

**FDA Virtual Town Hall Series –
Immediately in Effect Guidance on
Coronavirus (COVID-19) Diagnostic Tests Moderator: Irene Aihie
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Coordinator: Good afternoon and thank you all for standing by. For the duration of today’s conference, all participants will enter on a listen-only mode until the question-and-answer session. At that time if you would like to ask a question, press star 1. Today’s call is being recorded. If you have any objections, you may disconnect at this time. It is my pleasure to introduce Ms. Irene Aihie. Thank you, ma’am, 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 26th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-Co-V-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 from CDRH following opening remarks will provide a brief update. Following opening remarks, we will open the lines to discussion. Please remember that

we are not able to respond to questions about specific submissions that might be under review. Now, I give you Timothy.

Timothy Stenzel: Hello, everyone and thanks again for joining us today. It will just be me today. Toby is on a well-deserved leave and we hope that she is recharging her batteries and comes back strong next week and I did want to start-off with a few brief remarks.

A topic that seems to be well-recognized now and we certainly made some public statements about certain tests is false positives so we are still dealing with some tests that have been publicly mentioned by the FDA and we continue to look for all signals whether they be significant false negatives or false positives and certainly pay a lot of attention to any sort of false results, work with those who are reporting issues as well as the test developers, understand the issues, see if there truly is an issue and if so, to quickly resolve that and quell that.

And of course when something is known and decided to make that transparent to all of you, but in general false positives perhaps haven't received as much attention as false negatives but as we move into this pandemic and the response, you know, false positives are important to be aware of.

They can occur, there's no perfect test and you know, we have gotten some recent reports and made public those that have been confirmed to be issues and I just wanted, you know, as we move into also, as we move the opening of schools and workplaces, some of the populations that get screened are potentially low you know, percent positive populations.

And as we've talked about previously a while ago for serology tests even if molecular tests or an antigen test is quite specific and let's just plug-in some

numbers into our PPV calculator and so if you plug-in a 95% sensitivity and a 99% specificity against the sensitivity 95 and specificity 99 so many would agree that's a fairly high-performing test.

And if you put in a number of perhaps 0.2% positive but again that's 0.2, we have seen that relative level of positivity in a number of different populations who are doing screening or they're doing surveillance, you know, it's interesting because you plug that into a calculator for PPV or positive predictive value it's 1/6 or 16% and that's pretty low. That means that only one out of six positives is an actually true positive result.

We know that in some clinical settings based on a single positive result that patients can be moved into a COVID ward where presumably everybody else has been confirmed positive to have COVID and may carry the virus, may carry infectious levels of the virus, may increase the risk of transmissibility to anyone who goes into that ward and here you'll have a potential patient who is falsely positive, may be in an at-risk group due to the age or previous conditions and goes into that increased-risk ward or area and may unfortunately, you know, contract the disease.

So it's really important to not only understand the sensitivity and specificity of tests to the best of our ability but it's also important to understand what the positive predictive value for the population in that you're testing so let's hope that those remarks are helpful. Of course there's also the update that we've provided yesterday regarding the FDA SARS reference panel. We've made public announcements before about this panel.

Yesterday we released the first batch of results on almost 60 tests and we hope that this information is helpful. We assessed relative LODs in three different ways, one for essentially the sample that used or test that uses - sample test

that use - VTM and go into an extraction sort of chemistry from a liquid source and then we looked at dry swabs and separately we started looking at saliva.

We think that within a sample type, we have three different tables and that's publicly available information. Within a table you can look at relative LOD and you can understand I think to a great degree based on how we ask the testing to be done and our analysis, we have a pretty good rank order, a lower LOD to a higher LOD within a table but making comparisons between tables are a little bit more difficult because the method of assessing the LOD was not exactly the same and we do put some details about how those how the panel was used for the different sample types so that those that go to the table and try to use it understand what those differences may be.

So again we hope this publicly-available information on relative LODs will be helpful to the community. We have contacted a lot more developers in this first batch and so we're already working on finalizing LOD determinations for a lot more and we'll post as soon as we're ready to post the next batch. With that I think we can go into the Q&A portion of this meeting.

Coordinator: Thank you. If you would like to ask a question, please unmute your phone, 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. Our first question is from Alexis Sauer-Budge with Exponent. You may go ahead.

