

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

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

Coordinator: Good afternoon and thank you for standing by. At this time all participant lines are in a listen-only mode. After today's presentation you will have the opportunity to ask questions and you may do so over the phone by pressing Star 1 at that time. Today's call is being recorded. If you have any objections you may disconnect at this time. It is my pleasure to turn the call over to your host for today, Ms. Irene Aihie. Thank you ma'am, 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 41st in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health both from CDRH will provide a brief update. Following

opening remarks we will open the line for your questions related to development and validation of tests for SARS-CoV-2.

Please remember that during the town hall we will not be able to respond to questions about specific submissions that might be under review. Now I give you Timothy.

Dr. Timothy Stenzel: Thanks Irene and hello everyone and welcome back to another week. It's been a busy week at the FDA and I'm sure a busy week for all of you. And again appreciate all that you do.

You know, I think I said this at the beginning of these town halls but somehow I - it snapped back to call me Dr. Stenzel. I am Tim so when you call in and just refer to me as Tim. Thank you.

So I did want to give an update. You know, we continue to see an amazing number of submissions which is great, you know, many hundreds on a monthly basis basically. We are also really have ramped up our decisions. So we are currently over the last week averaging about nine decisions. That's N-I-N-E, nine a day.

And some of these are of course new original authorizations. They pop up as a new authorization on our FDA Web site. Many of them though are also supplements and amendments to existing EUAs. These don't - these aren't so easily spotted when we make these decisions. But if you go to a given assay and you click on the plus sign for that - on the web site you'll see all of the updates to their authorizations which are the supplements and amendments.

Also we consider a decision in our accounting when they issue and close out a pre-EUA feedback. And then of course there are negative decisions and those

we don't publicize typically, nor do we publicize, you know, when we close out a pre-EUA submission and give feedback to the developer. So not all of our decisions are publicly seen easily or at all.

So just want to kind of explain that in a little bit of detail. But we are working harder and faster than ever with more people whereas in the beginning of the pandemic, you know, we were making, you know, when we had an application making maybe one decision today. We're now making nine decisions a day.

So anyways let's get started then. Let's open it up for questions. Toby and I look forward to hopefully being able to help you today. Thank you.

Coordinator: Thank you. To ask a question please ensure your phone is not muted press Star 1 and when prompted clearly record your first and last name so I may introduce you. Again to ask a question press Star 1. And please stand by for our first question.

Our first question is from (Kay Taylor). Your line is open.

(Kay Taylor): Yes hi Tim. My question regards antigen test for home use either by prescription or over-the-counter that incorporates the use of a mobile phone app and wanted to look to see if we kind of have the general thoughts of FDA's current thinking in our head.

Per the non-lab template we would establish a set of critical smart phone specifications that we would outline before we would do any clinical testing or usability testing. Our thinking was to perform a clinical study with just a single representative iPhone model based on what we've seen with some recent clearances EUA authorizations and assuming, you know, such as

maybe the iPhone XR. And assuming that clinical study provided acceptable performance our question is more along the line what's FDA's current thinking about would that then allow other mobile phone models and operating systems that meet that initial set of critical smart phone specifications to be considered acceptable for use as alternative devices or is a kind of a stepwise approach that FDA wants manufacturers to take? But as you know there's a lot of smart phone operating versions as well as models out there.

Dr. Timothy Stenzel: So is this for reporting purposes only or is this to capture and analyze an image of a device to make a positive or negative call?

(Kay Taylor): It is both. So it would instruct the user through the test, the collection and testing process. It would, you know, capture an image and interpret the result and then also report it to authorities as needed.

Dr. Timothy Stenzel: So for reporting purposes it is not a requirement for an EUA authorization, at least the time of authorization to have a reporting feature. However in what you described we want to make sure on doing the review that the smart phone that you used to capture an analyze the image for determining whether something is positive or negative is accurate and reliable.

And so obviously different smart phones are going to have different cameras and different software. So it would be important for us to take a look at what the risks are for using something that's not used in a clinical study.

So I can't promise you that we wouldn't ask for some additional data on additional models or manufacturers if you're willing to allow them in your test. However that may not always require necessarily that you do a clinical

study but you do some sort of comparison study between the different cell phone models.

So that - your question is a great and important one and it's best answered specifically with one of our reviewers through our pre-EUA process. So I wanted to give you at least some flavor of what we've been thinking about and what's important that would help you formulate your questions to our reviewer.

