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. Today's call is being recorded. If you have any objections, you may disconnect at this time. All participants are currently in a listen-only mode until the question-and-answer session of today's call. I would now like to turn the call over to our host today and that's going to be Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello, I'm Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's 50th 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 and Dr. Kristian Roth both from CDRH will provide a brief update. Following opening remarks, with will open the line for your questions related to the development and validation of tests for SARS-CoV-2. Please remember that during this town hall, 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. Fifty town halls that was a milestone I didn't know I was trying to hit. So seriously though, the FDA has found this to be very helpful as a way to engage with stakeholders and hopefully you all have also found this to be very helpful. So thank you again for joining us this week and for the past 50 weeks for many of you.

So, I have a couple of updates today and then we'll go through the questions that were sent ahead of time and then open the lineup for live Q&A. So, last week right after last week's town hall, we issued EUAs for five serial antigen tests. I guess it was UA3 test one of them in a few different configurations, but five EUAs. We've issued another serial screening antigen EUA, I believe, the day after. And since then we have also issued one serial screening molecular test EUA.

So, those are all based on the serial screening supplemental template that we issued a couple weeks ago that we talked about on this call. And we're pretty excited that developers have been picking that up and we've been able to get several authorizations out under that approach and we know that there are other developers that are pursuing that and we look forward to keeping the momentum going there. We think this will be very helpful for the serial screening program that we know are being stood up around the country.

We also since the last town hall issued an EUA for the first antibody test that can be used with home collected specimens. So that test can be used with (unintelligible) blood spot samples and since two allowed for processing. And then just this week our COVID testing basic front page was updated. So that's available on the FDA website and provides a lot of good background information on Coronavirus testing and the different types of tests, when to get a test, things like that.

Probably all things that the developers who are our typical audience on this call already know, but it's a good page to share with folks who may be interested in that information.

So with those updated, I will move onto the questions that we got by email. Since started out, we got a couple of questions about validation studies for multi-analyte molecular tests looking at coronavirus as well as flu, RSV, et cetera. And the concern with acquiring archived influenza specimens particularly is one of the questions that we got. And asking whether FDA would consider the use of contrived influenza specimens for an EUA submission with the expectation that a perspective clinical study would be conducted post-authorization.

We do know that there's been some concerns with the ability to obtain archived specimens. And if you are, you know, running into that roadblock, we encourage you to reach out to us to discuss your specific situations. But for the most part, we do continue to recommend the use of archived positive and negative clinical specimens rather than contrived.

We know that, you know, they may be difficult to obtain, but that perspective testing is going to be with those, with actual clinical specimens is going to be generally what we expect for those types of studies. We have another similar question about studies for the same type of tests and also getting into studies that would support a potential 510K. We do generally recommend that you evaluate clinical performance of those multi NI tests with a perspective clinical study.

And for EUA, we have indicated that a single site using archived specimens would be sufficient and you may want to consider concerning the sample positivity due to possible degradation over time.

There was also a question in that same one about specimen types and whether it was okay to use a single swab to obtain an OP sample and then also an NT sample so that the specimens tested would be OP/NT. And actually whether that would be acceptable for a 510K submission. So we do accept specimens that are a mixture of a sample that are (unintelligible) specimens, but if you're seeking an upper respiratory claim for individual specimen types, we do recommend that each specimen is individually correct and we generally consider NP swabs, the pharyngeal swabs to be most challenging upper respiratory matric.

Kris, do you have anything to add on those questions about molecular analyte tests?

Dr. Kris Roth: Sure, I would say there's a long documented regulatory history for flu and RSV and those types of panels and there's numerous deficient summaries that are publicly available for analytes that are not in the SARS-CoV-2 and there's a lot of information there and a lot of questions can be answered by previous decisions on this.

Toby Lowe: Thanks, Kris. That's a really good point that all of that information is available on our website and it's very helpful for the test developer.

So moving along, we have a couple of questions about the biospire de novo. We do have a question about whether the decision summary for the biospire will be posted and it will be. We unfortunately are not able to comment on the timeline. We are working on getting that out. I'm sure everyone is aware

that decision summaries for de novo sometimes takes some time to get posted. But we are working to expedite that one.

We also briefly discussed just a little bit last week but there's a question about the biospire being challenging to have access to as a predicate since it's the only de novo currently in the - the only predicate for a future 510K for a SARS-CoV-2 test. And we did talk last week that you can use an EUA authorized test as a comparator for your clinical studies even though biospire would e your predicate for the submission itself.

