

FDA Virtual Townhall

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 until the question and answer session of today's conference. At that time you may press star 1 on your phone to ask a question. I would like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference over to Ms. Irene Aihie. Thank you. 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 59th 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, and Dr. Kristian Ross, both from CDRH, will provide a brief update.

Following opening remarks, we 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. Thanks everyone, for joining us again this week. One update

that I have before we get into the Q&A, is late last week we updated the Web page on SARS-CoV-2 viral mutations and the impact on COVID-19 tests. We added new information about a potential impact on the performance of the MESA Biotech Accula SARS-CoV-2 test, due to a genetic mutation at specific positions in patient samples.

That test was already listed on that Web site so it's not a new test that we've identified in the impacts from viral mutations. It's just an additional mutation that we have identified that impacts that test. Same as in the previous communications about the impacts on COVID-19 tests, we do not think that this impact is significant. But we are providing this information out of an abundance of caution and we will continue to do so, updating this Web page and sending out information about impact of viral mutations, as additional information comes about.

And with that, I will move onto the prepared Q&A that we have. So the first one is about antigen tests regarding using fresh samples and that FDA has generally indicated a preference for fresh samples for supporting antigen tests. However, this inquiry notes that there's a growing complexity of obtaining fresh positive samples and that the sponsor would like to freeze samples collected during a post-EUA study and then use frozen samples to support development of another assay for an EUA submission. And they're seeking FDA feedback on that.

And then along with that, they're also asking about achieving the sample sizes currently discussed for post-authorization studies and the difficulty in achieving those sample sizes due to dropping positivity rates and rising vaccination rates in the US. So they're asking what other options are available to reach those post-EUA study numbers.

So for the first question about banked or frozen samples, we do generally consider those to be acceptable specimens for clinical validation. But we do not recommend these samples to support at home testing either for prescription or over the counter since we do need to evaluate not only how the

users perform the test, but the performance impact of specimen collection when self-collected or when lay users are collecting specimens from other individuals. We would also generally want to see an evaluation of the impact of the freeze thaw cycles, I believe, on those specimens as part of your evaluation.

And then for the post-authorization study those are typically prospective studies and we do expect sponsors to attempt to fulfill the conditions of authorization. If they - if the sponsor is having difficulty obtaining additional prospective positives then we would ask that they email their review team, describe the situation and request an extension and/or, you know, propose other options for discussion.

And then this question did also ask about data collected outside of the US. And so we do think that that may be feasible, but we would want to look at the specific details of the sponsors' proposals. So you could reach out to the review team to discuss that specifically. The next question we have is regarding any guidelines that the FDA might have for an NGS test for long COVID.

And so generally the tests that we have authorized so far are intended for use in the detection of SARS-CoV-2 virus as an aid in the diagnosis of infection with the virus. If you're developing an NGS test for that type of indication, we would want to engage with you through a pre-EUA since the NGS validation is a little more nuanced than some of the other test types. And we would prefer to discuss with you about your specific test and claims and technology. So we can work with you on a validation approach that's most appropriate.

And in terms of a test specifically for long COVID, we are interested in learning more about the etiology and the reports of individuals who have been stricken with COVID-19 but don't recover fully over a period of weeks. And if you're developing a test to diagnose or monitor long COVID, we would also be interested in discussing that through a pre-EUA. (Kristian), anything you

want to add on that one?

Dr. Kristian Ross: No. I think, you know, as Toby mentioned, the data and, you know, studies are still kind of in progress and data's being generated for these types of individuals. And if there are approaches that, you know, folks have for kind of predicting this or, you know, helping this kind of area then I think we're definitely interested in speaking with you in the pre-EUA.

Toby Lowe: Great. Thanks, (Chris). The next question that we have is along the lines of questions that we've had on previous town halls. This is about FDA's policy on SARS-CoV-2 EUA submissions and, you know, sort of the timeline for the public health emergency. So they're asking when FDA will stop accepting new EUA applications; when FDA will stop accepting amendments to existing EUA products, when the current EUAs will expire; how long EUA products can be distributed after the EUA expires; and will there be a grace period for EUAs transitioning to 510(k)s?