(Kay Taylor): All right thank you Tim.

Coordinator: And our next question is from (Greg Slovatkin). Your line is open.

(Greg Slovatkin): Yes thanks Tim for taking my call. As you're well aware there is a big debate going on, you know, PCR test versus antigen-based tests. And, you know, this covers a gamut of populations being tested. I mean it's everything from, you know, the claims that one test is better than the other when it comes to asymptomatic patients that are being tested. It also gets into areas of what's more accurate.

And I guess my question is what is the FDA's current thinking on PCR versus antigen tests and when they could be optimally used? I guess that's my first question.

Second one, and this doesn't relate to either a platform in particular, but why is FDA still issuing EUAs that require a prescription for a test, you know, when there is such a desperate need to get mass testing done?

Dr. Timothy Stenzel: Okay so molecular versus antigen thinking and Rx. So Rx let's start with that is a mitigation on risk. So if patients, you know, don't have a clinician

involved with interpreting the test then we look at other mitigations to ensure accurate testing and that the reading of the test and the interpretation of the test is also good in the hands of the consumer.

So we are in - or we've authorized OTC tests that are without prescription. And so we are clearly very open to it. But we do ask for additional validation work for that. And, you know, as long as developers are willing to do those extra steps we're willing to give an over-the-counter claim to that assay.

Regarding molecular versus antigen, obviously we support both. From the FDA perspective our job is to take a look at the different technologies that can be brought to bear to help this pandemic and make sure that they are accurate and safe to use and that's our main consideration.

We're very supportive of all types of testing whether it's molecular, molecular point-of-care, molecular center lab, central lab or antigen point-of-care, antigen home, molecular home, molecular OTC, antigen OTC.

So we see that they're all able to assist in this pandemic. We know that in general molecular assays are more sensitive than antigen assays and there are some - therefore some trade-offs both ways.

I mean some people have said molecular assays are too sensitive, you know. And I think, you know, if you're looking at asymptomatic people and you don't know when they got infected a molecular test might identify somebody, you know, a week or two or more after they became infected and maybe they're not as infectious or are not infectious any longer versus antigen tests which are usually require more intact virus and aren't as sensitive.

Probably, you know, the good ones are, and the ones I think that we've authorized are good ones, are probably better able to tell, you know, who are the patients that are positive and truly positive. You know, those are probably patients that you want to make sure that you take appropriate measures to make sure that they don't transmit that to somebody else.

So the other thing is, you know, for central lab testing especially very high throughput, you know, unless you have an instrument that - and we have authorized one central lab antigen test, you know, and that's fairly high-volume but it's a lot easier to make the molecular test and do it in large volumes in a central lab.

But obviously a central lab is the high complexity lab environment and, you know, a point of care clinic, you know, would, you know, not be able to do a high complexity lab test but they can do waived or a deemed waived test. And so and also at home it would be similar sort of easy to use. And it's a lot easier to make an antigen test point of care and a minimal to home than a molecular for obvious reasons.

The other thing an advantage that antigen test can have is when they're good and they can be manufactured reliably which is a hard thing to do, they can be made in the millions of tests per month or more. I mean you've seen the press reports from some of the manufacturers upwards of 50 million and maybe going up to 100 million tests from a single manufacturer, single antigen test per month.

And those are volumes that, you know, are potentially order - in order or orders of magnitude greater than what the molecular manufactures and obviously individual labs, you know, central labs can test for. So we look at the strengths and weaknesses of all the technology and weigh them and look

at the benefit risk and if they can help out we're very supportive but they're very, you know, different uses I think.

Hopefully that answers the question. It was a good philosophical question. Thank you.

(Greg Slovatkin): Yes I - just one quick follow-up. I know you took some time there. I mean FDA has said previously that there's a higher chance of false negatives for antigen tests versus molecular test. I mean that's still the guidance, the feeling of agency right?

Dr. Timothy Stenzel: Oh very clearly antigen tests are more likely to have false negatives especially in important false negatives, especially in the first, you know, zero - day zero to day five or day zero to day seven. Performance is clearly lower in that period of time for symptomatic people than a real good central molecular test.

