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

**Moderator: Irene Aihie
October 28, 2020
12:15 pm ET**

Coordinator: Welcome and thank you for standing by. Today's call is being recorded. If you have any objections you may disconnect at this time. All participants are in a listen-only mode until the question-and-answer session of today's conference. And at that time you may press Star 1 on your phone to ask a question. 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 32nd 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 Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality here in CDRH will provide a brief update. She is joined by Dr. Brittany Schuck and Dr. Kris Roth.

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 Toby.

Toby Lowe: Thanks Irene. Hi everyone. Thanks for joining us again. Tim is not able to join us this week since he had a conflict so I've asked Kris and Brittany to join me to help with some of the more technical questions since as you all know I am a policy person.

So a couple updates quickly before we get into questions. First just want to point out as we head into the end of the year, the schedule for the town halls may shift so keep an eye on your emails. Our team that handles the Webinars will make sure to send out emails with updates on the dates for the town halls in case they're not every week.

And then the other update that I have is that earlier this week we updated the antigen template, the EUA template for antigen tests. And this update adds some recommendations regarding studies for screening of asymptomatic individuals and for multi-analyte antigen tests. So that template replaced the older one that was on our Web site and is available for test developers to use as you prepare your EUA request. And with that we can turn it over to questions.

Coordinator: Thank you. We will now begin our question-and-answer session. If you'd like to ask a question over the phone lines please press Star 1 from your phone, unmute your line, and speak your name clearly when prompted. Your name is required to introduce your question. If you'd like to withdraw your question press Star 2.

Again to ask a question over the phone line, please press Star then 1. One moment as we wait for our first question. Our first question comes from Shannon Clark. Your line is open.

Shannon Clark: Hi. This is Shannon Clark. Can you hear me?

Toby Lowe: Yes, we can.

Shannon Clark: Excellent. I'm with UserWise, the human factors consultancy specializing in human usability testing. My question is a little long but it has a lot of kind of history here.

I first asked this question about a month and a half ago and got the answer that if we're running a study with an antigen test we do not need to include Spanish speakers if we do not include instructions for use in Spanish.

A little more information about that - translation of instruction for use into Spanish and inclusion of Spanish speakers delays timelines by at least one month for development and adds between, you know, 30K and 50K and cost of development.

Only 2% of the US population primarily speaks Spanish, and it's basically impossible to find participants for usability testing that only speaks Spanish such that they would definitely rely on those Spanish instructions when interacting with the product.

So some weeks ago the FDA noted that yes so some weeks ago I asked this question and Timothy Stenzel noted that you actually do not include Spanish speakers if you don’t have Spanish instruction. But then around October 7 Dr.

Stenzel said something that was a little alarming to me about that this isn't true any longer. So do you have an update on that or is it still true that we are not required to include Spanish speakers as the statement in the template for non-laboratory antigen test use says the word should which is "optional?"

Toby Lowe: So all of our templates are recommendations. So, you know, to that point they are our current thinking and are recommendations they are not binding requirements. So specifically for the non-laboratory, the more - over-the-counter type consumer tests, we do have a recommendation to include Spanish speaking individuals in the testing.

I do not believe that we have that recommendation currently in the antigen template and, you know, as I said, for all of these, these are our recommendations. So if you have different approaches or you want to propose not including that, that's something that you can submit with your EUA request.

Shannon Clark: Okay thank you. And to clarify last time I checked, in a non-laboratory antigen template it did clearly state should include Spanish speakers. Did you update that in the last two weeks?

Toby Lowe: Sorry no. The non-laboratory...

Shannon Clark: Oh.

Toby Lowe: ...template is for both molecular and antigen. I was referring to the more general antigen template that is for laboratory-based tests. The…

Shannon Clark: Oh yes. So for professional use you wouldn't…

((Crosstalk))

Toby Lowe: So sorry that was - I was looking at the wrong template there. The non-laboratory base template does recommend usability including Spanish speakers. If you are proposing not to do that, that's something that you can include in your EUA request and we will consider that.