Alexis Sauer-Budge: Hey, Dr. Stenzel. I had a quick question with regards to updating the notification lists on your facts page. I noticed that the some of them for Sections A, B and D hadn't been updated for about a month. Are you still updating those regularly?

Timothy Stenzel: Yes, we are. I'll double-check on that. I will say that there are some of those, I believe A is voluntary to be listed there so just because somebody has let us know that they validated and may wish to pursue an EUA may at the same time may not give us permission to put it on the notification list but I'll make a note of that to double-check that that is the standard protocol for us to update those notification lists.

Alexis Sauer-Budge: Great, thank you so much and thank you for the hard work that you and your team are putting forward.

Timothy Stenzel: Oh, thank you for the comments, I appreciate it.

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

(Louis Perelmutter): Yes, thank you. Tim I want to thank you for your help and transparency of, you know, for all of us. I think it's been great. My question is we are submitting an EUA shortly for direct antigen tests and we're completing the validation studies now. With the nasal swabs for the nasal pharyngeal and also pharyngeal secretions, I guess my question is we want to go to saliva eventually. Do we submit one EAU and modify it or do we have to submit two EAUs?

Timothy Stenzel: So that's totally up to you. I you know, when you have a complete set of data for a particular sample type and you'd like to get you know, an EUA authorization sooner than later, then you may want to submit that before you have all your sample type validations, all the different sample types you want and the validations, the types you want and the validations done.

Because we, you know, once an EUA is authorized, we do allow updates to it, right, amendments to it with any changes that would require or new or we

recommend new validation. If you've already got some sample types where you definitely met our recommended minimums and the data looks good, then go ahead. I encourage you to go ahead and submit it particularly for antigen tests because we certainly want to have more antigen tests on the market as soon as possible.

(Louis Perelmuter): Yes, I agree. Okay, then, thanks a lot Tim.

Coordinator: And our next question is from Paul Barto. You may go ahead.

Paul Barto: Yes, hi, this is Paul Barto from McKesson. I had a quick question for you so back in late July the FDA posted I believe it was a template for submissions for at-home testing for antigen tests, maybe not specifically for antigen tests but my question relates to antigen tests, so my understanding of that is its set requirement for these and it stated that at-home tests would have to have accuracy of at least 90% relative to standard lab tests as well as needed to include a means to report results to public health agencies.

So my question is what is the standard lab test with which or I guess against which a manufacturer would compare their at-home tests and then I guess the second half of the question would be are visually read tests pretty much excluded since there wouldn't be a way to automatically report results to a public health agency?

Timothy Stenzel: Yes, those are a lot of really good questions and thank you for the opportunity to go over what our recommendations are again just to reiterate our templates provide recommendations, not necessarily requirements. There may be alternatives to get to the same place of validation and we're always open to those alternatives. We have given a lot of thought to what the recommendations are in our templates by the time we post them.

So I'm going to try to unpack these things one at a time and if I miss some thing, please let me know at the end so you mentioned that at-home test we had the recommended positive agreement or sensitivity of 90%. That is for something that is going to be over-the-counter without prescription.

So if there is something that's by-prescription then the recommended PPA or sensitivity is 80% and in fact if you're read Dr. Shuren's and my opinion last week in The Hill, we even suggested something as far as a single test result in the home situation can be as low as 70% perhaps if you had something like a serial test program where instead of just one test result you might have two.

You might package two tests and a patient might test themselves on Day 1 and Day 2 or Day 1 and Day 3, whatever the developer, you know, sees as beneficial to increasing that sensitivity. The other thing is that we are very open and we're very eager to authorize home diagnostic tests either over-the-counter or by prescription.

I have to say though we haven't received a single EUA application for a home test, not one and we've had our template out there for a long time and we've clearly expressed flexibility so we want to reiterate. We want to see home test submissions and we're willing to be very flexible here.

So the question of what is the comparator test is what you're asking, what is the standard lab test and this is typically thought and the outline behind this is a high-sensitivity molecular test. We specify that because we don't want to be comparing something less than the best possible standard and if you go with a less-sensitive test, it may not detect all cases.

The other thing to note is that if it's a rapid antigen test or even a point-of-care molecular test, we really are most concerned about the performance of that test that is its sensitivity against you know, a good comparator in those first five to seven days for those who are symptomatic and the first five to seven days after somebody becomes symptomatic.