So you're going to have negative results with an antigen test that will be on somebody who's symptomatic and has SARS. And you'd have to do a lot of hand waving to convince me that somebody in the first few days is symptomatic infection can't be infectious. And they're going to be falsely negative as sometimes in an antigen test, less likely to be false-negative with a good central molecular test. So it's why our labeling for antigen tests all say the negatives are presumed negative rather than negative.

(Greg Slovatkin): Thank you.

Coordinator: And our next question is from (Marianne Fikner). You may go ahead.

(Marianne Fikner): Good morning. My question is also about a smart phone application for interpretation of an at home test. As we all know smart phone manufacturers often push major updates or security updates to their operating systems. What's the agency's expectation around system validation or updating after major updates to a smart phone operating system?

Dr. Timothy Stenzel: I think it's just, you know, a wise thing to do for a test developer to monitor that. I mean ideally a test developer would have relationships with the manufacturers of phones or sellers of phones that they're using so that they can know ahead of time when an update might be coming.

You know, but if suddenly an update is made and it changes the performance of your test the FDA is going to want to know that right away. And if you're giving now inaccurate results out, you know, then that's - that would be a public health of public health importance.

(Marianne Fikner): Obvious...

Toby Lowe: And also would note that, you know, one thing that we recommend is that you discuss this topic specifically with your review team when you have your EUA request in because we would be interested in seeing your plans for addressing periodic operating system updates since obviously everyone knows that that happens. And depending on how robust your procedures are for handling those we may be able to build in some change control into an EUA.

(Marianne Fikner): Thank you very much.

Dr. Timothy Stenzel: That's to...

(Marianne Fikner): Very informative, thank you.

Dr. Timothy Stenzel: ...make it easy - that's to make it easier for you to make updates and not have to check in with them. Thanks.

(Marianne Fikner): Awesome, thank you.

Coordinator: And our next question is from (Mark Delvecchio). You may go ahead.

(Mark Delvecchio): Good afternoon Tim. Thank you for taking my call. My question is related to a molecular multianalyte tests. If a test developer wishes to seek a sample pooling claim for the SARS-CoV-2 target would it be necessary to validate and obtain a pooling claim for the non-COVID influenza or you know, RC targets or is there a mechanism that would obtain a pooling claim just for the COVID target, you know, for example a labeling restriction or something of that sort? Thank you.

Dr. Timothy Stenzel: Hey (Mark) so I'm just going to repeat it because you were breaking up a little bit there in the beginning. You have the molecular multi-analyte test and you want to do pooling and what validation requirements are there for the non-or recommendations are there for the non-COVID targets?

That's a question I don't know the answer to definitively as far as, you know, through labeling can we say that the other tests aren't covered. I don't know it - I'd want to check with our team. I'm not sure if we've gotten this question before.

You know in pooling, you know, would you mask the other results and so you would just have the ability to pool and just test for SARS with your multi-analyte test? (Mark) are you still there?

(Mark Delvecchio): I guess that's - yes I presume that's a possibility as well.

Dr. Timothy Stenzel: Yes well that would be an effective mitigation is that if someone wants to pool they're probably pooling mostly for SARS, not for the other diseases right?

(Mark Delvecchio): Right, exactly.

Dr. Timothy Stenzel: And if they would mask the other results then you wouldn't need to validate, you know, for the other analytes if you mask them.

(Mark Delvecchio): That's helpful, thanks. We could follow-up for the specific assays as well. I appreciate the...

Dr. Timothy Stenzel: Okay.

(Mark Delvecchio): ...thoughts. Thank you.

Dr. Timothy Stenzel: You're welcome. Thanks.

Coordinator: And our next question is from (Winley Zou). You may go ahead.

(Winley Zou): Hello. Yes thank you for taking our call. So I have a question here. So for the molecular test you said test is validated for NP swab and it can be used for NP and nasal swab as well. Is that true for antigen tests as well? Say if a manufacturer and says that their kit is good for NP swab, can I use it for anterior nasal swab or automatically I can do that or as the manufacturer when we do the validation we have also - we have to include the anterior nasal swab test well, not only NP swab?

Dr. Timothy Stenzel: Yes to talk specifically about the antigen test yes we would ask to see patient data for anterior nasal swab. And the antigen tests are less sensitive. They're more sensitive to differences in viral loads that might happen between the nasopharynx and the anterior. So and it's important to understand that performance difference.