Shannon Clark: Excellent. And I've been assessing for ten years. FDA's never required Spanish speakers in testing unless it's an integrated part of the user interface so yes thanks for clarifying that.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Wendy Strongin). Your line is now open.

(Wendy Strongin): We're developing a home use antigen test and we want to have an opt in surveillance feature. Is there anyone at FDA or at CDC that we can work with in order to be able to provide that information to the government?

Toby Lowe: You're referring to reporting the results to the government?

(Wendy Strongin): Reporting the results right? I know that it's not required but I…

Toby Lowe: Right.

(Wendy Strongin): …I know that FDA would like to have those results reported even from a home test if there's a way to do that.

Toby Lowe: Yes so we do have the recommendation in the template for non-laboratory tests to include a mechanism for reporting. If you have specific questions

about how exactly to implement that we do have a team that works a little bit more closely on the reporting issues. So the best approach would be to send us an email to the EUA template email address. That should be on the slides and we'll be able to direct your question to the right group.

(Wendy Strongin): Great. Thank you very much.

Toby Lowe: Sure.

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

Savannah Esteve: Hello. Hello this is Savannah Esteve also from UserWise. My question is regarding home use usability testing. The FDA recommended us to evaluate the labeling and instructions for a test kit using a multiple-choice questionnaire that historically the human factors community has found that multiple-choice questions are inappropriate for assessing comprehension of labeling. And so we always ask these questions directly to participants and rarely have them fill out forms themselves. Has FDA human factors team confirmed that multiple-choice questions for human - or for home use human factors testing is the most effective way to assess labeling IFUs?

Toby Lowe: I'm not going to be able to answer the question directly of what the human factors team has assessed unfortunately. But I can say that if you have an alternate approach that you'd like to use that's definitely something that we can consider and we just ask you to send that in for consideration.

Savannah Esteve: Okay. And just to clarify this was sent to us in an email, not necessarily outlined in a template so that's why we're trying to follow-up here. So you're suggesting that we just go ahead and submit with our plan and then wait to hear back or am I understanding that correctly?

Toby Lowe: Yes so you can send in the question or the approach that you're looking to take we can discuss that with the team that works primarily on the home test issues and get back to you on that.

Savannah Esteve: Okay and should those questions be directed to the templates email address?

Toby Lowe: Yes that's a great first spot to start and we can direct it from there.

Savannah Esteve: Okay. Thank you.

Toby Lowe: Yes.

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

(Gustavo Heteray): Hi. Good afternoon. My name is (Gustavo Heteray) and my question is in reference to using a real-time PCR equipment to do the reference final validation. So we're trying to help a Chinese company called (Enshare) Biotech comply with the required reference panel.

As such we have a question regarding the devices that may be used to perform the test. We have at our disposal an ABIs 7500 Fast Dx REAL-Time PCR instrument and a SLAN-96 P REAL-Time PCR system. However the IFU in the EUA mentions an ABIs 7500 REAL-Time PCR system. Is it possible to perform the reference panel using the ABIs 7500 Fast Dx REAL-Time PCR system or the SLAN-96 REAL-Time PCR system as we do not have access to the one mentioned in the IFU?

Toby Lowe: So if you're referring to performing the reference panel as a condition of the authorization which is typically what the - how the reference panel is currently

being used then the performance of the reference panel does need to be in line with the instructions for use in - of the authorized test so that the - so that it does - it is reflective of the test that was authorized.

(Gustavo Heteray): Oh okay. They have introduced an amendment including the equipment that I have mentioned. But the amendment has not been reviewed. I guess maybe pending the reference panel results?

Toby Lowe: So I'm not able to answer any questions about a specific test. Generally we do expect the reference panel to be performed using the authorized test. If there is any specific questions about any, you know, an amendment or any authorizations there those should go directly to the review team.

