manufacturer that wants to make a claim for an asymptomatic claim for their test. So the short answer is on them - answer your questions are standing orders were fine and yes then they can order that asymptomatic testing.

And then our pathways, you may not know this, but it allows labs like yourself to validate their tests notifying us and then they have - and then you have - 15 business days to submit their EUA occupation. And all the while they start testing and continue testing while we review the application. And this also includes pooling. Pooling falls within that guidance of saying it's validated pooling and then make the data 15 business days later.

You may have some questions that may not be addressed by our templates already and that's why I'm willing to get on a call with you to go into more detail about that and likely the most efficient way. And so if you send an email to the template email address and say that I said you know, I'd like to get on a call with you they'll connect with us okay?

(Lily Wong): Okay great. Thank you. Thank you very much for the clarification. And just to clarify you're saying that if the lab is not going to claim a asymptomatic - make an asymptomatic claim if we have a standing order from a physician that would test the asymptomatic population we would then not need to do - provide the - you know, do the validation testing, you know, logging 20 asymptomatic that's required by the, you know, the June 16 updated template correct?

Dr. Timothy Stenzel: That is correct and the physician understands that you haven't validated I'm sure for that indication. But if they have the order, they can order the test on anybody that falls under that sort of suspected of COVID. And that could be asymptomatic in high-risk situations which going back to school in the fall

might fall under that.

So we have no issue with that and there's a clear description in the - in our FAQs on that. Toby, do you have anything to add? I think I may have covered it pretty well but you may have something else to add?

Toby Lowe: Yes, I think you covered. You know, the key as Tim was saying is, you know, the labs cannot offer the test for a broad - for broad screening if it's not, if it has not been validated in that population but a provider can order it as they see fit.

(Lily Wong): Great. thank you very much.

Coordinator: Next question is from (Mark Heckman). Your line is now open.

(Mark Heckman): Yes good morning Tim and Toby. How are you today? I'm just following up on my question that I asked a couple weeks ago. You may have answered it last week's call. I was not on it but just wondering when the template for full at-home testing is going to be released?

We still have a lot of people out there that need to be tested quickly and right now the way that the big-box tests are going and things like that with there's logistic issues getting swabs, reagents and things like that we feel a full at-home test right now is ready to go. So I just have to hear you input on that. And if you answered it last week just say that answered it last week and I'll hang up.

Dr. Timothy Stenzel: Well it is a priority and we're very interested in home testing. And we are still working on the home testing home collection for serology but we can provide feedback to folks who contact us, same for molecular at home testing. Toby can you give any other more specific updates than I did?

Toby Lowe: No unfortunately we can't share specific timelines but we are working to get that out as quickly as possible.

(Mark Heckman): Thanks very much.

Coordinator: Next question is from (Andrew). Your line is now open.

(Andrew): Hi Tim. How are you? I had a quick question on the umbrella serology testing program which is that based on what it says online it sounds like it's really geared towards the lateral flow test and a basic ELISA kit which would probably I'm guessing be more of like reagents in a box.

We have a client who has a device which is a high throughput system for serology testing and I was wondering if a device like that would be a good candidate for the umbrella program?

Dr. Timothy Stenzel: Yes so the umbrella program - and but Toby you can correct me if I say incorrectly is designed for those tests that can go to the NCI, it's the current place where this program is being or these kits are being tested.

The any test that can easily show up there. And we test it at the NCI. So anything that requires large equipment, non-standard equipment so that's why you see primarily at the moment for lateral flow and for ELISA be easily done in that environment.

So anything else could be a little bit more of a challenge for us to do. And without that NCI testing result that we're asking everyone that falls under that do, you know, we have the alternate just regular pathway for review which, you know, just includes an EUA submission.

You can notify once you validate and follow that guidance and then you can go ahead and market a new test while we - and then you're - you'll submit that EUA package within - by two weeks of notification and we start reviewing it at that time.

(Andrew): Okay that sounds good. And then just to double check the device in question is a pretty small footprint device that can kind of go on a bench top. It's not really large equipment. Would that still be something to do as just a regular EUA with a notification?

Dr. Timothy Stenzel: So instruments can be submitted to NCI but there's - is a pathway to check on this and Toby you may know the details. I think you just send a request to the template email address they'll move you over to the NCI? We just want to make sure that the NCI's comfortable with receiving that piece of equipment and operating it there. But it certainly sounds feasible and I know Toby has some thoughts too.