Now we're not requiring for an antigen test that they do a nasopharyngeal swab. A matter of fact I encourage most to try to validate and get their recommended sensitivity with anterior nares or, you know, worst-case mid-turbinate swabs because those are much better tolerated. They can be if you validate it for self-collection they can be self-collected.

They are then amenable if you have a good antigen test and it's easy to use for home use either prescription or over-the-counter. So, you know, whereas, you know, a consumer cannot perform nasopharyngeal swab on them selves, at least not safely.

(Winley Zou): Okay. Okay good. Thank you so much.

Dr. Timothy Stenzel: You're welcome.

Coordinator: And our next question is from (Anna Gozrelli). You may go ahead.

(Anna Gozrelli): Hi. We're developing a breath test for screening COVID. Last week I asked about the PPA or sensitivity requirements. You mentioned that you would think about it and discuss it and give an answer. I was wondering if you have any thoughts on the subject.

Dr. Timothy Stenzel: Yes we do. I can give you some of our current thinking and philosophy as it comes to breath test. This is all still being developed so I wouldn't - but I

think our team can provide you with even more specifics if you sent an email to the templates email mailbox. But I want to point you in sort of the flavor of where we're going here so you understand and can ask good questions hopefully.

One is when you think about the benefit risk of a breath test and in aiding in this pandemic, you know, if somebody is symptomatic versus somebody who is asymptomatic, the benefit risk favors testing the asymptomatic populations with a novel device such as this, especially if it has a high sensitivity in the asymptomatic population.

You know, if someone's symptomatic and it's a totally novel device when they're, you know, when they're, you know, when the concern about finding positive people is more moving into the asymptomatic population now as we try to control the spread of disease. If someone's symptomatic they should be isolating, you know, and masking and all those things and get tests but if the tests don't make sense then.

So the benefit risk really favors using the breath test in the asymptomatic population. We would want to see that, you know, it has a relatively high sensitivity in asymptomatic population. And since this is a novel technology and we don't have the same sort of experience, you know, even with other respiratory viruses like we do with molecular and antigen we will probably want to see more positives in the asymptomatic population than we would ask for an antigen or a molecular test for authorization of asymptomatic screening because we want to make sure it's not going to be, you know, orders of magnitude more. It's just going to be a little bit more but we think still reasonable.

And the other thing is with a breath test it's really hard to do cross-reactivity testing. Now first of all the actual analyte isn't the virus or other viruses. It's, you know, volatiles. And so how do you get at cross reactivity? And really the only way we could think of that's very doable and will allow developers like yourself to move forward is to test symptomatic people with a SARS test and also a respiratory panel test. Both should be authorized. There are some respiratory panels that have - and they've been authorized that have SARS on it so it would be one test.

But you test, you know, a sufficient number of symptomatic people, somewhere around maybe 5% or 10%, maybe 10% of them are going to have SARS today of the symptomatic population. The rest of them are going to have some other respiratory disease, mostly viral, you know, rhino non-novel corona, et cetera, RSV, some flu, et cetera.

So you should without having to test that many patients you should be able to see, you know, and a good panel that would detect most of the non-SARS viruses that are infecting patients these days and causing symptoms, you wouldn't take that many patients who are symptomatic with this kind of comparison study to show if a breath test is specific for SARS or not.

So that's our current thinking. If you send us an email at our templates email address for an update on our current recommendations and thinking for breath tests, we can provide you with some more information than we have in the past okay?

(Anna Gozrelli): Yes thank you.

Coordinator: And our next question is from (Ling Tau). You may go ahead.

(Ling Tau): Hi Tim. Thanks for taking our questions today. I also have a question about a smart phone-based reader test system. And I was just wondering when asked to provide hardware requirements for a test system that includes a smart phone and a test does the agency have a standardized list of requirement categories, for example processor type, camera, et cetera, or is it sort of up to the test developer to provide that list of requirements assuming they can then justify why those are relevant to the submission?

Dr. Timothy Stenzel: Yes I mean we take an open-minded approach and we - to this. So we don't really know what the needs of your tests are, right? You know it better than we do as far as the requirements on whatever the variables are when it comes to smart phones and cameras and image analysis.

We also don't specify that you have to use a smart phone to read a test, right? But I'm trying to think if we have actually authorized a smartphone reader for SARS or anything. I don't remember that we have. So as was usual with something that's novel -- and we're totally open to it -- we learn a lot with the first developers who come to us with data and learn a lot about what our recommendations for others would be based on actual data.