(Gustavo Heteray): Okay then we'll find an equipment as mentioned in the IFU. And in regards to the software does the software have to be the exact same software or could be - could it be a more updated software on the equipment?

Toby Lowe: It should be the test as authorized.

(Gustavo Heteray): Okay all right well thanks a lot. That answers my question.

Toby Lowe: Great.

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

(Avita Tripati): Hi there. Thanks so much for taking the question. I'm wondering about changes to EUAs. Can you may be expand a little bit about the thought process and policy on changes? Like should we be following the 510(k) change notification guidance and how you'd like to see that (unintelligible) worked out.

Toby Lowe: Is this for a test that you have that you have already authorized?

(Avita Tripati): Our test is not yet authorized. We're hoping for that soon. However, you know, due to supply shortages we're anticipating there might be a need to say have alternative swabs or other components of the product get updated. And if so we just want to be able to plan for what additional testing. And if there is any additional regulatory review we want to be able to plan that into our timelines.

Toby Lowe: Sure. So you're, you know, the best bet is always to include as much flexibility as you can in your authorization or in your test that you are submitting for authorization so that, you know, if possible we can authorize it with a variety of components.

If you want to add additional components later on that's something that you would submit in a supplemental EUA request. When you - do you get authorized - your letter of authorization will include conditions of authorization that spell out what types of changes should come in for a supplemental EUA request in order to update the authorization.

And a lot of the tests that are already authorized, you know, have those kind of - they all have those conditions. So you can see those on our Web site if you wanted to take a look at what - how those conditions are drafted.

And I can also note that we do have some information on our FAQ page about alternate testing supplies. So for example we - we talk about the different types of swab types that can be used, most test now those that are being authorized - are being authorized for use with all of those, you know, NP swabs OP, mid turbinate and anterior nares. So we do talk about that.

If you wanted to add a new specimen type all together like adding saliva that would be something you would come back in with. And these questions - or my responses rather all presuming that you're talking about a distributed test kit.

So those are all the different considerations that you would want to look at as, you know, what you want to be able to include in your original instructions for use and what you might want to add later.

(Avita Tripati): All right. All right thank you very much. That's helpful.

Toby Lowe: Sure.

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

(Margot Emery): Hi. Thanks very much for all the useful information you've provided us. I just had a question regarding a term that I've heard used different ways and wanted to get some clarification from you the term screening. Can you clarify what you mean by the term screening?

Toby Lowe: Sure so when we refer to screening - and we do have information on this up on our Web site on the FAQ page. We have a question that discusses the difference between surveillance, screening and diagnostic testing.

So when we talk about screening we're talking about testing primarily asymptomatic individuals to look for occurrence at the individual level. So this would be, you know, a broad testing of asymptomatic individuals who do not have any known exposure with the intent of identifying individuals who were infected but don't have any symptoms either because they have not yet

developed them or because we know that with this disease there are a number of individuals who are infected but do not present with any symptoms.

(Margot Emery): Okay thank you. That's very helpful. That's the way I understood it but I've heard it used different ways so I wanted to make sure I got a clarification from you. Thank you very much.

Toby Lowe: Great no problem.

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

(Jeff Dray): Hi. Thanks very much. We are planning to pass in a pre-EUA submission for an application for a home use configuration of POC virus sensing platform. We are relatively new to this area.

And question is if we are going to seek guidance or advice from the FDA is it worthwhile submitting a partially populated template so that we can make a connection and get that kind of heads up guidance? I mean Dr. Stenzel's been pretty encouraging in previous calls with regards to at-home submissions. So we want to see if this is a good idea.

Toby Lowe: Yes absolutely. As much as you can complete the template and include in your partially completed template where you have specific questions that's the easiest way for our team to take a look at what you have and provide the most appropriate feedback.