The question also was asking about whether there are other options such as testing to the reference panel to support a 510K. And while we do consider another EUA authorized comparator to the acceptable we do really want to see the perspective clinical study in your 510K submission. You can also include reference panel results and the clinicals that are from your authorized EUA if you have one and leverage those but they would not be, generally they would not be considered to be sufficient on their own to support a 510K clearance.

Kris, anything to add on that one?

Dr. Kris Roth: Sure, I think, you know, in this time between while we're waiting for that decision to maybe be posted, you know, the granting letter is posted and it does have the special controls noted for these types of tests and you can take a look at those special controls and design your studies to mee those requirements as well.

Toby Lowe: Great, thanks. So moving on, we have some questions about asymptomatic screening. And particularly related to the supplemental template that we put out and asking about the post-authorization validation studies. Generally we would want to see your proposal for a serial testing plan and the post-

authorization study in your EUA request. And we would discuss that with you during the review particularly the statistical plan which is what this question is focused on. We would want to go through that with you in detail. So we can't really get into too many details on the specific book on this call because it will be specific to each individual test and each approach that you're looking to take as a test developer to validate your test.

And then along the same lines with serial screening using that supplemental template, we have some questions about the additional data that we would expect to see. And so, you know, the way that supplemental template is laid out is that it is there as an approach sot that if you have symptomatic validation data and you've been authorized for testing symptomatic individuals, that template allows you to expand your or to request expanding your claims to asymptomatic serial screening without doing that additional asymptomatic validation ahead of time. That would be the post-authorization condition.

So generally, you know, for most cases as long as nothing else is changing, so you're not changing your patient population such as point of care to at home or other changes that might impact the usability. We would not expect to see additional validation clinical or usability as long as nothing is changing except for going from symptomatic to serial screening. And we could discuss that on a case-by-case basis if there are things that are changing whether there is additional data that we would need to see.

And then there is another question along the same lines asking about removing the prescription requirement when going from prescription to over-the-counter. We do have recommendations in the template for OTC use that's in the nonlaboratory use template for molecular and antigen tests. The supplemental template that we've been talking about also can support this

move from prescription to over-the-counter because one of the requirements for over-the-counter is that there is an asymptomatic claim.

We generally would not authorize a test for over-the-counter use if it does not have that broad asymptomatic screening claim since that's how we would expect it to be used over the counter. And so if you are able to use the supplemental template to get that asymptomatic claim, as long as everything else about your test is appropriate for over-the-counter use and has appropriate labeling, usability user comprehension for a lay user then we would be able to do that over-the-counter labeling for you as well in that same EUA request.

All right, we have a question about developing a point of care molecular diagnostic leader and (unintelligible) system and what the recommendations are for sensitivity specificity and validation testing. Also for (unintelligible) testing in that situation, so pooled sample collection. So we do include validation recommendations in the molecular diagnostic template for point of care testing and for pooling. We have not as of yet authorized any tests for pooling at the point of care and so we would want to have some further discussions about that and how you intend to implement that. So tat we can make sure that it is a plan that is appropriate for a point of care setting.

But generally, we would encourage you to take a look at the template to look at the validation recommendations that we have there for the number of specimens and the validation approach and if you have alternative validation methods that you'd like to discuss you can reach out through a EUA to discuss those.

And that question was also asking about whether pooled testing is considered a diagnostic or a screening. And I do want to clarify that we, you know, we have talked a lot about diagnostic testing and screening testing. And we talk

about screening when we're talking about testing asymptomatic individuals that have no reason to suspect that they have COVID-19 and doing that broad screening to capture those asymptomatic individuals.

But really a screening test is a subset of a diagnostic test. It is looking to get an individual result and to identify individuals who have SARS-CoV-2 present and has that, had COVID-19. So it is considered to be a diagnostic test from a regulatory perspective. We just generally refer to it as screening to be clear about the implication that we're talking about with the patient population.

And Kris, did you want to add anything there about this question about point of care testing or pooled testing?

Dr. Kris Roth: No, it's just that I think you stated it correctly. Our, you know, we have an open approach. We haven't kind of done it yet, but that's something to work on the future, thanks.