And that's because those are the days that we think and I think there's good literature to support this that that's the peak period of potential ability of those individuals to transfer the virus to somebody else and so we want to definitely identify those people and in the asymptomatic population we want to identify people with similar levels of virus and so we don't look in particular at LOD for a number of reasons.

One is there's no international standard so it's really hard to set something that can be applied evenly across all technologies and developers but also it's not always the direct relationship between LOD and clinical performance especially if you want to be sure and identify people who have transmissible levels of virus.

You may not need to have the ultimate in sensitivity as far as limited protection goes but you do want to detect those that are most likely to be able to pass-on that virus to somebody else so and the third thing was visually-read tests. So we haven't authorized, I mean, we've probably authorized just one visually-read test.

There is a lot I know in development and hopefully they will come to the market in the relatively near future and there's nothing wrong with the visually-read tests first of all and now the Abbott BinaxNow is a visually-read test and its performance looks good and we look forward to its full availability in the market and the usefulness in this pandemic.

And then you asked about how to report that information. So home tests performed outside of a CLIA lab are not required to report results to the reporting agencies. It's not required by law is my understanding. We do want to stimulate thought about how the tests can be reported in order to aid our public health response to this pandemic so we do in that template ask what are your thoughts about how you can facilitate reporting of results even in a home test situation.

So hopefully I've clarified a number of things and I'll just pause to make sure that I've been helpful to you.

Paul Barto: Yes, I think that's helpful. I appreciate it. I'm still a little confused as to why it was specifically - my understanding was the FDA requirement mandated that the tests approved for at-home use would need to have a means to report results to a public health agency so you're saying that that's not a requirement, right?

Timothy Stenzel: It is not a requirement. It is not something that we would use to make a decision on whether or not to authorize that test or not. It is a question in the template and that's because we are trying to be a good federal partner and stimulate thought in this area because we think that it's a very responsible thing to do and try to find a way to report these results so that we're tracking the pandemic as best we can.

Paul Barto: Excellent, thank you, I appreciate it.

Timothy Stenzel: Yes.

Coordinator: And your next question is from (Leukner C.N.). You may go ahead.

(Leukner C.N.): Hi, Tim, hi, everybody. Thanks again. You just answered a lot of my questions with the last caller but let me expand a little bit. Thank you for posting the LODs also. That is interesting because as you mentioned there's no sort of international kind of comparator way in terms of standard for the limited detection for SARS (Co-V) 2 to my knowledge.

But in terms of infectivity level, viral load for let's say symptomatic and asymptomatic, are you aware of any sort of studies or results that are you know, going to be informative, for developers around I know it's like probably the million dollar question what that level would be or, you know, do you have an estimate of what's clinically relevant in terms of being infectious?

Timothy Stenzel: Yes, so that is you know, that is the \$100,000 question, thank you for asking that. You know, there are a lot of different ways to try to get at that but none are ideal so we have seen variable information in data with regards to if you try to use CTs of a comparator test for giving different populations.

We have clearly seen different levels of virus in asymptomatic populations from symptomatic populations, typically lower when there's a difference. Sometimes they don't appear to be different but we don't understand but clearly we see populations where the asymptomatic levels are lower.

And you don't have the framework or the guard posts of knowing when somebody's infected unless they had a known exposure that you're then following and tracking them with, you know, because they don't have symptoms so you can't have the same guideposts that we can have for evaluating test performance in symptomatic populations where for example with direct antigen tests, we very specifically ask you to collect in day after

symptom onset information as well as day after PCR test results so that we can start to define when is the peak performance days after symptom onset for point of care tests?

So what we have attempted to do is provide as much flexibility to add an asymptomatic claim to anybody who wants one. We've clearly authorized some already. We also have the situation that if you're truly non-prescription, home use, over-the-counter, we do want to understand the performance in the symptomatic population because you don't have a clinician involved in selecting, ordering, interpreting a test result in the home situation to any of their patient in evaluating that and knowing okay, you're symptomatic, you're positive or asymptomatic and you're negative, what does that mean versus you want to know if you're carrying the virus and you know, you would really want to know what are the various risk levels?