So as much detail as you can put in there and then any places where you want to specify, you know, for example if you're not sure how to do your clinical study and you include maybe your draft protocol and ask specific questions

that you have then when you're pre-EUA gets assigned to a reviewer they'd know where to focus their attention.

(Jeff Dray): Outstanding. Thanks very much.

Toby Lowe: Yes.

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

(Gwen Goodman): Hi and thank you. My question is once a test has been approved and authorized and the requirements change what is the responsibility of test provider to change protocols, et cetera to conform with the new requirements?

Toby Lowe: So by new requirements are you referring to when we update a template or something else?

(Gwen Goodman): That's what I'm referring to yes.

Okay so if there's a test that is already authorized, if we update the template the developer of that already authorized test for the owner of that EUA does not need to do anything. If there are additional steps that need to be taken we will reach out directly to the EUA holder.

(Gwen Goodman): Very good. Thank you.

Toby Lowe: Sure.

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

(Sheri Ocosik) Hi. This is (Sheri Ocosik). Toby, Brittany and Kris thank you very much for being on - taking this call. I do have a very basic question. Dr. Stenzel two weeks ago mentioned that there was a backlog of NCI testing for the serology tests and that that backlog was getting cleared.

Having submitted an EUA and also waiting for authorization or saying no for the past five months it would be good to understand if there is any plans from you guys to sort of just say since we can't get the NCI testing done in time we'll just deal with the EUA directly and move on.

I - the reason I'm asking is because we've been trying to and our reviewers have been extremely good at responding but since this is a policy question I just wanted to see if you have any updates on the NCI testing and how it's delayed the EUA authorization for a lot of us?

Toby Lowe: Thanks for that question, so try to answer it a little bit and then I'll see if Brittany wants to add anything there. So we do prioritize the tests that are being tested at NCI based on a number of factors including the data that we are already aware of before they perform that testing. And we do find that we get very useful information from the NCI testing so right now we are tending to rely on that. But I'll turn it over to Brittany to see if she wants to add anything there about the backlog or the prioritization?

Dr. Brittany Schuck: Yes obviously we are reviewing all EUA requests as quickly as we can. And as Toby mentioned we - and Tim has mentioned previously - we are prioritizing reviews based on several factors, and we are also prioritizing testing at NCI. And priority for testing at NCI is being given to tests with complete submissions. So we have complete validation data in the EUA request and where the performance is adequate based on the data submitted in EUA request.

And we are continuing through that process. There is a Frequently Asked Question on our Web site regarding how we're incorporating the results from the NCI's evaluation into our decision-making for EUA requests. It highlights there some of the concerns we've had in particular for lateral flow devices. And for those reasons we generally have the NCI evaluation prior to any authorization particularly for lateral flow devices, and for other technologies as well like the ELISA, chemiluminescence immunoassays, et cetera.

(Sheri Ocosik): Thank you.

Toby Lowe: And just to emphasize one of the points that Brittany made we do prioritize for NCI testing those submissions that have complete EUA requests and that look good prior to the NCI testing. So it's very unlikely that there would be a test that, you know, we would be otherwise ready to authorize that we're not prioritizing for NCI testing.

(Sheri Ocosik): Well I mean what I would like to understand is just as a follow-up is that how would we know because, you know, we know that we're on the queue and been on - in the queue since May 20, end of May? And as I said our reviewer has been fantastic. I am not I have nothing but good things to say about her.

But the question still is we don't have an idea of whether our - and I've had multiple questions from the reviewer which I have addressed as quickly as possible.

What I don't have an idea of is whether or not we made the priority list and whether or not we are - we can expect a result anytime soon? So that's - I mean I - we do get questions from the sponsors because they're all international sponsors and they're, you know, wanting to sell their diagnostic

in the United States. But the problem is that even after notification nobody wants to buy the kits unless you have a full authorization.