It's really hard to, you know, we do have a research branch in our center who could look at something like this but they aren't to my knowledge at the moment. They have so many, you know, interesting things to study but and one of those is actually digital health so or digital technology rather which is an image scanner and analysis of tissue. So they - we do have a program there and that's probably the most amenable thing that we understand relative to this.

But the - there's a whole lot of variables when it comes into scanners of a rapid test, lateral flow test, you know, from what is the color of the line to the

thickness of the line to the lighting to the background. And obviously different cameras or different software may impact that.

So you're really the best ones to inform us based on your examination of different smart phone options and your test what's going to work best and how you define that. And then we'll look at your validation when you define those parameters and determine if that is something we can authorize.

(Ling Tau): Okay thank you. Is this something that you would recommend that we reach out more directly for a more detailed conversation around or can we just present the data as part of our submission and then go from there?

Dr. Timothy Stenzel: You know, it never hurts to send us a pre-EUA and state your thinking and study design because we may spot things that you may not think of and which would help you in your development and to prevent any hurdles later on where you might have to do some repeats so - or repeat testing.

So and especially essentially novel if we can take a quick look at it and spot anything that's obvious. But as I said this is going to be, you know, new for us to know what are the variables around accurately reading a test over the smartphone and what are the important questions for us to ask in the validation plans okay?

(Ling Tau): Great thank you so much.

Coordinator: Our next question is from (Raymond Boulet). You may go ahead.

(Raymond Boulet): Actually some of the previous questioners have actually addressed my question so thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: And our next question is from (Kay Taylor). You may go ahead.

(Kay Taylor): Yes, Tim I just wondered if you had an update on the reference panel testing by the CDC for EUA authorized antigen tests. Have they started reaching out to antigen manufacturers to request samples of the product? Can you just give a general status on where that is?

Dr. Timothy Stenzel: Yes, I think they're getting relatively near to starting. But, you know, the CDC is inundated with mission requests. And we are currently thinking of other options and looking into them. And we don't have what I would call a great option right now.

For those developers that can utilize in their assays the various strains that have been deposited, BEI and either have been heat inactivated or perhaps more appropriately irradiated and inactivated through radiation that may be more amenable to antigen tests, you know, we're going to be reaching out.

There is - we have some preliminary data within the federal government that says that irradiated SARS can be accurately detected by antigen tests. So but I don't know if that would be across the board for all antigen test developers or not if their test is sensitive to radiation of the virus or not as far as reactivity and inclusivity testing goes.

But if they - it is amenable to all or most. One option is that once these strains deposited at BEI and have been inactivated by one or another method those developers that don't have BSL-3 facilities can get that material and perform the testing.

So we're just working through that. The downside I'll just say to that is it takes BEI a while to inactivate virus. And obviously they don't just, you know, irradiate it or heat denature it. Then they go ahead and test it to make sure that it is non-infection or noninfectious.

So it's not something that they can rush through and do. So we're hoping long-term the inactivated virus material that BEI manufacturers will be useful to this effort. So that's our current thinking as of today.

(Kay Taylor): Okay thank you.

Coordinator: And our next question is from (Franco Calderon). Sir you may go ahead.

(Franco Calderon): Hello Tim and Toby. Thank you again. So my question is related to - I actually have two related questions but one is related to last question.

So we actually have been able to find a BSL-3 facility to conduct the analytical studies. And they looked at J, the requirements on Part J of the antigen test and we want to go home use, so we have to refer back to the other one.

And they have informed us that based on the requirements there that they're not going to be able to help us. So my question is if they are able to let's, say complete most of those analytical studies would FDA be amenable to maybe allowing us to do the remainder post EUA? That's one question.

The other question is I have noted to date I believe there are 13 EUAs for antigen tests. None of them are yet from a company that has an OEM based in China. That is our case. So while we are able to gather up resources and join OEMs that could potentially produce tens of millions of these tests per day if

we put, you know, three, four of them together I wonder if you can give me a really thick feedback regarding one the possibility of a Chinese OEM getting EUA because I haven't seen one?

And two, how difficult would it be to have three or four OEMs producing the same test for a test developer provided that obviously is the same test?