You know, are you at risk for serious or is somebody in your sphere of influence at risk for you being a carrier? Do you have any episodes in your life that would put you in an increased risk of being a carrier? All those things. As I mentioned earlier on, positive predictive value is also important and you don't want a lot of in the home situation a lot of false positives for a number of reasons.

So here's what we've outlined as what we would like to see as recommended validation of asymptomatic and that is we would like you to collect asymptomatics. Those can be very if you already have a test on the market and people are submitting samples and some of them are clearly marked asymptomatic, we are fine with banked samples.

If you have CT results and you look at your population of asymptomatics and, you know, and in the population that your test is looking at, it's appropriate

population for whatever claims you're going after and those two populations look very similar and that's also retrospective data but it's also some of that information that we're willing to put, you plan a prospective study.

We are allowing enrichment studies so there's lots of schools, workplaces, universities that are doing surveillance and/or screening that are identifying asymptomatic positives and hopefully they're willing to team-up with test developers and so you don't have to do, you can enrich, you know, and find those asymptomatic much more quickly if you can team up with an effort like that and if you can't use the residual sample collected on that individual who's positive, And then you could under the appropriate, you know, consent, we'll say, not that that's necessarily an FDA requirement just you want to do it right due to local-state-federal law you can re-contact that individual, have them come in or go to them or send them a kit and have them retest themselves hopefully within a short period of time after they were positive in their screening or surveillance to add to your asymptomatic population.

We do want to see what the molecular results are for that. We also have recently expressed that our interest to even be more flexible on the pre-market, on the pre-authorization side to allow enrichment of asymptomatics so typically if you're adding an asymptomatic claim, it might be 20 patients that we want to see pre-market and now we're saying that if only if it's 20 that we would allow half, 10 of those to be asymptomatic and then add to that with matched symptomatic and a good matching scheme would be to look at people with similar CTs.

And then post-market after you've been authorized, complete your prospective collection of asymptomatics. We take that totality of evidence into play so if you have a really great looking test in the symptomatic population and, you know, in those first five to seven days you, you know,

you do really well, you know, we're going to take that into account when we look at asymptomatics because clearly in this population where we know that they can pass the virus along and you're doing well, we just want to see is there any differences in sample type that you're using the way you're collecting in an asymptomatic population that brings-up any concerns?

So again these are recommendations in our templates. We're always willing to look at the totality data to make the very best public health decision so long-winded, apologize for that ...

((Crosstalk))

(Leukner C.N.): That was very helpful, very, very helpful.

Timothy Stenzel: ... address your ...

(Leukner C.N.): Thank you so much. Thank you so much.

Timothy Stenzel: You're welcome.

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

(Jeff Terryberry): Yes, good day, how are you? My question is regarding serology testing and the latest EUA template we have from June - end of June - doesn't have any recommended or required tests for seroconversion but a lot of the IFUs for the EUA approve kits contain seroconversion data and so we're just wondering whether we need to get seroconverted samples that have longitudinal sampling from the day of detection to, you know, a sufficient time point for development of the antibodies?

Timothy Stenzel: That's not a currently recommended study, you know, to serial test patients and determine when they become positive and when they become negative, that is the individual patients. We do ask for data relative to symptoms and/or PCR tests and I would go to the template and look at the recommendations.

In that we can, I mean, we've now been authorizing tests and putting it into the EUA summaries or IFUs, you know, by day period and I forget what those are exactly are but obviously we want to know. If we test anything within seven days of symptoms or PCR tests, you know, seven to 14, 14 to 21, greater than 21. I think roughly is what the bins are.

You know, even a really good serology test for IGG, you're not going to necessarily have a lot of positivity or as much in those first seven days post-symptoms but we do want to see really good performance say by 21 days, right, so and if your test isn't sufficiently sensitive to detect, you know, a high percentage of antibodies, you know, so if it's IGG, you know, you like to see 90%.

We do take-in, you know, we do take into account that a test may ultimately meet that mark after a certain number of days in our authorization.

(Jeff Terryberry): Understood and so in our sample collection demographics for the samples we have got so far, I don't think the number of days since diagnosis are routinely chronicled but it is confirmed, they do have confirmed, you know, predicate testing for molecular and even some in some cases comparisons to other serology tests but so is it required to have the number of days since diagnosis for that sample?