So, you know, we have talked about this a bit before. We are still accepting EUA requests both for original EUAs and supplemental EUA requests for amendments to previously authorized tests. We don't have a timeline that we can comment on for a transition plan, but we have previously announced that we are - the center is working on a transition plan for devices offered under EUA. And that's a guidance document that's included on the center's guidance priority list for FY '21. That's - the title on that priority list is the Transition Plan for Medical Devices Distributed Under Enforcement Policies or Emergency Use Authorization during the COVID-19 public health emergency.

And generally, unless it's revoked, an EUA is in effect until the public health emergency is terminated. And that is a, you know, specific termination by the Secretary of HHS that goes along, you know, sort of the end of the declaration that the Secretary makes at the beginning of the public health emergency, to allow FDA to start using the EUA authority. And so the, you know, at some point in the future the Secretary then terminates that emergency. But that is

not something that we would expect to happen for quite a while.

You can see that there are previous public health emergencies that still have not been terminated, looking at Zika and Ebola as examples there. So, you know, while we can't anticipate when the public health emergency will end, we, you know, we can make clear that we're committing to helping to ensure that the public has access to a wide variety of test options for COVID-19. And we do continue to review EUAs and we plan to continue to do so as long as there is a public health need for that to be done.

Regarding conversion to 510(k)s, we have mentioned the last few times on town halls as well as in previous town halls, that anyone looking to submit a 510(k) submit a pre-submission for - so that we can discuss your proposed validation approach to make that process go as smoothly as possible. The next question we have is let's see, about a molecular point of care COVID device for an EUA. This company intends to submit an EUA request and is asking about a notification letter for the manufacturer to commercialize the device while the EUA is under review.

So just to clarify, there are - this question appears to be referring to the notification policies that are included in the guidance document, the policy for Coronavirus Disease 2019 Test during the public health emergency. And that policy guidance document does include the notification policies that, you know, puts together a process for a manufacturer following completion of their assay validation to notify FDA that their assay has been validated and that they intend to begin distribution or use of the test.

Generally, FDA would acknowledge receipt of the notification and add the name of the test developer and the test to our Web site listing. We do have a list of all notified tests on the FAQ pages. And, you know, in the guidance document it outlined a process for the test developer to submit a completed EUA request within 15 business days of the notification to FDA that the assay has been successfully validated. And if that's not done we generally removed the test from the Web site and may take additional action as appropriate.

There are a couple of important things to note here. One is that submission of an EUA request is not the same as notifying under the policies in the guidance. A test developer that intends to use the notification policy must specifically notify per the process outlined in the guidance and should not assume that they're considered to be notified simply because they submitted an EUA request.

And then another thing that I want to note is that this question specifically mentioned the point of care device. And the notification policy is specific to tests being used in high complexity CLIA-certified laboratories. Tests that are not yet authorized are - under CLIA, are limited to use in high complexity CLIA-certified laboratories. So that would generally not apply to point of care devices unless that point of care setting is - falls under a CLIA-certified laboratory - a high complexity CLIA-certified laboratory certificate.

All right. The next question we have is about quantitative viral load molecular tests for COVID-19. And this would be a test that would measure viral count per milliliter, not a test that would just report the CT count. The question is asking for FDA's viewpoint on the medical importance or usefulness of such a test, whether we would support or encourage the development of such a test; whether it be used for screening similar to other tests for other patient populations that we would recommend it being for, as well as the review priority that, you know, we're - that this would fall under.

So generally now that an international standard is available, it is possible for a meaningful quantitative test to be developed. And we are glad to engage in discussions about validation of such a test. There are limited guidelines for use of this type of information. So we would want to engage in a discussion of the appropriate intended use and we would, you know, that discussion would need to be in the context of the specific test setting and technology being proposed.

So we would encourage you to submit a pre-EUA so that we can discuss those

options with you. And (Chris), do you want to add anything on that one?

Dr. Kristian Ross: Yes, thanks. I think there's just a lot of different options in this - for this type of intended use. And so unfortunately I don't think we can really provide some specific answers to these questions. There's just too many different ways to go. But certainly having the international standard will help tremendously. And I think we're ready to engage. Thanks.

Toby Lowe: Great. Thanks, (Chris). And that is all the prepared Q&A that we have. So we can open up the lines for live questions.

Coordinator: Thank you. If you would like to ask a question by phone, please press star 1, unmute your phone, and record your name clearly. Your name is required to introduce your question. If you need to withdraw your question, press star 2. Again, to ask a question by phone, please press star 1. Our first question comes from Shannon Clark. Your line is open.