Toby Lowe: Great, thanks. We have a question about how presumptive positive results should be treated in calculating the NPRA, NPPRA and a clinical study and whether they should be treated as positive or inconclusive. Generally we would recommend, I think this question is talking about the results for the comparator test. So generally we would recommend that you follow the result interpretation of the test that you're using as the comparator. So the EUA authorization for the comparator test should have a result interpretation section that indicates how those results would be considered.

And I think in the, Kris, you might want to touch on how we have those (unintelligible) table. I think we do include presumptive positives as positives in the 2x2 table for calculation for PPA. Is that right?

Dr. Kris Roth: Correct, yes.

Toby Lowe: Great. Okay, the next question is asking about over-the-counter corrections with testing in a lab for PCR testing. So this would be nonprescription, direct to consumer home collection and whether asking about what template to use. So we do have nonprescription direct to consumer home collection tests that we have authorized. And the authorization documents on our website would be a great starting point for looking at how those were laid out and what we looked at.

And the question is also asking about whether they can use a hybrid of the over-the-counter home collection kit and molecular PCR templates. And that is absolutely a good way to go. Those templates are on it to be complementary since there are situations such as this one where pieces from each of them would be appliable and we would suggest that you do pull the parts that are applicable from each of those and include them in your EUA request when you submit them.

So question is also asking whether the new supplemental template for a serial screening test can be used. And yes it also can be used in that situation.

And asking about how many participants are required for an over-the-counter usability validation. There is a usability study recommendation in the nonlab template but that really is focused on testing that are completed - that are performed completely outside of a lab. Those fully at home tests and that recommends, I believe, 100 participants for OTC use. For home collection, you can take a look at the home collection template which I believe is recommending for e-Participants. If you have further questions about your specific situation, please reach out.

And I believe that is all of the questions that we've prepared ahead of time. And so we can open things up to live questions now.

Coordinator: If you would like to ask a question at this time, you may press Star 1. Again to ask a question at this time, press Star 1. Our first question will come from (Shannon Sharp). Your line's now open.

(Shannon Sharp): Good morning, this is (Shannon Sharp) with user-wide consulting. So I have a very specific question about the human factor validations testing or usability study for OTC. So historically when we're performing human factors validation testing we performed self-selection test cases to demonstrate that layperson understand the outer packaging and aren't purchasing the kit when they shouldn't. Do they understand that the product should not be used for children below two years of age?

So does the agency expect that we run this test case for all users in the study, all 150 participants? That is 50 participants, 50 teams including users who don't typically need this information? Because we're actually finding in our studies that adolescents who typically are not shopping for one-year-olds they generally are unsuccessful with this test case because they don't have a representative level of motivation or attention similar to what you'd see with parent participants or adults.

So in summary, does the FDA expect that we perform self-selection testing in general? First question and then second, can we proceed with not testing adolescents for test cases that they would very rarely perform?

Toby Lowe: That's for that question. So, you know, with are interested in user comprehension and making sure that the packaging is understandable for a lay

users. I think we are open to approaches that are reasonable in the emergency setting. And if you have a particular proposal for, you know, what you think is reasonable based on the labeling that you have, we would be open to discussions about that and considering the approaches that you are proposing.

I think if you have historical information showing that teenagers typically don't understand this, but also don't need, that's something that you could include in your submission. I think that would be a very good conversation to have in a pre-EUA specific to your situation so that we can consider the plan that you in place.

(Shannon Sharp): Excellent, thanks so much.

Coordinator: Our next question will come from (Stan Tally). Your line is no open. (Stan), please check your line. Your line is open. Okay, our next question will come from (Ray Vanzulas). Your line is now open.

(Ray Vanzulas): Hello, thank you for taking the question and thank you for continuing this series. My question is first some context, my company is developing devices, molecular devices for COVID testing that speak to increasing scale capacity of VGR tests in a 24-hour period and a variety of solutions are in development.

The specific question I had related to that is whether FDA would be open to consideration in either a resubmission or perhaps other kinds of discussion to consider clinical performance data that was generated outside of the US. Specifically we have a device combination that's been in use under the CEIBD mark in the UK since December. And significant clinical data is being generated and is now sitting with a peer-review publication.

And we would like to have an opportunity to discuss those results and an opportunity to perhaps discuss an efficient path to authorization for a similar device combination in the United States. Thank you.

Toby Lowe: Great yes, so we have accepted data from outside of the US for clinical studies. We generally for point of care want those studies to be done in the US because we have found some issues with making sure that point of care studies done outside the US are truly applicable to a US setting. So in that case we would want to see them done here, but for central lab tests, we would definitely be able to considering data from outside the US and we would be interested in talking to about that approach and how, you know, how it is applicable to a US population.