Timothy Stenzel: Well, the short answer is it depends. It is a recommendation. We'll want to see your data and your line listings to understand performance as best we can

but it really protects you the developer to understand this because certainly people can start to lose reactivity. Antibody levels can start to wane after six weeks to eight weeks and then you can start to lose TPA sensitivity or simply because there's been so many days after infection and, you know, in some cases at least the level of antibodies or the detectable antibodies start to go away.

And so while we do recommend sort of that peak period that you look at for serology test between two weeks and two months so that you have the best shot of showing that your test is performing well when it should.

(Jeff Terryberry): Yes. Okay, thank you for that.

Timothy Stenzel: You're welcome.

Coordinator: And our next question is from (Koda Moody). You may go ahead.

(Koda Moody): Good afternoon, can you hear me?

Timothy Stenzel: Yes.

(Koda Moody): Thank you for taking my question. Thanks for putting the FDA's SARS CoVid reference panel comparative data. That has been very, very useful. My question is related to this. Do you have any plan for providing a reference panel for antigen test developers as well as serology test developers because this panel, such panel is very, very useful for developers so if you can just let us know what your thoughts on providing a reference panel for antigen test developers as well as serology test developers?

Timothy Stenzel: Sure, those are absolutely great questions, we still have a very active program at NCI, our federal partners in the FDA are still testing kits that have been sent to NCI and we're moving into our third panel and are already planning the fourth panel.

It has been a lot of work, doable, but a lot of work to source the samples that have sufficient volumes to create these panels at NCI, to properly vet them with the various QC testing that we do and making sure that we know their history and that we are doing the very best job that's possible to match Panel 1, Panel 2, Panel 3, Panel 4 with regard to the types and samples, the titer of the samples so that we can as best as we possible with the limited resources on some of these samples match performance expectations between the panels.

So a ton of work goes into this and it would be phenomenal if we had enough samples and sample volumes to be able to do this for serology. It is quite challenging to source those samples in that kind of situation to make it widely available. It's always been a goal and it's talked about frequently within our federal partner team and anyways, they're just some real challenges in getting those samples.

They're not unlimited so with the FDA reference panel that went out starting in May, after it was developed, we grew up at the FDA virus and we then inactivated, we tested that it was inactivated, and we created the panel but that is a renewable resource through culture. On the antigen side, we've definitely had this conversation with our federal partners.

It is definitely something that would be ideal to have as well. It also has its challenges so we essentially you know, to do this well and we've had a program that CDC has led for a number of years relative to flu where they make an annual proficiency test panel available for various key strains of flu

for primarily for rapid antigen tests but molecular tests have also been very active in using those panels to surveille.

You know, flu, when you grow a virus and you create these panels, there's less perhaps concern about this as a biological agent, flu relative to SARS so there are additional considerations for SARS but it's definitely been on the plate for conversation. The other thing that I did want to follow-up isn't really a question about are these international standards.

The reference panel that we sent out, as soon as the international standard for molecular is available and we're looking at potentially year-end, we will anchor the FDA reference panel to that and we'll be able to translate the results like we've posted to international in units. We think that will be a huge advance and on top of what we've already done.

Similarly the international community is working on international standards for antigen tests and serology tests and so we're obviously monitoring and interact at table and doing what we can to assist in that development work and can be ready to implement the two worlds that become available when we do have some available so long-winded answer, great question, would be tremendous resources and all I can say is that we're doing our best to work on it right now.

(Koda Moody): Yes, thank you and one thing in spite of the things we submitted out test to NCI it is four months and still NCI has not evaluated the serology test so the second thing is that in case we will be able to help you put together reference panel. We have the resources so is there any way that I can talk to you or anybody else we should be able to provide help you generate those reference panels?

Timothy Stenzel: So somebody on our FDA team, you have a contact. You should have a contact.

(Koda Moody): Still we have not been assigned a reviewer.

Timothy Stenzel: Do you have a contact within our EUA review team?

(Koda Moody): Yes.

Timothy Stenzel: The larger team, it may not ...

(Koda Moody): Yes.

Timothy Stenzel: ... okay. They should be able to provide you with an update at least weekly about where things stand and why you stand where you do. If they are not being transparent enough, please send an e-mail to the template's e-mail box asking it to be forwarded to me and I will look into providing you as much detail as I can on the status.

(Koda Moody): So regarding the reference panel, is there any way I can talk to you or anybody else? We'll be able to help you setup serology reference panel.