Dr. Timothy Stenzel: So I'll answer your second question first. You know, EUA authorization holders can expand manufacturing to new plants. They don't have to - and there's no FDA review of that. We expect you to, you know, do the performance of the tests and the new manufacturing site matches the performance at the original manufacturing site but that it's not something that under EUAs that we review and make an authorization decision around.

As far as foreign OEMs we treat everybody fairly. We make decisions based on data and the quality of the submission. It doesn't matter where it comes from. And we haven't authorize that many antigen tests compared to molecular tests, but very clearly we've authorize the molecular and serology tests from many countries of the world including China.

So it's not a, you know, it's not any sort of, you know, global issue that I know. So what matters is the quality of the test and the quality of the submission. That's what matters to us okay.

(Franco Calderon): Okay. And regarding the first question do you - so by the way my question was not whether FDA had a bias towards a particular nation. That was not, you know, what I meant if that was perhaps what you interpreted.

My question was perhaps have you seen a pattern from companies that are submitting tests made, specifically antigen tests where the performance is not meeting FDA requirements in this case for home use 90% sensitivity?

And so the other one again would FDA be amenable to let's say the BSL-3 is able to complete most of those requirements, so Part J the analytical part, would FDA be amenable to a post to letting us do that post EUA?

Dr. Timothy Stenzel: We've been flexible when it comes to authorizations and what can go into a post authorization study to fill out an application. We want to have a good sense of the performance of the assay and we very clearly allow on a case-by-case basis depending on the benefit risk calculation on the submission what we have to allow post market study to fill it out.

I would, you know, as far as manufacturers of antigen tests go, here is the maybe not well kept secret or maybe it is a secret that it's a lot harder to develop a good antigen test than it is to develop a good molecular test. Now, you know, I've developed both and I can tell you it's a lot easier to develop a good molecular test than a good antigen test.

(Franco Calderon): Okay.

Dr. Timothy Stenzel: And it's also much easier to manufacture molecular tests than antigen tests and I've done both. So that's probably more of a factor here.

Lateral flow tests and, you know, there's serology in antigen tests. I'll let you know. I mean we're declining 2/3 of serology tests that are coming, lateral flow serology tests based on NCI data, 2/3. We're only authorizing 1/3 that test at - tests performed at NCI and reviewed by the FDA.

I think that's the nature or the difficulty in making really super high quality, quality high enough for the US market from the lateral flow business. And it probably is the same in antigens. I know we've denied some antigen tests. I haven't done the numbers as far as the ratio goes. But it wouldn't surprise me at all if the ratio was very similar, that it's 1/3 authorizable and 2/3 not based on data.

(Franco Calderon): All right thank you very much.

Coordinator: And I show no additional questions at this time but again if you'd like to ask a question please press Star 1.

Irene Aihie: Operator I will give it a few minutes or a few moments if - to see if we have any more callers coming into the queue.

Coordinator: One more coming in right now. One moment.

Irene Aihie: Okay thank you.

Coordinator: Our next caller is (Christopher Benson). You may go ahead.

(Christopher Benson): Hi Tim. I had a quick question about EUA, I'm sorry, UDI requirements for an EUA test. I can't find it anywhere in the recommendations. I'm assuming the UDI G10 requirements for Class II and higher tests are not applicable right now for an EUA?

Dr. Timothy Stenzel: I believe they are not applicable. Toby do you know?

Toby Lowe: I believe that is the case. It would probably be best if you can send that question in to the mailbox so that we can confirm but I'm pretty sure that they are not applicable.

((Crosstalk))

(Christopher Benson): Yes, because I think they're somewhere locatable for people who can find it easier than, you know, sending in emails, but thanks for the advice.

Dr. Timothy Stenzel: You're exactly right (Chris).

Toby Lowe: Yes.

Dr. Timothy Stenzel: And I was going to ask Toby to take a note. Let's find that out and provide that definitive answer on the next town hall call and consider whether or not we put it on the Frequently Asked Questions page.

Toby Lowe: Yes.

(Christopher Benson): That would be great. Thanks Tim.

Toby Lowe: Appreciate the feedback. Thank you.

Coordinator: Our next question is from (Gloria). You may go ahead.

(Gloria): Hello. Yes, I have a question on the reporting. So we are developing and antigen test and we are willing to provide it with in a mobile app for guiding the users through the test and for reporting the result could also be an option if we're reading the HHS specifications for COVID-19 data reporting it's really oriented to point of care testing.