So we understand how busy you guys are and we really, really appreciate all the time that everybody is putting into it but, you know, and while I've heard about the priority list I just don't know how I'd know what my list is for my medium priority or low priority because it was a full submission whatever we submitted. So that's what I am asking and if there's policy a saying...

Dr. Brittany Schuck: Yes, if you're continuing to interact with your lead reviewer on the information sent in that means that there are questions about the information that's been - that have been provided and so those might be clarifying questions to make sure they understand what has been provided in the submission to assure that it is complete and has all the information that we would need. And then there may also be subsequent emails with deficiencies with things that are not adequate in that particular submission.

So if you're having those continued interactions with the lead reviewer that means that there's still outstanding questions that have not been resolved and we would not be prioritizing testing until those issues and those questions have been resolved. So that's one way to know sort of where you are in terms of how likely it is the testing would be imminent.

(Sheri Ocosik): Okay. I want to thank you again. I'm going to ask my lead reviewer what she thinks but I want to thank all of you for the time that you've put in during these town halls and all the help that you are providing us. So I greatly appreciate it and I'm pretty sure the rest of the community greatly appreciate your help. Thank you.

Dr. Brittany Schuck: Thank you. That's always nice to hear.

Coordinator: Our next question comes from (Lumna Syed). Your line is now open.

(Lumna Syed): Hi. Thanks very much everybody. Again just reiterating the previous caller, we do really appreciate these calls. And I know you're mentioning that there may be a change in schedule. Hopefully we're not eliminating the calls in any way.

But my question is related to home diagnostic molecular tests in particular related to the package insert. Traditionally for home testing a paper package insert is required. However, you know, now with mobile medical applications and electronic instructions for use because it's a lay user - traditionally it's been paper package insert. But now that one of the requirements for utilizing this - these products is the use of a mobile application in order to process the sample and have the associated usability testing I'm wondering if there is a possibility to include the quick reference guide or quick reference information in paper format with a reference to how you can get paper if necessary but eliminate that paper from the packaging of the products unless it's not required to have the full package insert shipped with the product in paper format only, the QRG or QRF?

Toby Lowe: So I think that would depend a little bit on what information you intend to have on the quick reference guide and whether the information on that would satisfy the device labeling requirements. So that's something that we may need to look at on a, you know, more specifically for your situation. And so if that's something that you can email in to our email box we can take a closer look at that.

(Lumna Syed): Okay that's great that that could be a potential pathway. It will help to eliminate cost and reduce cost to the users ultimately if it's a viable package.

((Crosstalk))

Toby Lowe: Yes that's yes it's another consideration would be the population that you're intending to use this. So if you were to eliminate, you know, paper instructions and only have this be app-based then that would remit the use of the testing to individuals who have an appropriate device, you know, an appropriate smartphone or whatever, you know, device it is that…

(Lumna Syed): Right.

Toby Lowe: …your app would run on.

(Lumna Syed): And that's a requirement already anywhere right, to use the product? So that's why I'm saying because that is a requirement to use the product is to have an app.

((Crosstalk))

Toby Lowe: For your device?

(Lumna Syed): Yes, yes.

Toby Lowe: Okay. Yes.

(Lumna Syed): Okay yes so it would be great to understand which elements are necessary to go in. And, you know, if this could then carry forward for 510(k) as well. So perhaps I will send you a question in the EUA templates email and maybe that could be answered that way. Does that make sense?

Toby Lowe: Sure. And I think, you know, the device labeling regs, especially the IVD specific labeling regs are a good place to start. So we would want to make sure that, you know, that all of those labeling requirements are covered.

(Lumna Syed): Yes I mean we are covering 809.10 in the paper insert. And, you know, in terms of the IVD regulations in general for lab products, you know, those are not lay users. They're for professional user purposes. Paper package insert is not required. Electronic package insert is acceptable.

What I'm specifically asking for is for home users or non-lab users layperson kind of environment. Yes that's the key distinction otherwise the elements are there.