You may also want to consider including in your submission some information on the prevalence rates in different, you know, where it was studied as well as the circulating variants. Because we may want to see how the different variants are addressed if there are different variants circulating in the place where the study was performed versus here in the US. Kris, do you have anything to add there?

Man: No, it's an interesting question especially, you know, the variants aspect of it. You know, as we see more and more genetic variants emerge, you know, this question may become more applicable going forward.

(Ray Vanzulas): Yes, so just in terms of logistics, would it be best to put all of that together in a presubmission format and then request a teleconference discussion on it?

Toby Lowe: I think that you could include it all in your submission. Kris, did you want to see a presub for that or just include it in an EUA request and we could discuss any issues after further review?

Dr. Kris Roth: I think at this point we prefer to see the EUA request and if you have existing data, you know, that would be helpful to take a look at as well.

(Ray Vanzulas): Okay, very good, so straight to the request. Thank you very much.

Coordinator: Our next question will come from (Susan Sharp). Your line is now open.

(Susan Sharp): Hi, thanks Toby. Quick question, if you're looking to add swab pooling to an existing EUA, can this be done a supplemental submission for the existing EUA and which, you can use the molecular pooling template for the swab pooling as well. Is that correct?

Toby Lowe: Correct, yes. If there's an existing EUA and you want to add swab pooling that definitely can be done through a supplemental EUA request using the name after a template with the pooling information in there. And if you have, you know, alternate approaches to validation that you're looking to consider, you can reach out with those as well.

(Susan Sharp): Thank you.

Coordinator: Our next question will come from (Annie Bright). You line is now open.

(Annie Bright): Hello, thank you for taking my call, we had a question for antigen tests the have been recently approved and we've heard they all have mobile apps and that the mobile appreciate would be required four months after EUA approval's been achieved. Is this correct? And also, we wanted to confirm the requirement for the mobile app which is just to basically ensure that the individual would be able to send the data to their physician. Are there any other requirements for the appreciate?

Toby Lowe: So the appreciate is something that we've included as a post-authorization condition for some of - for tests that did not have reporting capabilities generally. So this is, for the most part, related to having the ability to report results to public health authority. So for laboratories there is a requirement for labs to report results to public health authorities, that requirement does not exist for home tests. But obviously reporting to public health authorities is very important for monitoring the pandemic.

So the mobile app is one way to enable that reporting from a home test to the public health authorities. So that's something that we have not required preauthorization as an authorization requirement for these at-home tests but we have worked with the developers to put a plan into place to get those, to get that reporting capability worked out within an agreed upon time frame after authorization. And I believe that's what you're referring to with those mobile apps.

(Annie Bright): Yes, and then basically because you know, we currently are a company that currently doesn't have any you know, software engineering, anything like that. So we would be, you know, trying to work with a company. So we're trying to figure out like which other requirements would we have to look at for the appreciate. So that's mainly reporting, right? If one capability and sending the data to the physician or directly to the state?

Toby Lowe: So reporting to the public health authorities, I believe is what we're generally focused on there although reporting, you know, the ability for an individual to report to their personal provider is also beneficial. But the public health reporting is really the focus of those post-authorization conditions. And the requirement for those are something that we can work with you on during the review. It's not something that you necessarily have to have fully worked out

before you come in. You know, we really want to get tests out, get good tests authorized as quicky as possible and that's one of the reasons that this is, you know, being added as a post-authorization condition rather than something that we're requiring upfront because we don't want that to hold up the authorization.

(Annie Bright): So, we wouldn't have to worry about incorporating it into our clinical studies or our usability studies.

Toby Lowe: We would discuss with you during your EUA whether there would be a need for additional usability post-authorization for that.

(Annie Bright): Okay, I see.

Toby Lowe: As long as it's not needed to perform the test in your initial authorization, we wouldn't expect to see usability with it at that stage.

(Annie Bright): Okay, I have one more question. So regarding stability testing, stability studies for home use and also for professional use, is the expectation that the testing should be done in the United States or can we do it outside of the United States if you were having issues with like customers and everything if it's manufactured in China?

Toby Lowe: You said this is for stability studies?

((Crosstalk))

(Annie Bright): No, stability.

Toby Lowe: Okay, so for stability that can be done in a lab.