Toby Lowe: Yes so I think, you know, to Tim's point about the NCI testing absolutely, you know, reach out and we can connect you with the right people to see whether your device can be tested at the - or through the NCI program.

Regarding the umbrella EUA I just want to clarify that the umbrella EUA was issued, it was intended to be - to ease an administrative burden mostly on our side of things just to remind the administrative process of getting the authorizations out.

As you'll see we haven't actually added any tests to the umbrella EUA. At this time we have issued all of the serology EUAs, as individual EUAs because they were more appropriate for the specific situation of the tests that have been authorized.

So from the developer or the test perspective you'll submit all the same information to us and then we can work with you to determine whether it is appropriate to go through the umbrella pathway or the individual pathway. But from your perspective it would be the same data that would be submitted, you know, with the exception of whether a test is appropriate or not to get the NCI testing.

(Andrew): Got it. And I think you answered this on a previous call so apologies if you already answer this. But in terms of samples, because the big kind of attraction to the umbrella is that NCI is getting all the samples ready which could potentially be hard to get for the device manufacturer. Is there any opportunity if the manufacturer wants to do the testing themselves to get the samples from NCI?

Dr. Timothy Stenzel: So I'll add that the umbrella applies to those developers who want to claim basically serum and plasma. and there. I don't know but that's an important concept because we only test on serum and plasma at NCI right now. And so that's fine with you you're if you're fine with your test being serum and plasma.

And the only testing that's done other than to let's say somethings like isotypes from validation than you can totally use that pathway through the umbrella if it's an appropriate test to be evaluated at NCI, okay?

(Andrew): Got it. Okay very helpful. Thank you so much.

Coordinator: Next question is from (Troy Ogilvy). Your line is now open.

(Troy Ogilvy): Thank you. Thanks so much to you guys. This is the second time that I have been on the call. I missed a couple weeks because I've been very busy trying to

line up the emergency use authorization to get 30 IgG and 30 IgM. Tim the lead position that we did finally working with a university in Washington DC is very anxious to maybe talk to you get some clarity on therapy and what we can do for EUA.

To bring you back to remembrance of what our company is. We have already tested and been approved through a couple blind study for lead testing using oral fluid where we collect ultra-filtrated blood plasma through our patented process. We are already, you know, with blood plasma we know we have more accuracy than any venous blood draw or any serology so therefore we're looking to just do the parallel as to how we can help with COVID.

And where we are at right now is just getting clarity on what the EUA would particularly need from us. And we would - our lead physician has requested to talk to you Tim so that he can be very clear because they test about 1000 people a day. We also have our epidemiologist out of Texas which has - can-do sampling as well.

And our tests as you know if you can't remember it can be a home test. So I don't know if that qualifies for the umbrella and other things. But our test is non-evasive, it's an oral swab and it collects ultra-filtrated blood plasma. So I want to know is there anything else that we would need because we're trying to get that collection done in the next 30 days to submit as an EUA.

And is it possible that our lead physician from the Washington DC University can speak with you to get very clear on what he would have to do for the medical assay?

Dr. Timothy Stenzel: Right. So if - what's the sample size that goes into, in your collection device or into the device itself?

(Troy Ogilvy): Yes, our collection device is the...

((Crosstalk))

(Troy Ogilvy): ...swab where we collect our - and our patented process is the gum line. We collect ultra-filtrated blood plasma. And our clinical study that was already done for our lead test which is already approved and marketed with 99.19% accuracy with 99% specificity and 96% sensitivity.

Dr. Timothy Stenzel: Okay. And so go ahead and send an email to our templates email address. And if, you know, do ask the question of them because they may be able to quickly answer it but if not, I'm happy to get involved. And you can just request…

(Troy Ogilvy): Okay.

Dr. Timothy Stenzel: …you know, if they can't answer your question to get me involved, okay?

(Troy Ogilvy): It - yes is there a way Tim that someone could email me maybe your phone number because I sent a couple of emails to that template email and it kind of gets shuffled?

Dr. Timothy Stenzel: Just asked to speak to - if you've had that experience just ask to be forwarded - email before to Dr. Stenzel okay?