Shannon Clark: Good morning. This is Shannon Clark with UserWise Consulting. We specialize in human factors testing, so I'm a little unclear on some of the requirements surrounding clinical evaluation testing for over the counter use. In human factor testing we would never ask a - we never trained participants for OTCs, we never ask them to please follow the instructions for OTCs. And we also wouldn't make them aware that they can follow each step with an app during OTC use, just to simulate a realistic use case.

But in recent responses to the update it seems like what we can do in the clinical evaluation for OTC is to ask them to please read the instructions prior to proceeding into their session. And so this is a layperson in the clinical evaluation with self-testing. Would it be appropriate to ask the participants to please read the instructions and follow each step of the instructions, throughout that clinical evaluation, such that the scope is whether the instructions are understandable by intended users?

Toby Lowe: Thanks for that question. I know that there are, you know, some - there is

some information in EUA templates about the study design, and I know that we have also had some, you know, specific discussions with sponsors about particular study design questions. I believe that we would want the study design to be as close to a true use case as possible. You know, generally that would not include, you know, verbally telling an individual to specifically read the instructions and follow each step. But I will ask (Chris) to weigh in on that because he's probably been in more of those study design conversations.

Dr. Kristian Ross: Yes. I think I'd agree to that. You know, the key take home, you know, message that Toby is trying to, you know, get across here is that it needs to, you know, simulate a home use environment as much as possible. And clearly, you know, any direction that user's going to get to look at something, follow something, do this, don't do that, I mean that's, you know, something that's not going to be available to that person, you know, when they buy it off the shelf and take it home.

So again, you know, this kind of depends on the details of what the study is. You get a, you know, simulated home use environment, because it's actually home use. So I think you need to have those discussions in context of an actual, you know, detailed clinical study plan as well.

Shannon Clark: So it seems like the only difference between human factors testing and clinical evaluation testing, is that in clinical evaluation testing you may or may not be required to observe users. That seems like maybe that's optional. And you would collect actual specimens and provide an actual result. Whereas in human factors testing you definitely observe but you may not give the participants an actual result; maybe a mock result. Is that true that that is potentially - the differences between these two types of tests is quite limited?

Dr. Kristian Ross: I see it - I, you know, on the face yes, I would agree with that. But again, of course there's always details. You know, the usability study or human factors study really has a, you know, you've got different goals, right? So you're going to evaluate that study differently. You're going to generate different

types of data. So I think we understand that. And you don't maybe necessarily need to have a live result in that type of study.

Shannon Clark: Okay. Thanks.

Toby Lowe: Yes. I think there's, you know, there's also, you know, especially for EUA studies, you know, we've tried to work with sponsors as much as possible to simplify everything. And so, you know, if there are ways so that the, you know, clinical study and the usability could be combined into a single study, that's something that we, you know, would be happy to help talk through. And so I think that may be where some of the confusion is coming in as well, because that's something we've been trying to encourage, to streamline everything.

Shannon Clark: Great. Thank you.

Coordinator: Thank you. Our next question comes from Alex. Your line is open.

Alex Weinberg: Hi. This is Alex Weinberg with UserWise Consulting. During over the counter human factors testing for an antigen test kit with mid turbinate swabs, we've concluded that participants or users may over insert or under insert the swab. And does the FDA have any published research that they can share or guidance to share as how precisely to define insertion that's too deep or too shallow?

Toby Lowe: I'm not sure if we would have any published research about that. I believe that there are some CDC recommendations regarding specimen collection for different specimen types. So I would suggest that you start there. If you are having trouble finding what you're looking for and have specific questions, you can send those in and we can try and help with that as well.

Alex Weinberg: Okay. I'll use that as a starting point. Thank you.

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

(Annie Wright): Hello. My name is (Annie Wright) and I'm from (Wantagh), USA. A few weeks back someone was asked a question about conducting a submission for a combo device, so it would be Flu AB and then COVID-19 antigen test. And at the time, Tim indicated that the Flu AB can be submitted without 510(k) clearance. And I was wondering if this could also apply - I just want to confirm it can also be applied for OTC products.

Toby Lowe: So there are a couple of things there. Just to clarify, I believe that the statement from Tim that you're referring to, was about an EUA submission and whether an EUA submission could include Flu AB if that Flu AB portion of the multi-analyte test had not previously been reviewed by FDA. And that is correct that you can do that.

(Annie Wright): Correct.