(Annie Bright): Can you - so it doesn't matter where the lab is?

Toby Lowe: Right, that can be outside the US.

(Annie Bright): Okay.

Toby Lowe: It's just the clinical and the usability that we really want to see in the US or point of care tests.

(Annie Bright): All right thank you very much.

Toby Lowe: Sure.

Coordinator: And our next question will come from (Richard Montega). Your line is now open.

(Richard Montega): Yes, with will be running a perspective study for an expanded respiratory panel. And since we already have an EUA authorized, a Coronavirus test with a decent limited detection. We're at 1800 ND per mil. Is there any problem with us using our own test as the comparator for the SARS-CoV-2 portion of the study?

Toby Lowe: Kris, do you want to talk about this one?

Dr. Kris Roth: Sure, for a 510K study, I think the evidence or the performance evaluation is a little bit different than the EUA.

(Richard Montega): Yes, we're assuming we'll be running perspective study for 510K.

Dr. Kris Roth: Sure for your SARS-CoV-2 analyte and other analytes, is that correct?

(Richard Montega): Correct.

Dr. Kris Roth: So you'd have a comparator method that would cover all of the analytes in your study and for SARS-CoV-2, I think we would likely recommend two out of three EUA tests. So performing three EUA tests on all samples and if you know, two out of three positive defines a positive. It's likely what we would recommend for that.

(Richard Montega): Okay, thank you very much.

Toby Lowe: And this is something that, you know, as you are heading toward a 510K that we do recommend that you come in with a presubmission rather to discuss that study design.

(Richard Montega): Okay, thank you.

Coordinator: Our next question will come from (Susan Sheldon). Your line is now open.

(Susan Sheldon): Hi, thank you Toby and Kris for doing this. I have one question about the antigen template. It describes the comparator and when you look at what's posted on the webpage, it's difficult to figure out which one meets all those conditions. So I did the best I could and came up with clarified COVID-19 test kits, manufactured by Quadrant. Is that an acceptable comparator for an antigen test?

Toby Lowe: Yes, there is a clarify test kid is an appropriate comparator. And we have as we've mentioned, I think, on the call before (unintelligible) for others awareness. If you do have questions about what is an appropriate comparator

or if a specific test that you're looking to use is an appropriate comparator, you can send that into the EUA mailbox and we and get back to you on that as well through that mailbox.

(Susan Sheldon): I appreciate it, thanks.

Coordinator: Our next question will come from (Mark Delzecco). Your line is now open.

(Mark Delzecco): Good afternoon Kris and Toby. This is Mark. I have an administrative question related to the periodic CDRH emails that are put out regarding the status of various diagnostic EUAs. They're usually categorized into four separate categories. New, which obviously what that is. Reissue, updated and revised EUAs and I'm often asked what the differences are between those and quite frankly I don't know what they are. So hoping you could describe what the differences are between those three categorizations.

Toby Lowe: So I'd have to take a look at the specific email to know exactly which emails you're referring to. But generally, you know, new is sort of obviously. Reissue is typically when we reissue the complete letter of authorization. That's usually done for things like an update to the intended use. You know, whether it's going from symptomatic to asymptomatic or adding pooling, things like that, that are large changes would be done through a reissuance of the letter.

Updates and revisions, I'll see if Kris might have more on the difference between those two, but there are certain changes that we can grant through what we refer to as a granting letter. And those are included on the EUA table as you look at a specific test. There's often a little plus sign next to the row and if you click that some of them will have other documents and those will be a letter granting an EUA amendment in many cases.

And a lot of times those are for smaller changes like an update to the labeling that would not change the intended use in any way. We also sometimes update labeling for things like adding the reference panel results. And so those are some of the changes that would get updated on our website, but don't require a reissuance of the letter of authorization.

Kris, I don't know if you have any other thoughts on the difference between updated and revised.

Dr. Kris Roth: I don't, but I think they generally fall into the category of, you know, the letter.

((Crosstalk))

(Mark Delzecco): Sorry. I'm just curious because people ask me that all the time and I don't know the difference, so but thank you. I appreciate the information.

Toby Lowe: No problem.

Coordinator: Our next question will come from (Sandy (unintelligible) Stevenson). Your line is now open.