(Troy Ogilvy): To Dr. - okay so Tim your last name you mean?

Dr. Timothy Stenzel: Stenzel, S-T-E-N-Z-E-L.

(Troy Ogilvy): You've got it. Thank you so much.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Next question is from Eric Konnick. Your line is now open.

Eric Konnick: Hi Tim and Toby. This is Eric Konnick from the University of Washington in Seattle. I have a question about home collection and stability testing. So in the most recent EUA template that's online the - we can use a right of reference for the quantitative data for up to two day shipping but there's a note that says if you plan to allow testing of samples that have been shipped by three to five day mail please expand the shipping study times below.

And I went to the document that's referenced in the in the template, the ISTA 70 2007 shipping standard and there they have a similar table to what you have with just a couple of the individual steps expanded. So is - are we correct in assuming that if we follow that standard that would be sufficient for an EUA application?

Dr. Timothy Stenzel: No that's more detail than I can absorb and know. You know…

Eric Konnick: So I'll give you the scheme within the home shipping and stability standard is basically to do excursions based on whether or not you think it's going to be a summer or winter temperature. And so basically for the winter profiles thinking ahead, you know, where we're going to be. You know, it's held at minus 10 degree C for eight hours a goes up to 18 degree C for four hours, minus 10 for two hours 10 degree C for 36 minus ten for six hours.

So this is described in the same document that's referenced, this ISPA standard. But in that when it says okay if you're going to go to 72 hours you don't need to

expand each one of those conditions equally. You only expand the longest one essentially to the requisite amount. I want to make sure that so again, thinking ahead, you know, we're in Washington State we do testing for, you know, like 1/4 of the country in terms of geographic area.

And so thinking to the winter where, you know, we're going to have snow delays and things like that we really do need to have, you know, up to five day shipping time if we're going to have people collect at home and send in assuming they're going to be self-quarantined that type of thing.

And so two days really isn't going to be adequate so we really do need to expand that. And so we're just trying to, you know, logistically figure out how we're going to do that and…

Dr. Timothy Stenzel: Yes, no and that's important right? And that's why we put that in there. You know, to be honest I'm not, I am not the expert in the office about these stability shipping studies which you can do by the way entirely in the lab. You don't have to actually ship.

Eric Konnick: Yes.

Dr. Timothy Stenzel: And so you have better control around it. And so you may know (Gina) in the office. I don't know if you've ever had direct contact with (Gina) but why don't I just connect - I think I have your contact information. Why don't I just connect you with her. And she is going to be the one I think is going to be able to get you the best feedback. You know, she was the lead reviewer on say the last four home collections.

Eric Konnick: Okay.

Dr. Timothy Stenzel: And so she's resident expert in home collection okay? So I will connect you up with her as soon as possible after this call okay?

Eric Konnick: Okay I'll maybe I'll just shoot you an email and that way you have everything at the top of your inbox.

Eric Konnick: That will work. Thanks.

Dr. Timothy Stenzel: All right. Thank you.

Coordinator: Next question is from (Margot Enright). Your line is now open.

(Margot Enright): Hi. This is (Margot Enright). Thank you for this forum. We're an antibody test manufacturer and I was asked this question so I thought I would direct it to you because I wasn't sure what the answer was. We know that antibody tests and PCR measures different things as they measure different stages with the disease process. If there's a discrepancy between the antibody test and a PCR test, is there a referee to resolve the discrepancy?

Dr. Timothy Stenzel: No there's - so antibodies are used in two - I'd say two of the three main types of tests commonly used. And one is antibodies are used to capture an antigen. And you call that an antigen test. That's like the rapid flu test or rapid strep test. The other type of test actually looks for antibodies in the patient's blood for example that they've developed antibodies against SARS COV-2.

So you as an antibody developer could provide antibodies to both those kinds of developers. So and is the answers depend on - the more precise answer depends on what kind of test it is. So you just start out with - is it a direct antigen test where it's a rapid

((Crosstalk))

(Margot Enright): Yes, no it's - yes, it's a rapid antibody test that measures the combination of…

Dr. Timothy Stenzel: Okay.

(Margot Enright): …combination of IgG, IgM combined…

Dr. Timothy Stenzel: Okay.

(Margot Enright): …not individually and it's a lateral flow.