Toby Lowe: Okay. Sure. So if you can send that in that's something that we can take a closer look at your proposal.

(Lumna Syed): Okay great. Thanks so much.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Frank Ocalltharon). Your line is now open.

(Frank Ocalltharon): Hi good morning and thanks for taking the time to answer our calls. So let's assume that I engage EUA for my antigen test and then later on I want to come add influenza A and influenza B capabilities to that antigen test that already has EUA. Can I just amend and do that or does that process have to be a completely new one, a new EUA?

Toby Lowe: I believe so it depends a little bit on what the change is to the test. So that's something that we would consider depending on how you'd be changing your

test. But it would also depend on whether you're continuing to - whether you would be marketing two versions of the test or whether you would be switching completely to the new test because we would, you know, if you're intending to market two versions we would want those to be two separate authorizations.

(Frank Ocalltharon): I see, got it. Okay that answers my question. Thank you.

Toby Lowe: Sure.

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

(Alexander Voltand): Hello?

Coordinator: (Alex)…

((Crosstalk))

(Alexander Voltand): Hi, kind of somewhat unusual question. Over the last several months there is - was at least one study came out indicating successful training dogs to detect COVID-19. What would be a compliance requirement for deploying trained dogs to identify out potentially infected individuals for future screening in public settings like airports or malls or private settings like workplaces? Would a trained dog be considered a test as far as FDA is concerned?

Toby Lowe: That is something that we could answer through the mailbox if you can send your question in.

(Alexander Voltand): Right great. Thank you.

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

(Tom Sayer): Yes thank you so much for the opportunity. This is regarding sensitivity for the EUA for the antigen test. In Section 7, your clinical evaluations you say that approximately 10% to 20% of the clinical specimens should be low positive RTC PCR CT counts of greater than 30.

In light of a lot of research that indicates that a person is most likely not contagious at higher CT levels have - can you tell us how you would evaluate results of an antigen test that perhaps did not reflect positives at the higher CT values if it was being used as a screening test?

Toby Lowe: Kris is this something that you're able to address?

Dr. Kris Roth: Partially I suppose. You know, I think what you're may be referring to is maybe a low sensitivity antigen test is that correct?

(Tom Sayer): Well right, an antigen test that would be highly sensitive at the lower CT values but might not result in a positive at CT values greater than 30 because of the low viral load at that level.

Dr. Kris Roth: Right so analytically it's a low sensitivity test compared to PCR. So I think there are some recommendations in the new template for tests which have a lower sensitivity and perhaps, you know, a serial testing strategy could be considered. And that's, you know, something that I don't think we have comments we could offer to you right now. But that's a strategy that you could, you know, propose as long as you're kind of hitting that 70% kind of PPA mark with respect to a high sensitivity RTP CR test.

(Tom Sayer): Okay great. Thank you. I do see that strategy for serial testing. Okay that answered my question. Thank you.

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

(Dana Hummel): Thank you for taking my call. My question is regarding the earlier comments about the priority for NCI testing. I believe you said that more complete EUA submissions are higher priority. And we sent our test to the NCI back in July and we have not submitted our EUA because we need the NCI results just to complete the clinical validation testing recommended by the FDA. All the other performance data looks good and all of our other data is ready.

So should we - are you recommending that we submit a partially completed EUA application so that you can see all the other data and information we have prepared to help move us up in the queue at the NCI? Otherwise I just wonder if our test is viewed as a lower priority since you do not have any of our EUA information?

Toby Lowe: Brittany do you want to take this one?

Dr. Brittany Schuck: Sure yes. We would encourage you to go ahead and submit the information that you do have, documenting in the Clinical Agreement Study section of the submission that you have sent your test to NCI, and that your intention is to leverage that data to support the clinical performance of the device.