So we are wondering if there is some guidance in case of reporting for an at home test what would be needed on personal data and on data of the user? And also do we have to encounter a mechanism to yes predict and to say something about the prevalence in the region the consumer is behaving so you could give an indication on the, yes the PPV and the NPV so it's a more yes, just trusting the results?

Dr. Timothy Stenzel: I did - I'm not sure I caught the last part of your question. The first part I caught was you're developing an app to guide the person through the testing and to report the results that you aren't using the smart phone to actually read the result but maybe you are?

(Gloria): No it's readouts on the reader. Yes.

Dr. Timothy Stenzel: The reporting is guiding and reading - guiding them through and reporting the results.

(Gloria): Yes.

Dr. Timothy Stenzel: And then you want to know what are the point of care or home recommendations for reporting and how you do it and how you insure confidentiality...

(Gloria): Yes.

Dr. Timothy Stenzel: ...and mindful of HIPAA requirements. And those are all really important questions.

And the, you know, the facts are that we are still struggling with how to do that reporting well. Even if you have an app to report to connecting it to the database and getting authorizations from all of the states, you know, and the federal government to be able to do that and connect it all up report results that is a mission in process. And...

(Gloria): Yes.

Dr. Timothy Stenzel: ...we're fortunate to have our office, the office I lead is a chief medical officer who is an expert in this, Dr. Sara Brenner who's actually on loan right now to HHS to work primarily on this reporting question.

And it's - I know that there's Web sites and there's documents that are available but I don't have them at my fingertips, Sara would. It's probably something Toby and Irene that we want to add to our slide deck that we provide at the town hall, some materials around our reporting and since we've had a number of questions about reporting and those links to important documents that can guide developers.

But we're very interested in working with you. So if you send us an email to the templates email address and you ask for that to be forward into Dr. Sara Brenner, B-R-E-N-N-E-R, Sara will get back to you with as much as she can tell you about the process now.

(Gloria): Okay. And my second then on the prevalence could it be maybe it was already discussed earlier that Rx the prescription and the mitigation of risk does FDA also considers a prediction of the prevalence of COVID-19 in the region where the app is installed and a user is doing the test as a mitigation of risk? So yes if it is low prevalence region then already results might be less supportive that are and that kind of mitigation, is that's open for discussion?

Dr. Timothy Stenzel: It's an interesting question. Certainly in a low prevalence population your risk - your PPV is going to go down, your Positive Predictive Value's...

(Gloria): Yes.

Dr. Timothy Stenzel: ...going to go down but your NPV is going to go up. But we've heard that false positives with antigen tests especially in point-of-care congregant settings where then they move a patient based on their test results into a COVID ward can expose someone who doesn't really have COVID to SARS and developing COVID. So it's a complex thing.

The other thing is and obviously if you're prevalence is higher then it's kind of the reverse. But, you know, one of the challenges with that is you'd have to have - first of all you'd have to have, you know, even to consider it you'd have to have really good prevalence data and up to the minute prevalence data which we don't have. And then you'd have to have an adaptable system that had some geo-locator that says well you're in this ZIP Code and this is the prevalence and so this is the number to use, you know, for your mitigation.

So it's an interesting idea and I don't want to give you any more definitive - I don't want to give you any definitive answer on it. We're always open to new ideas.

(Gloria): Okay.

Dr. Timothy Stenzel: So if you want to propose this in a pre-EUA or an EUA as the mitigation please do. I can't guarantee the results.

But like I said, you know, this town hall is to help educate folks about our current thinking. But we learn just as much from developers, you know, as you do from us. So, you know, thanks for asking a creative question.

(Gloria): Okay. Thank you.

Coordinator: Our next question is from (Mac Clement). Your line is open.

(Mac Clement): Hi there. Thanks for taking the call. This is a little bit off-base but I work for a company where to both medical distribution and then we're also into development as well so we have a biotech arm. We have our own med techs, et cetera.

We've had a few positive tests within our own organization and are going to set up we hope by the end of this week some surveillance testing. There shouldn't be any issue with that should there, using our own tests - I mean using the tests - not tests that are not developed yet but tests that we're already distributing, antigen tests? Does that make sense?