Dr. Timothy Stenzel: Right so, you know, at this point, you know, the best truth for antibody test development is to know whether or not the person is PCR positive and then you know how many days after symptoms you're performing the validation and/or and also we would like to know how many days after the PCR. But having that PCR positivity for the patients enrolled in your study tells us yes, they did have SARS COV-2.

And that is actually helpful to developers because you were to try to compare to another serology test and may not be gold standard and you might end up with a potential false positive because not all a lot of the serology tests don't have, you know, near 100% detection.

So really for developers the serology tests these rapid antibody tests it's best to use PCR. And for your positive population that should work great for your negative population is somewhat ideal if you can get your hands on pre-COVID serum and plasma to do your study setting for specificity because you know that those folks weren't exposed.

Anybody, you know, post - you know, in population that you're selecting patients from where you know that COVID's been SARS-CoV-2 has been circulating could have been exposed and they could have been asymptomatic. So that's the challenge.

So in knowing a little more about the details about what the challenges are and what their discrepancies are. And maybe you can just if you can briefly say it might be an important thing for me to know and discuss on this forum. So what can you just follow-up with more detail about what your concerned about?

(Margot Enright): Yes, the concern was that PCR samples that and then PCR positive some of them anywhere from seven days to over 100 days and there are some possibilities of discrepancies between the two and if there are discrepancies how we would justify and resolve discrepancies.

Dr. Timothy Stenzel: Yes that's a difficult one.

((Crosstalk))

(Margot Enright): I know that's why I called you because I didn't have a good answer either so...

Dr. Timothy Stenzel: So, you know, the discrepancy is that the antibody is not detect it. We know that not everybody or not every - most serology tests as I said don't detect IgG at 100% at any point necessarily. Some do at some point, a lot, you know, after say 15 days more and more tests are positive because the immune system has mounted its adaptive response and antibodies are being are circulating that you can test.

If you're seeing false positives that's a situation where you have people who are screened with PCR but after, you know, SARS COV-2 has been circulating and

they are PCR negative whenever they were tested but now they're antibody positive that hopefully that doesn't happen that often.

(Margot Enright): Okay.

Dr. Timothy Stenzel: We do recommend that folks when they do studies you kind of try to get most of your samples between two weeks and two months after the PCR positive. That protects you both ways because antibodies can wane overtime and maybe if they're negative if you test them 100 days out because the antibody was there at one point but that now has gone away.

And another thing is if you have a fairly close time period between PCR test and the history of no symptoms and then you do the testing for the negative population, you're more likely just to have truly negative patients. I hope that helps.

(Margot Enright): Yes that's very helpful. Thank you very much, really appreciate it.

Coordinator: Next question in the queue is from (Shri). Your line is now open.

(Shri Enri): Hi Tim. This is (Shri Enri). I wanted to comment and thank you primarily and the (NC) team and all of FDA for being so proactive about this EUA process. Having a few of them in, myself I've thoroughly enjoyed the experience working with you guys.

My main question has been answered about the home use tests. I do have a question about this particular Webinar series. Is this going to continue on for the next couple of weeks or is this the last one scheduled for the future because I'd like to hear about the home testing?

Dr. Timothy Stenzel: Yes, yes, yes no there is probably unfortunately there's a lot more to discuss and there's a lot more to come. You know, as schools look to reopen. as workplaces look to reopen, you know, there are a lot of, you know, important questions to be asked. So at least through the month of July we're going to be here weekly. And I wouldn't anticipate an abrupt halt but we'll make the decision towards the end of July.

(Shri Enri): Thank you.

Coordinator: Next question is from (Amy Leser). Your line is now open.

(Amy Leser): My question's been answered. Thank you.

Coordinator: Next question is from (Susan Rowley). Your line is open. (Susan) if you're there please check your mute button.

(Susan Rowley): Hi. Is this better?

Coordinator: We can hear you.

(Susan Rowley): Great. I just wanted to ask given that we're a couple months now into the EUA process if the timeline or approximate turnaround time through NCI is about still about ten days or has the timeline extended due to the burden placed on the NCI organization doing all the independent studies and does that effect then the actual review time of the EUA request? Thank you.