Toby Lowe: You can submit an EUA request for a multi-analyte test that, you know, where the Flu AB portion has not previously been reviewed. In terms of over the counter, we have not to date, authorized a multi-analyte test for over the counter. We have not in fact, you know, within or outside of the emergency authorized a flu test for over the counter. There's not really an indication for testing asymptomatic individuals for flu. That's not an indication that we have authorized or encouraged at this point.

So (Chris), I don't know if you want to add anything there on that discussion.

Dr. Kristian Ross: No. I think you covered it perfectly. Thanks.

(Annie Wright): So basically we would not - it would not possibly be accepted by the FDA or reviewed by the FDA if we did submit something like that?

Toby Lowe: If, you know, over the counter flu is something that you're really interested in pursuing, we would encourage you to submit a pre-EUA if it's a combo with COVID or a pre-submission if it was a non-COVID, or a non-EUA test. And

that's something that we could discuss with you. But at this point, we do not have any indication that there's a reason to test asymptomatic individuals for flu.

(Annie Wright): Okay. All right. Thank you so much.

Toby Lowe: Sure.

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

(Kodumodi Venkat): Hello. Good afternoon. Thanks for taking my call. I am (Kodumodi Venkat) and I'm from (Dentracore). I heard the last week when Dr. Timothy Stenzel, when he was answering a question about the - how long it takes to get the response on the EUA applications for different applicants. He mentioned that around 5500 applications are received in a year including COVID and non-COVID applications that around 300 staff members at US center.

And he mentioned that it is a large volume. So we appreciate the US center is working hard to really support the large volume of applications in the industry. I think you are over stretched and overwhelmed with the applications. And we as an industry, especially the small businesses, we are really hurt because of still not getting enough response from your center.

Do you think it will help as many small industries, the small businesses, meeting together and then seeking help from FDA Commissioner's Office to give US center more resources to get there, or even taking it to the Small Business Administration or even DHHS through our Congressional representative to President Biden's Administration so that, you know, you can get more resources to support that?

Toby Lowe: You know, thanks for your support. We are definitely working hard to support the large volume of submissions. We do understand the frustration from, you know, the industry side of things and the impact that this can

have. You know, we - resources is an area that we, you know, are always looking at in terms of what we can do.

And, you know, probably the best approach I would think from, you know, for businesses, would be to go just, you know, discuss with your, you know, if there's an association that you're affiliated with, they're usually good groups to have some of those discussions with and see, you know, if there might be discussions that are relevant to what you're looking to do.

(Kodumodi Venkat): Thank you.

Coordinator: Thank you. Our next question will come from (Laura D'Angelo). Your line is open.

(Laura D'Angelo): Hi. Thanks for taking my call and for holding these calls for 59 weeks. I have the kind of question that might - I mean I understand it might just refer me back to the yet to be the published guidance. But do you have any preview on the (cost side) for CLIA waivers post - or during the transition? So given that, you know, point of care trusts are deemed to be CLIA-waived at this time, is it going to be - if you have any insights of dual submission pathway or is it going to be, you know, CLIA waiver by application submitted separately, or, you know, broken into point of care not waived and point of care waived so everything is going to end up point of care waived? Is there just any insight that you can spotlight there?

Toby Lowe: That's, you know, a good question. There, you know, I can't unfortunately, talk about, you know, what may or may not be in the guidance document since that's still in the works.

(Laura D'Angelo): Yes.

Toby Lowe: I can tell you that, you know, I can tell you that we do plan to issue that transition guidance as draft with a comment period, you know, to allow for stakeholder input prior to finalization. So we don't at this point, intend for it

to be an immediately in effect guidance really that we've done for several guidances during the public health emergency. So I think that can give you a little bit, you know, since I'm sure you're familiar with FDA guidance process, I think that will give you a little hint into timeline there for when that transition process would be taking place.

But, you know, with that said, you know, you're correct that tests are deemed to be CLIA waived when they're authorized for use at the point of care during the emergency. That is not a CLIA categorization. It will not, you know, be in place after the EUA is terminated. So, you know, I would suspect that it will be, you know, somewhat of a normal process, you know, depending on whatever the transition plan is that's put into place, you know, to get that sort of permanent categorization. We would go through, you know, a similar process to what we normally go through for submissions.

And, you know, whether that's a dual or CLIA waiver by application, will probably be - depend on your particular circumstances.