Dr. Timothy Stenzel: So well yes so it's a bit complicated. So first of all the FDA has tried to provide some clarity on this on our FAQs with regard to what is diagnostic testing what is screening, asymptomatic screening testing...

(Mac Clement): Right.

Dr. Timothy Stenzel: ...and what is surveillance testing and has clearly said that for COVID-19 at least the FDA is not going to be regulating surveillance testing.

So but one of the challenges which you mentioned with the antigen test is it's a single use for typically for a single patient.

(Mac Clement): Right.

Dr. Timothy Stenzel: And it's hard to do purely surveillance testing when you have one patient and one result and it's right there in the patient sees the result or is the test itself. So that isn't, you know, when a patient gets a results back or an employee gets the results back that tells them that their positive or negative that is not what we would typically think of it as surveillance testing.

(Mac Clement): Okay.

Dr. Timothy Stenzel: Surveillance testing is population-based. Typically it uses pooling. And then if you have a positive pool at least the FDA current thinking on this, is that if it's positive pool you can say to that pool of people, go get a CLIA lab test and get a results.

(Mac Clement): OK.

((Crosstalk))

Dr. Timothy Stenzel: And so the negative people you can say you're negative but you don't direct them to get it. You don't direct them to get a CLIA test.

(Mac Clement): Okay thanks, appreciate it.

Coordinator: And our next question is from (Rainer Zirnan). You may go ahead.

(Rainer Zirnan): Hi. Thank you for taking my call. I have a question regarding requirements of usability study for molecular point-of-care claim. The July 28 template doesn't really specifically outline the requirements and I'm aware of the other

template dated July 29 which refers to human usability studies for non-prescription OTC tests or for prescription only test.

So do I understand correctly for point-of-care molecular test we should follow that guidance and include 30 participant in that human usability study? Or if not could you just quickly give me some advice on what is the extended - the scope that's required for the point-of-care claim? Thank you.

Dr. Timothy Stenzel: Okay so you have - okay hold on. I just want to make sure I understand. You have a point-of-care test. It's molecular test?

(Rainer Zirnan): Correct yes.

Dr. Timothy Stenzel: Okay. And you want to know this is point-of-care not a home - it's point-of-care test. You want to know how you do the user in a CLIA waived setting testing, because I don't remember that we had 30. I - we have 30 positives for the point-of-care clinical study validation.

And then we do want to see - it would be great to see more than one clinic although I don't think that's a formal requirement. But we do like to see five to six different people if I remember correctly from the template, perform the test and not just, you know, one person in one clinic performing the test.

If you move into the home setting either OTC or Rx then we ask for clear user studies and the numbers are bigger for that. So I don't know that we have time to pull up the template for point-of-care molecular but I thought it was fairly clear.

But if you have any clarifying questions about what's in the template what you need to do, it's best handled through our templates email address. But I

think I roughly covered this accurately. Toby can probably tell me if I'm wrong or not what the user studies are for point-of-care tests?

(Rainer Zirnan): Yes.

Toby Lowe: Yes.

((Crosstalk))

(Rainer Zirnan): Tim can I just...

Toby Lowe: Yes you know, there is discussion about the operators and site and test users and how to evaluate that as part of the clinical evaluation.

(Rainer Zirnan): Yes I guess my - maybe I wasn't entirely clear. I'm fairly clear on the clinical study and what we do there but I was wondering whether we are required to do an additional usability study that will be part of the submission beyond the clinical study?

Dr. Timothy Stenzel: Not for point-of-care.

Toby Lowe: No I believe we've built that...

Dr. Timothy Stenzel: We've got...

Toby Lowe: ...into the discussion, the clinical study so that it would streamline things for you.

(Rainer Zirnan): Okay. Thank you very much -- appreciate it.

Dr. Timothy Stenzel: Yes.

Coordinator: And this concludes our question-and-answer session. I will now turn the call back to Irene Aihie.

Irene Aihie: Thank you so much. 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](http://www.fda.gov/training/cdrhlearn) by Friday, February 12. If you have additional questions about today's presentation, please email [cdrh-eua-templates@fda.hhs.gov](mailto:cdrh-eua-templates@fda.hhs.gov).

As we continue to hold these virtual town halls we would appreciate your feedback. Following the conclusion of this 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](http://www.fda.gov/cdrhwebinar). Again thank you for participating and this concludes today's virtual town hall.

Coordinator: And this concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please stand by for post conference.

END