(Dana Hummel): Okay and as a follow-up I saw once we submit our pre-EUA that we technically only have either ten or 15 days to submit the complete EUA which should include the clinical validation data. However, you know, if we don't receive the NCI results within that timeframe then we can't submit the

complete EUA. So I just wonder if you have any comments on how to handle that?

Toby Lowe: So I think what you're referring to is actually notification. So that's different from the pre-EUA. Notification is only appropriate if you have completed validation of your test.

So if you're waiting for data from NCI then you would not have completed your validation yet. So notification is for tests that have fully completed their validation and notify us that they intend to begin offering their test prior to EUA authorization. And then under that policy that's been our - in our testing policy guidance. Then we do expect to see a full EUA request submission within ten business days. But it doesn't sound like that would be applicable to your situation. So you…

(Dana Hummel): Okay.

Toby Lowe: …can submit your either pre-EUA or EUA request depending on whether you have additional questions. If you don't have any additional questions then you just are awaiting on that data you could submit an EUA request as Brittany indicated.

(Dana Hummel): Okay. And then once we do have the NCI results we would do the notification?

Toby Lowe: Yes. You could do notification once you have the NCI results provided that all of your other validation is complete.

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

Toby Lowe: Sure.

Coordinator: Our next question comes from (Jackie Chin). Your line is now open.

(Jackie Chin): Hello. I also have a question about the NCI results for Brittany. Hello can you hear me?

Toby Lowe: Yes we can.

(Jackie Chin): Hello? Okay great.

Toby Lowe: Yes.

(Jackie Chin): Perfect. Thank you. And then this is a follow-up question on the previous caller. I think Brittany mentioned that NCI results can also be expanded to ELISA or the - chemiluminescent test. Is a true because I was under the impression that NCI testing only tests the lateral flow test, the lateral flow-based serology test?

Dr. Brittany Schuck: Yes. NCI does have the capability to evaluate a manual ELISA and chemiluminescent immunoassays, tests that would typically require like a plate reader and equipment like that. Specialized instruments that are specific to a particular manufacturer, NCI may not have access to those. But we may ask that certain ELISA and chemiluminescent immunoassays that are manual, and can be evaluated by NCI, to be evaluated by the NCI.

(Jackie Chin): Oh okay. That's very helpful. So if we have a specialized chemiluminescent reader then NCI will not be able to evaluate it. And then are there ways we can get the instrument evaluated outside of the NCI program?

Dr. Brittany Schuck: So it also does depend what type of instrumentation. So NCI has been able to evaluate certain tests that have small readers that have been able to be shipped to the NCI. So it really does depend. If you have a question about whether or not your particular device would be amenable to evaluation at NCI you can email the OIR Policy mailbox and we can help figure out if that's possible.

(Jackie Chin): Oh this is great. Thank you so much. Thank you, very helpful. Thanks.

Coordinator: As a reminder to ask a question over the phone lines please press Star then 1 and clearly record your name. Our next question comes from (Sarah Saw). Your line is open.

(Sarah Saw): Hi. I just want to thank you again for holding these calls weekly. I have a follow-up question someone asked earlier about changes to already authorized devices. And the conditions of use do not clearly address some of the smaller changes that may happen.

So for example if changes were made to software components of an authorized product which if we were in the 510(k) paradigm could be documented using internal documentation can that same pathway be applied instead of submitting an EUA amendment?

Toby Lowe: So I'm going to turn this over to Kris in a moment but I think some of this depends on how the components of your test are specified in your authorization. So, you know, buffers are something that might need to be looked at specifically by the team to take a look at that.

But if, you know, if you're for example if your test was authorized for use with a specific manufactured swab and you wanted to switch to a different one

the fact that it was named in your authorization would mean that, you know, technically you should get that change authorized.

If on the other hand the - your EUA was authorized for use with, you know, sort of more broadly with nasal swabs then that would be something that you would not need to come in for that change. So it depends. And, you know, that was sort of a - almost a silly example but you can sort of use that to understand how that might apply to other components.