Dr. Timothy Stenzel: Yes so I have an overall average time from device receipt to device transmission. And right now it's in the dashboard it's taking about 17 days. So that's about between two and three weeks once a device has been submitted. If it's on - this may or may not depend on whether it's on the high priority list. I

would have to defer to others because we do take a look at application and make sure that it's appropriate to go forward with the NCI. But that's the data I have right now.

So it is moving along at a fairly decent clip. The - and then of course we offer the notification pathway for devices to notify us and then the EUA so people can market in the mean time. So we are trying to drive all these numbers down as fast as possible.

(Susan Rowley): Thank you very much. That's helpful.

Dr. Timothy Stenzel: All right you're welcome. And with that I do need to apologize. I'm going to turn it over to Toby. And I do today at this time have another pressing commitment and you'll be in good hands with Toby. And I'm sure that if there's anything that she wants to check on afterward she can. Thank you, Toby. Are you there to turn it over to?

Toby Lowe: Thanks. I'm just going to tell everyone to email Tim.

Dr. Timothy Stenzel: Yes that's the way it's going today isn't it. I don't know about that. My box is already pretty full. All right thanks everyone.

Toby Lowe: Thanks.

Coordinator: Next question in the queue is from (Christina Yang). Your line is now open.

(Christina Yang): Hi. This is (Christina). Toby thank you very much for issuing the new pooling guidance. And our company's interest in screening our employees. So we would like to know currently are there any CLIA labs testing or commercial PCR test kits tested for pooling?

Toby Lowe: Sure. At this point there are not any EUAs that have been issued that include pooling. We are working with developers towards that. And we do note that the notification pathway is available for developers that have validated pooling and want to begin offering that while we review their EUA.

(Christina Yang): Great. And so Toby when, you know, there is a kit in a pool where we able to check the proof list on your Web site under COVID-19?

Toby Lowe: Yes. The it would be, when you do authorize a test kit that includes pooling that would be noted in the instructions for use that are posted on our Web site. And I'm sure once we offer the first one, we will definitely be announcing that.

(Christina Yang): Excellent. Thank you very much.

Toby Lowe: No problem.

Coordinator: Next question is from (Lewis Promo). Your line is now open.

(Lewis Promo): Yes thanks very much Toby. Does the commercial neutralizing antibody test done by immunoassay require an EAU [sic] and if so are, where are they listed and where can I find them?

Toby Lowe: So we have not yet authorized any tests for neutralizing antibodies. We are again working with the developers on that. That seems to be a common theme. And we look forward to doing that. We do - they should be coming in for an EUA yes.

(Lewis Promo): Okay so you don't know when as yet right?

Toby Lowe: Unfortunately no.

(Lewis Promo): Okay. Okay thank you.

Toby Lowe: Sure.

Coordinator: Next question is from (Machini Fernando). Your line is now open.

(Machini Fernando): Hi Toby. Thanks for taking my question and we're finding this forum has really been helpful. My question is do you have – hello? Can you hear me?

Toby Lowe: Yes, yes?

(Machini Fernando): Yes so do you have any guidance on validation of a EUA test on a platform that is not specified within the EUA? And if so, what panels do you recommend to use for that process?

Toby Lowe: I'm not quite sure I'm following. So you're looking to get an EUA for a test kit without specifying the platform that it should be used on?

(Machini Fernando): No. If there's EUA approved test can I try to use it on a different platform and…

Toby Lowe: Okay.

(Machini Fernando): Yes.

Toby Lowe: Yes so, you're from a high complexity CLIA lab?

(Machini Fernando): Actually my focus is elsewhere. It's global health focus. So I just wanted…

Toby Lowe: Okay.

(Machini Fernando): …to see if there was any guidance along those lines.

Toby Lowe: Yes. So if you take a look at the COVID-19 test policy guidance that we've issued there is a discussion for modifications made by high complexity CLIA certified laboratories that are modifying the EUA authorized test. And that's for, you know, just like you're talking about modifications to components such as the platform that it's being run on. And it talks about validating those modifications using our bridging study and that we would not accept an EUA for tests that are validated in that way.

(Machini Fernando): Okay. And Toby thank you. Do you have any recommendations for panels that we could use for that process in the diagnosis as well?

Toby Lowe: For sorry, recommendations for what?

(Machini Fernando): Panels, sample panels that we could use for the validation process?