(Laura D'Angelo): Okay. Thank you. And thanks for also, you know, the general work in kind of easing the CLIA waiver process.

Toby Lowe: Thank you.

Coordinator: And once again, if you would like to ask a question at this time, you can press star 1 on your phone and record your name when prompted. Our next question comes from (Ashwood Damin). Your line is open.

(Ashwood Damin): Hello. Thank you very much for taking my question. I have a general question about product tweaks or updates while it's awaiting EUA. So if a manufacturer decides to submit a slightly improved version of a product that's currently awaiting EUA, do they maintain their queue in the application line or is it sent back at the beginning of the queue again? Thank you.

Toby Lowe: So, you know, the tests that are awaiting review are, you know, not

necessarily in a sort of first in first out type of queue. So it's not necessarily that, you know, it's not like we're going to send you to the back of the line if you submit something to add to your submission. The - adding something to your submission would not, you know, like I said, it's not going to put you to the back of the line.

If anything, if it's, you know, if there's something about what you add to your submission that like you said, improves the test or, you know, adds something that is considered to be a priority for FDA review then it would potentially bump your submission higher up on the queue. But, you know, generally there are a variety of factors that impact the, you know, where a test is in terms of priority for review. And so the details of each submission would be considered as we determine what is sort of next steps for review as reviewers become available.

(Ashwood Damin): Okay. Thank you. For some manufacturers it's been the case where the FDA has told them to withdraw the current application and resubmit the new one. Does that apply to that case as well?

Toby Lowe: So there, you know, there are definitely situations where we might tell, you know, a sponsor that, you know, as submitted we don't necessarily think that their submission is likely to be successful or that we think there's, you know, a significant amount of additional validation that we would want to see, or other things like that, that might take some time to do. And in those cases we may, you know, discuss with the developer options that might include withdrawing and resubmitting once they have more of a complete package.

Again, since it's not a, you know, sort of first in first reviewed type of queue it is based on various priorities and details about each submission. We would then evaluate the new submission when it came in to determine whether it is a priority for review at that time.

(Ashwood Damin): Okay, thanks.

Toby Lowe: (Chris), do you want to add anything to that about, you know, the review tiers or anything?

Dr. Kristian Ross: No. I think you covered it. And I think it's, you know, it depends on what the test is and if it answers a significant improvement. For instance, if there's an improvement in throughput right, if you're going from 1000 to 10,000 per day or something like that. You know, that may even, you know, increase the priority of that test. I think, you know, really on a case by case basis and it depends on, you know, what changes, you know, you're implementing.

Toby Lowe: Great. Thanks, (Chris).

Coordinator: Thank you. Our next question comes from (Richard Montagna). Your line is open.

(Richard Montagna): Yes. This is (Richard Montagna) from (Reanix). Toby, we sent a question last week that you did respond to, that had to deal with a pooling of saliva. And you had suggested last week, if we take a look at the Quadrant Biosciences EUA, which we have done, and that raises another question that we actually sent in yesterday by email, but I think we might have missed the deadline.

And the question is since Quadrant uses a defined saliva collection kit and we will be using archived specimens, will FDA find it acceptable if we took the archived specimen, took an aliquot of it, ran it in our tests, and took another aliquot of the same specimen, put it into the Quadrant collection device which begins their process for real time PCR, so we can get the CT values and show that at least 25% of the samples in the pool are in fact a low titer. We're just asking if that would be acceptable.

Toby Lowe: So, you know, I think some of the - I don't think you mentioned what type of collection device you plan to use and whether you intend to evaluate your test.

(Richard Montagna): Yes. We are actually submitting...

Toby Lowe: You know, you said archived specimens...

(Richard Montagna): Yes.

Toby Lowe: ...with...

(Richard Montagna): I should have made it clear. We already have authorization for saliva, using our own collection device.

Toby Lowe: Okay.

(Richard Montagna): So we're looking at two...

Toby Lowe: Oh, perfect.

(Richard Montagna): So we'd be looking at two different collections our own for our test and then the Quadrant one for the real time PCR component of it.

Toby Lowe: Got it. Okay. (Chris), do you want to weigh in on that study design question?

Dr. Kristian Ross: Sure. Yes. I think it's likely going to be acceptable. You know, you're going to want to see some sort of bridging study if appropriate. You know, just established that the buffer, is you know, kind of behaving in a predictable manner. But I suspect that we would want to kind of see this written out a little bit more detailed because obviously the devil is always in the details. But I think, you know, on its face again, it seems acceptable.