(Sarah Saw): Right so…

Toby Lowe: You know, if you're looking at the section kits for example it's going to be your test is generally authorized with specific extraction kits. And to add new ones we would expect you to come back in.

(Sarah Saw): Right so if we're…

((Crosstalk))

(Sarah Saw): ...using like extraction kits as an example it would be like maybe it's even the same extraction kit air quotes, but there's a small change to a buffer in that extraction kit. But the mechanism by which it works none of that has changed. And if it were the 510(k) pathway this would clearly be an internal documentation change.

Toby Lowe: Sure. So that might be a specific enough question that we would want to get into the details but I'll see if Kris wants to weigh in at all first.

Dr. Kris Roth: Yes thank you. I would just like to echo Toby's point. You know, it's somewhat governed by the extent to which your labeling specifies those

reagents. And I know we've seen some small changes to extraction buffers perhaps removing, you know, certain components due to shortages. And I think that really needs to be taken a look at by a subject matter expert rather than just kind of providing a blanket policy because certainly, you know, small changes in pH or what the composition of buffer is versus taking away carrier RNA for instance, I mean those are two very different changes that may need to have considerations by someone who's on the review team.

Toby Lowe: So I think, you know, you seem to have a very specific change in mind. The best bet would be to send that into the, you know, to the EUA mailbox or to the review team if you have the lead reviewer that you're working with and we'll be able to take a look at that more closely.

(Sarah Saw): All right thank you so much for your time.

Toby Lowe: Sure.

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

(AJ Detta): Oh hi. Thank you for taking my call. Quick question, so we're developing a neutralizing antibody serology test detecting specifically the proportion of antibodies that are neutralizing. Is there a template imminent for those kinds of test involvement or should we just submit to the (unintelligible) EUA email for guidance?

Toby Lowe: I believe Tim has mentioned on previous calls that there is a template in the works for neutralizing antibody. I'm not able to give sort of an estimate of when that might be out but that is something, you know, we are looking to provide more guidance in that direction.

In the mean time if you are ready to move forward with your test you are always welcome to submit your EUA request or pre- EUA if you have questions that are still unanswered.

(AJ Detta): Thank you. Thank you.

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

(Kendall Craddick): Yes. Thank you for taking my question. My question is in regards to an approved EUA test. Can a clinical lab perform a validation to modify an EUA -- and I'm thinking specifically of about stability and storage requirements of the specimen -- and if so how does that affect the classification of the test and what kind of validation requirements come into play in that scenario? Is that considered an LDT or do we need a resubmission or how do we handle that?

Toby Lowe: Sure. So we do have some information in our policy guidance about modifications to an EUA authorized test that can be made by a clinical laboratory. So that would be a good first place to look. But yes a clinical laboratory can make those changes. It would make the test an unauthorized test.

So if the test is being performed outside of the authorized instructions for use or using, you know, different components or whatever the modifications are that is - that would be outside of the authorization.

(Kendall Craddick): Yes okay. So I guess where I'm unclear is what - how it's classified afterwards. And maybe I'm - if you've already spelled that out in the in some other document I can find that I guess. But with some of the changes recently…

Toby Lowe: So…

(Kendall Craddick): Oh sorry go ahead.

Toby Lowe: Sure. I'm not quite sure what you mean by classified. None of these tests are classified at the moment but they are, you know, it would be considered a test that is being offered, you know, as an unauthorized test. And we have indicated in the guidance document that we would not expect to see EUAs for those modifications to an authorized test.

(Kendall Craddick): Okay. Thank you.

Coordinator: I'm showing no additional questions in the queue at this time. I would now like to turn the call back over to your host Irene.

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 Thursday, November 5. If you have additional questions about today's presentation, please email cdrh-eua-templates@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 in this concludes today's discussion.

Coordinator: Thank you for your participation in today's conference. You may disconnect at this time. Speakers please stand by.

END