(Susan Katy Stevenson): Hi, this is (Susan Katy Stevenson). Toby and Kris and all of the folks at FDS thank you so much for all the hard work that you're doing. We're working with a small company and I think I know the answer to this question, but they have specifically asked that we ask the agency the following. Whether or not there's an EUA pathway to obtain quote unquote pan EUA authorization for a sample home collection device. Where the collection device has demonstrated the required performance with an authorized EUA

molecular test. And if they wanted to expand it to be used with other EUA authorized molecular assays could that be done without additional testing?

Toby Lowe: So, I'm not sure that I fully understand the questions. So let me give a little bit of information and ask for a little clarification. So we have issued a couple of EUAs for collection devices for molecular testing. Those so far have been for saliva. An in that case, those were issued specifically because there was not any legally marketed collection devices for the collection of RNA in saliva.

And so those were issued under EUA with fairly general indications for molecular testing. And then the assays are, you know, authorized for use with saliva using one of those.

So I'm sure if that's the type of situation that you're referring to or I'm not quite sure what you're getting at with a pan SARS-CoV-2 claim for a collection device.

(Susan Katy Stevenson): Yeah, I think that you've answered the question.

Toby Lowe: Okay, great and, you know, I don't know if the device that you're referring to is for saliva or something else. You know, depending on what it is for and whether there is you know, a need for it, from you know, from an emergency perspective would be one of the factors that we would look at as to whether or not it would be considered for an EUA. You know, for example a lot of swabs available and they are 510K exempt generally. So that might be an area that we would consider for an EUA depending on the specific situation and the specific device.

(Susan Katy Stevenson): It would be for something like a dried blood spot sample collection production.

Toby Lowe: Okay, and I know that for dried blood spot, there are some assay-specific issues. So we would have to look at the specific validation and whether there, you know, is a broad claim that could be considered or whether it would need to be validated specifically with each test. But that's something that we could have further conversations about specifically about that.

(Susan Katy Stevenson): Okay, great, thank you.

Toby Lowe: Sure.

Coordinator: And our next question will come from, I believe it recorded their name as (Von Say). Their line is now open.

(Von Say): Yeah, hi. Thanks for taking my call. I have a client that's basically developing an at-home COVID-19 neutralizing antibody test. And the question really relies around the neutralizer comparator method that is recommended in the template, the EUA template. Essentially the client is asking because of the current methods that are recommended if the plaque reduction neutralization test or the focused reduction neutralization testing and it requires, you know, cells and virus. Can they use for neutralizing comparative methods something that's recently been EUA, the gen script C-pass method?

Toby Lowe: So unfortunately, I am not an expert on the serology tests and don't have anyone on from the serology team today. So I don't know that I'm going to specifically be able to answer the question. But I think that it's something that we would want to discuss in a pre-EUA. But generally, I think that is not a comparator that we would think is appropriate. So we would want to have

further discussions. Send that into the mailbox and we could get one of the SMEs from the serology team to get back to you on that.

(Von Say): Okay, I already did submit that as a question to the IDT team.

Toby Lowe: Okay, great then I'm sure that if they haven't yet, they will get back to you shortly on that one.

(Von Say): Okay, super, thank you very much.

Toby Lowe: Sure, sorry I can't give you more on that one, but I know the SMEs will be able to.

Coordinator: Next question will come from (Sarah Burlucky). Your line is now open.

(Sarah Burlucky): Hi, on a previous call, you had said that unsupervised self-collection of anterior nasal and (unintelligible) swabs in a healthcare facility didn't require an FDA authorization. My question is does that also apply to saliva collection within a healthcare facility?

Toby Lowe: So within a healthcare facility, for self-collection, unobserved, we do think that you should consider the usability and the appropriateness of lay collection without observation. And we would expect that to be part of your validation. So if that's the intended use that would be how you should validate the test,

But we do not consider that to be equivalent to home collection because it does not have the same, you know, some of the same issues in terms of (unintelligible) transport and shipping and things like that.

(Sarah Burlucky): Okay, so that could be applied to any sample types that we appropriately validate?

Toby Lowe: That's correct.

(Sarah Burlucky): Thank you.

Coordinator: Our next question will come from (Shannon Clark). Your line is now open. (Shannon)?

(Shannon Clark): Hello, this is (Shannon Clark) again, (unintelligible) Consulting. I just had a question. If we are planning to get OTC designation but we would like POC designation in the meantime, can we complete the clinical evaluation for OTC and submit that in lieu of point of care clinical studies with healthcare providers? So use lay user data as an input to a point of care only submission as we're working to complete that human factors study for OTC?