(Richard Montagna): Okay. Thank you very much. So when this question does make its way to your desk you can obviously ignore it since you've answered it. Thank you.

Coordinator: Thank you. Our next question will come from (Franco Calderone). Your line is open.

(Franco Calderone): Thank you for taking my call. So I have two quick questions. So one is about the remaining market opportunity for at home antigen tests. So we have been working on ours for ten months now and we're still sort of battling the Part J of the template regarding the analytical and the clinical. The clinical really has shown to be pretty consistent concordant with PCR tests. So the question there is I mean from a market opportunity standpoint, it looks like we may be a little late to the game.

So is it wise to continue on this road or does it make sense to move onto something else? And that something else is neutralizing antibodies. So the question there is would FDA be amenable to a purely qualitative LST test where the test shows - well actually, it might be a semi-quant in a sense, where the tests will show over time let's say if you were to test a few times in let's say six months after the first test, two lines - control line, test line, that shows over time, you know, the test line wins out? Would that be amenable to FDA or do we need to be a lot more quantitative in that regard?

Toby Lowe: Thanks for that question. So for the first part of your question about antigen, home antigen tests, I'm not sure that we would be - that we're able to weigh in on the market opportunity. I think that's, you know, a business decision that you would have to make as to whether or not to continue pursuing that.

And then for the second part of your test were you asking - you're asking about whether we would consider a purely qualitative lateral flow neutralizing antibody test? Is that...

(Franco Calderone): Correct.

Toby Lowe: Did I get that right?

(Franco Calderone): Correct. Correct. But the way we are designing the test is that it would require let's say maybe three tests over a six month period, which would show, you know, that there are is decreasing presence of antibodies related to your immunity from the vaccine. Or from natural infection. But not in any

quantitative way, which is really not that different than, you know, the test that I just took. I'm not going to mention the name. It's a well-known lab.

It's a semi-quant neutralizing antibody test. And basically what they told me was okay, any result greater than 1 is positive and my result was 20. So that makes sense.

Toby Lowe: Yes. So we do have the neutralizing antibody template posted to our Web site and there are recommendations for a validation of a semi-quantitative tests in that template. So I think that would be, you know, where I would suggest you look for the recommendations there. But we do, you know, we do have those out there. So we are - the validation recommendations in the template and we are considering those. I don't know that we've had - I'm not sure if we have, you know, had much in terms of lateral flows that have been, you know, that have been successful with that semi-quantitative neutralizing...

(Franco Calderone): Yes.

Toby Lowe: ...antibody research there.

(Franco Calderone): Right. Okay. Okay. I will look at that template. Thank you.

Toby Lowe: All right.

Coordinator: Thank you. And as we continue we do ask that you please limit yourself to one question. Once again, please limit yourself to one question as we continue. Our next question will come from (Eromi Gardena). Your line is open.

(Eromi Gardena): Hello. This is (Eromi Gardena). So this is a follow up on a question that Dr. Stenzel answered last week, regarding the validation of rapid self-testing antigen tests and, you know, maybe there is also going to be antibody tests that could be available. And the mobile apps that are being used to capture and transfer this data to the HHS database. And FDA saw this coming and

then as you know, had the design-a-thon and we are one of the winners of the - that contest.

And my question is do we - so to - what we do is it's test agnostic and we have a mobile app that can capture the data on individuals and then - in groups and then transfer it directly to the HHS database. So, you know, the test developer doesn't have to do that part. And my - do we have to submit a 510(k) for the software for this product? Because we were not told that this is necessary, because it's just capturing the positive/negative - the positivity or negativity of the test and then transferring it. And so I didn't know whether we have to do a software validation for these. It's test agnostic.

Toby Lowe: Sure. So unfortunately, I was not particularly involved in the design-a-thon so I may not be able to answer all of your questions. We do have some experts on our team who would be able to, if you want to send in your question with, you know, with some more specifics of what your app does and what you're looking to do.

(Eromi Gardena): Okay.

Toby Lowe: You know, I think that some of the answers will be dependent on - specifically, on how your test interfaces - or sorry, how your app interfaces with the test that it would be used with...

(Eromi Gardena): Okay.