Toby Lowe: Oh to do the validation, sure. If you take a look at our FAQ page there's an FAQ about test materials that are appropriate for assay validation. And it's under the test validation FAQ section on the FAQ page. And that's FAQ lists out from the priors of validation materials.

(Machini Fernando): Thank you so much. That's very helpful. Thank you.

Toby Lowe: Sure.

Coordinator: Next question is from (Kelly Leanhart). Your line is now open.

(Kelly Leanhart): Hello. Thank you so much for holding this press conferences. I was just curious if there was any place that's publicly available to see where I can find information for who working on EUAs for pooling test? Hello?

Toby Lowe: Yes sorry I was just thinking. I don't think so. So right now the publicly available information that we have on, you know, there would name specific developers is the notification list that we have on our FAQ page and then the authorized EUA list on our EUA page.

(Kelly Leanhart): So if a lab working on the EUA for pooling test wanted to connect with other labs working on tests would there be any way for them to connect through you guys?

Toby Lowe: That's - I have to think about - that's not typically something that we would facilitate but we definitely do want to encourage collaboration in this area.

(Kelly Leanhart): Great thank you so much.

Coordinator: Next question is from (Kitsap Peterson). Your line is now open.

(Kitsap Peterson): Thank you so much. I want to start out saying thank you for all the work your group is doing. I've had email sent your template and got a reply back way after normal working hours. So I know how hard you guys are working. We got…

Toby Lowe: Yes.

(Kitsap Peterson): …a little confused and I just want to because the Boston University question was similar. We ended up signing a pre-EUA mid-May and we didn't understand the difference between the EUA and pre-EUA. And we were kind of

in limbo around for a while until we figured that out and finally got the EUA in and got the confirmation letter so we could start working in New York and other places that require that.

So maybe making it a little more clear. We are a small company and we are relying on revenue from our investment in putting our efforts into participating and hopefully containing this epidemic. So the timelines are becoming very important for us as some of the contracts that we're working on now are asking for a published EUA. So that's where I think a lot of other smaller companies are. And I think I know that you're prioritizing your work as well so that's just…

Toby Lowe: Sure.

(Kitsap Peterson): … a shout out to any small companies that are working to participate in this work. And the last comment is that we are working...

((Crosstalk))

(Kitsap Peterson): ...on putting this on extend sequencing so we don't have any scalability issues in the future. So that's our goal we are innovative.

Toby Lowe: Great thank you. And to provide some of that clarification, you know, so that you submitted a pre-EUA and then an EUA. It's unclear to me whether you've also notified. So if you want to clarify that the pre-EUA process is primarily for situations where you have not completed validation and you need some questions answered and want to have some dialogue about what appropriate validation would be. That maybe is beyond what's in the guidance and in the template.

And then the notification is what we would expect when you have validated your test and plan to begin offering the test prior to an EUA. And so if you are currently offering your test you should have either a notification in place and be listed on our notification list on our Web site or have received an EUA authorization to be listed on our EUA page. So the - there is a difference between a notification and the EUA request.

So the EUA request is what you submit when you are ready to move forward and present all of your validation data for our review. The acknowledgment letter that you get from submitting an EUA request is just an acknowledgment that we have your submission in-house. Once we have completed the review and have reached a decision then we will issue hopefully an authorization letter specifically for your test. And that's when the EUA would also get posted on our Web site.

(Kitsap Peterson): Fantastic thank you. So then there is that process notification list that we actually submitted this to you? That's on your Web site too?

Toby Lowe: So are notification list is on the FAQ page. The first section of the FAQ page is what laboratories and manufacturers are offering tests for COVID-19. And there's a series of questions in there that list out the names of the laboratories and commercial manufacturers that are offering tests under the different policies in the guidance documents. And so in order to offer a test prior to receiving an EUA authorization you should notify under that policy and get listed on one of those lists.

(Kitsap Peterson): I would take that beyond because now that is one of the questions that we're getting. So this is fantastic. Thank you so much.

Toby Lowe: Sure no problem.

Coordinator: Next question is from (Mark Wagner). Your line is now open.

(Mark Wagner): Hi. Thanks for taking my question. I'm hoping to get some clarity on sample pooling and test modification for CLIA certified labs. And my question is many labs follow the policy for modifications of both previously EUA authorized COVID-19 assay.