Toby Lowe: So, let me make sure I got the question right. So you have a test that is designed for over-the-counter at home testing but you want to start with point of care, is that right?

(Shannon Clark): Yes, so first of all just get that point of care authorization and then three months later once the human factor study is done, then we would pursue OTC.

Toby Lowe: So generally, yes, you can. But generally we would prefer that tests that are designed for at home use be submitted as that complete submission. You know, obviously we have a lot of submissions that we're working through and from a resource perspective, it is more beneficial both for, you know, for FDA reviewers and for the public health to have those tests available as quickly as possible. And so it's a much more streamlined process for us to be able to

review the complete dataset and the complete submission all at once and go through straight through that so that over-the-counter at home testing authorization which is really designed for and will be most beneficial in that setting.

(Shannon Clark): Okay.

Coordinator: Our next question will come from I believe they recorded their name as (Talisha Lee) or either (Alicia Lee). Your line is open.

(Alicia Lee): Hi, thanks for taking my call. I wanted to get clarification on the antigen template regarding multi-analyte panel. So it's stated that if your device has been previously FDA clear for influenza or other respiratory pathogens, you should also test at least 10 retrospective positive clinical specimens of each previously clear analyte. So our (unintelligible) assay is a POC antigen test. I wanted to double check that this requirement can be met with in-house side-by-side analytical testing?

Toby Lowe: So you're looking to do the validation for a previously cleared or basically for adding SARS-CoV-2 to a previously cleared point of care antigen test? That was previously cleared for flu or other respiratory analytes?

(Alicia Lee): Yes, previously cleared for flu. We're wondering if that particular template requirement of testing of at least 10 retrospective positive clinical specimens if that is met for analytical testing or is it speaking to a clinical study?

Toby Lowe: That is for analytical.

(Alicia Lee): Okay, and then just to double check, so is there any additional clinical evaluations required for the previously cleared influenza part of the multi

analyte panel? Or are we just able to reference previously clarified 510K data?

Toby Lowe: So we would want to see those retrospective clinical specimens which we talked about, testing in-house. And then you would be able to leverage information from your previous clearance.

(Alicia Lee): Okay, thank you very much.

Coordinator: And as a reminder, if you'd like to ask a question, you my press Star 1 and record your name clearly for question introduction. Our next question will come from (Roxanne Chain). Your line is now open.

(Roxanne Chain): Thank you. Yes, we would like to add saliva as a sample type to our existing EUA and understand we need 30 pared saliva and NP in the clinical validation study. So my question is for the saliva samples, currently we have a mixture of broad saliva as well as saliva collected using an FDA approved device. And counting them together we will have more than 30. Is this something that's acceptable to the agency? Or we have to have you know, 30 raw saliva and 30 saliva collected using an approved device?

Toby Lowe: So first question would be when you say an approved device, do you mean one of the, so a collection device that has an EUA authorization?

(Roxanne Chain): Yes, that's correct. I'm sorry, yes EUA.

Toby Lowe: Okay, so we do, you know, we want to see the test validated the way that you're intending for it to be used. So if you are intending for the saliva specimen to be collected using one of those authorized collection devices, then we would want to see the paired specimens in that device. If you're

intention is for the test to be used with raw saliva, then we would want to see it validated in that way.

(Roxanne Chain): So that means that you would like to see - well our intention really is to validate raw saliva. So you would like to have 30 paired raw saliva with NP, then?

Toby Lowe: That's correct.

(Roxanne Chain): All right, thank you.

Toby Lowe: Yes, we want the 30 paired to be with the specimen as it would be intended to be used.

(Roxanne Chain): Understood, okay thank you.

Irene Aihie: Thank you, Toby. That will be our last question. I just want to thank everyone for participating today. This is Irene Aihie. We appreciate your participation and thoughtful questions during today's town hall. Today's presentation and transcript will be made available on the CDRH learn webpage at www.FDA.gov/training/CDRHlearn by Friday, April 16. If you have additional questions about today's presentation, please email CDRH-EUA-templates@fda.hhs.gov.

As we continue to hold these virtual own halls, we would appreciate your feedback following the conclusion to today's virtual town hall. Please complete a short 13-question survey about your FDA, CDRH virtual town hall experience. The survey can be found now on www.fda.gov/cdrhwebinar.

Again thank you for participating. And this concludes today's virtual town hall.

Coordinator: This concludes today's virtual town hall. You may now disconnect. Thank you for your participation on today's call.

END