Toby Lowe: ...in terms of, you know, whether it would have any impact on the performance of the test itself. And so we would want you to be sure to have some information about that when you send in your question. And then we can get that over to the right folks here. So if you send that to CDRH-EUA-Templates@FDA.HHS.gov and you can...

(Eromi Gardena): Just a minute. Where do I get that information from? CDRH - you - is there some Web site that I can look at and get the information? I don't want to take

too much time.

Toby Lowe: Yes. It should be on the slides that are being shown on the screen right now.

(Eromi Gardena): Oh, okay.

Toby Lowe: It'll also be in the transcript and on the Web page I'm sure.

(Eromi Gardena): Okay.

Toby Lowe: But if you - yes, if you send that in, it's CDRH-EUA-Templates@FDA.HHS.gov. And you can note that you asked the question on the town hall and that I suggested that you send it in. We can make sure it gets to the right person.

(Eromi Gardena): All right. Thank you so much.

Toby Lowe: Sure.

Coordinator: Our next question will come from (David Ratiger). Your line is open.

(David Ratiger): Hi. I have a question about the EUA supplement to add additional claims to an existing EUA and how that affects existing product in the field. So upon authorization of an EUA supplement is all existing product under the original authorization no longer authorized? Because that would obviously bring up issues of field action for recalls, etc.

Toby Lowe: That's something that we can work with you on during the review of the amendment. We would want to understand, you know, how much product is on the market with the previously authorized labeling and, you know, what your plans are if you have plans, to, you know, sort of do an in field update. You know, that's - those are details that we can work through with you during the review of that supplemental EUA request.

(David Ratiger): I see.

Toby Lowe: And (Chris), do you want to add anything on that?

Dr. Kristian Ross: No. I think that's exactly right. We would want to kind of get some predictability as far as, you know, what the change will entail and how you're going to implement the change. And I think we've done that quite a few times for folks.

(David Ratiger): Okay. Thank you.

Coordinator: Thank you. And once again, if you would like to ask a question at this time you can press star 1 on your phone and record your name when prompted. Our next question comes from someone whose name was not recorded. But if you pressed star 1 your line is now open and you may ask your question. And caller, we're not able to hear you in conference. Please check the mute feature on your phone.

Man: Hi. This is (Unintelligible). I'm not sure whether you're referring to me. But I appreciate having the opportunity to ask a question. I have a follow up question to the question that was submitted by one of my colleagues regarding the pathway of marketing a product while the product is undergoing EUA review. So did I understand correctly that if we are talking about a molecular point of care product, this modification pathway may not be applicable?

In other words, is there any way if we want to get authorization of a point of care product, to market it while the product is under review? Or is it not a possible pathway? Thank you.

Toby Lowe: You are correct that there is - that when I answered that question earlier I did say that the notification pathway is generally not applicable. The notification pathway is, you know, for tests to be offered prior to receiving an EUA. And under CLIA which is overseen by CMS, the CLIA regulations stipulate that

any test that is not FDA authorized is limited to use at CLIA-certified laboratories that meet the requirement for testing high complexity tests.

So generally, point of care tests are used in settings that operate under a CLIA certificate of waiver. And so that would not be something that can be done with the notification pathway.

Man: Thank you. But just to clarify, what about - is an option for us if we wanted to sell only to CLIA - to high complexity CLIA laboratories, even though we strive for a point of care designation? Could we, while the product is under review, sell to high complexity CLIA laboratories?

Toby Lowe: That is potentially an option depending on the use and, you know, the use of your test and whether it would fit the other aspects of the notification policy. So that's something that - it may be worth sending in some additional details about the test so that we can take a look at that.

Man: Okay, great. Yes. Good.

Toby Lowe: I would suggest when you send that in, take a look at the guidance document first and look through so that you can explain in your email how your test fits into the description of the policy and the guidance.

Man: Great. Thank you very much. I appreciate it.

Coordinator: Thank you. We are showing no further questions at this time. I will now turn the call back over to Ms. Irene Aihie.

Irene Aihie: Thank you. 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 Web page at www.FDA.gov/Training/CDRHLearn, by Tuesday, June 15. If you have additional questions about today's presentation, please email CDRH-EUA-Templates@FDA.HHS.gov.

As we continue to host these virtual town halls, we would appreciate your feedback. Following the conclusion of today's town hall, 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. Again, thank you for participating. This concludes today's virtual town hall.

Coordinator: This does conclude today's conference. Thank you for participating. You may disconnect at this time.

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