For example can a lab do pooling as a modification to the test and validate using a bridging study or must they follow the molecular diagnostic template for adding a pooling strategy to a previously authorized EUA which would require submitting a new EUA or waiting for the test manufacturer to submit an EUA amendment?

Toby Lowe: Right. At this time we are expecting EUA submissions, EUA requests for pooling. The notification pathway is available for adding pooling as well followed by an EUA submission. We don't believe at this time that bridging is an appropriate validation for adding pooling to an authorized test.

Coordinator: Next question is from (Jessica). Your line is open.

(Jessica Wasserman): Hello this is (Jessica Wasserman). For the serology tests for the NCI validation is that mandatory or is there an option to submit say with your data and then also maybe a third-party validation of some recommended test? Thank you.

Toby Lowe: Yes, we think that NCI data is really helpful for validating the serology test. If you have a particular situation that you think would be a good alternative approach, we would encourage you to speak with your lead reviewer on that.

(Jessica Wasserman): Thank you.

Coordinator: Next question is from (Sarah). Your line is open.

(Sarah): Hi. Can you please clarify whether an on-site healthcare worker observes collection is considered equivalent to a healthcare worker collected specimen and would not require an EUA?

Toby Lowe: So we…

(Sarah): (Unintelligible) a portion?

Toby Lowe: I'm sorry what was that?

(Sarah): I just - like the home self-collection it's clear that that would require in EUA. I'm just curious about the on-site self-collection if it's observed?

Toby Lowe: Sure. So we do consider those to be separate and distinct things. We have indicated that home collection requires and EUA. On-site health self-collection observed by a health provider does not necessarily require a separate authorization. We've indicated on our FAQs that both the mid turbinate and anterior nares specimens are appropriate for on-site collection.

(Sarah): And is there a definition of a healthcare worker?

Toby Lowe: There is not.

(Sarah): Okay thank you.

Coordinator: Next question is from (Cynthia Swin). Your line is now open.

(Cynthia Swin): Hi. Thank you very much. Regarding the pooling test I'm a little confused why the alumina test isn't considered a pooled test with the number of samples that get pooled in that. I know there's tags on the samples but it still seems like a pretty pooled test to me. I know that's asking about a specific test but it seems like, you know, multiple times they said that there's no pooled test but that particular high-volume test does pool the samples together.

Toby Lowe: Yes that's an interesting question unfortunately I'm not familiar enough with that test. I do know that it was validated and authorized. If you want to send in that question, we can direct that to the right individual who will be able to answer that for you.

(Cynthia Swin): Yes thanks.

Coordinator: The next question is from (Sina). Your line is now open.

(Sina): Hello can you all hear me?

Toby Lowe: Yes.

(Sina): Hello. Okay fantastic. So thank you Toby and Irene for hosting this call and for answering questions. My name is (Sina) and I'm a scientist at the California Institute of Technology. And I'm working with collaborators at UCLA to develop a NexGen sequencing based/COV-2 test.

We've submitted it for an EUA and I've been developing the software to process the NGS data and call the samples. So we plan on submitting amendments to the EUA so it, can that be done in the interim between EUA submission and the EUA being granted. And is it appropriate to submit one

solely for analysis infrastructure?

Toby Lowe: I apologize can your repeat the distinction there what you're asking?

(Sina): Yes sorry. So the first question is can we submit amendments to the EUA in the interim between us having submitted the EUA and the EUA being granted so in the time period?

Toby Lowe: Yes…

(Sina): And my second question was…

Toby Lowe: …I would work with your, will work with your lead reviewer about how to incorporate anything additional that you're requesting as part of your submission.

(Sina): Okay. And the second question is - is it appropriate to submit one solely for the software analysis infrastructure?

Toby Lowe: I am not sure I'll be able to answer that without additional details about what the device is doing and what the software would be doing. So it's probably best to have that discussion directly with your lead reviewer so that we can get into more of the details.

(Sina): Okay that sounds great. Thank you so much.

Toby Lowe: Thanks.

(Sina): And now I'd like to turn the call over to Miss Irene Aihie.

Irene Aihie: Thank you (Ted). This is Irene Aihie and 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, July 14.

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 discussion. Again thank you for participating and this concludes today's discussion.

Coordinator: This concludes today's call. Thank you for your participation. You may disconnect at this time. Speakers, please stand by.

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