Timothy Stenzel: Yes, you can contact me through the same means and I'll make sure that I connect you with the folks that are, you know, very closely and are involved in setting-up reference panels.

(Koda Moody): Thank you.

Coordinator: And our next question is from (Todd Lewis). You may go ahead.

(Todd Lewis): Hello. My question is in regards to screening versus diagnostic testing and let me pose a scenario for you so if we have we're offering rapid testing to say different facilities like employers or nursing homes, that type of thing, is it within the limits to use those as a screening test, get the answer at that screening and then for people who test positive take the sample for the confirmatory testing that'll be performed by PCR in the lab if it was an antigen test or ELISA in the lab if it was an antibody test?

Timothy Stenzel: So on our frequently-asked questions or FAQs on testing for SARS (Co-V) 2 page, we have a description as to CMS and CDC about the differences between diagnostic testing, screening testing and surveillance testing and you know, and whether or not a test protocol fits into which of those buckets it fits into.

If it's clearly been defined as screening, then that testing and the reporting is required to be done in the lab that has the CLIA certificate whether it's waiver or otherwise so I would point to those FAQs on our Website. If those don't answer your questions and you don't know whether you fit into the screening or surveillance, then I would urge you to send us an e-mail at the cdrh-eua-templates@fda.hhs.gov site and with specifics and we'll do our best to give you a very clear answer.

(Todd Lewis): Yes, so we're a CLIA lab and we'd be part of the screening process. Also for the rapid test, I just didn't so they still fall under the FDA purview so I'll look at that frequently-asked questions page ...

((Crosstalk))

Timothy Stenzel: If it definitely falls under the screening bucket and not the surveillance I'm happy to go into a little bit more detail here with you so is the test that you're using for screening, is it, you know, is that a kit?

(Todd Lewis): Yes, it would be FDA-approved rapid test with a high sensitivity so it would lean towards more false positives and then anybody that came up positive, just a quick and dirty test to sort through the people real quick and the screening view, you'd screen everybody that was say an employer and then anybody that came-up positive, then you would do confirmatory testing on them.

Timothy Stenzel: Yes, so you're really talking as I made an intro into today's conversation about a low percent positive situation where you're likely to have even if the test has a fairly high specificity, the chances are greater than none that not that a positive result is a false positive, not because it's necessarily a bad test.

It's just that the incidence of positives in that population is so low so doing a confirmatory test in that situation makes absolute sense to me and then I would just, you know, be aware of the CLIA CMS regulations on the certificate, you know, for that testing is, requirements for that testing is being performed with that point of care waived test.

(Todd Lewis): Okay. All right, sounds good, thank you.

Timothy Stenzel: You're welcome.

Coordinator: And our next question is from (Jonathan Cohen). Go ahead sir, you may go ahead.

(Jonathan Cohen): Thank you. Tim, on one of the first calls you had several months ago, you introduced a colleague who was focused on sort of software applications, data

analytics, data collection algorithms and so forth. Could you refresh my memory as to the name of that individual and how it was a woman, how she could be contacted?

Timothy Stenzel: Yes, Dr. Sara Brenner. She is the Chief Medical Officer for the IVD Office at the FDA. She is currently on a detail, we say, to the testing task force, an HHS task force in HHS focused on data analytics. She would typically would be on these calls but when she started that detail, this time period overlapped this call. The time that she was involved with the task force overlapped this call so she could no longer participate in this particular call.

Well if she joins me on CDC calls routinely and APHL calls on a weekly basis or on an every-other-week basis for those calls but again Sara Brenner and you can reach out to her through the cdRH-eua-templates@fda.hhs.gov e-mail and the team that receive those e-mails will put you in contact with her.

(Jonathan Cohen): Thank you.

Coordinator: The next question is from (Jessica Washerman). You may go ahead with your question.

(Jessica Washerman): Hello, yes, I have just kind of a bunch of questions on the antigen test validation so first of all with regard to the POCs or CLIA waived, we all know that there's no CLIA waived serology test but all of the antigen tests were CLIA waived and I just wanted to confirm that since this is not a POC section of the antigen template that I recall on this call that you referred people over to the molecular template but is there anything to know about because we're going to get started our validation on an antigen test about that POC piece?

And then I also have gotten confused about asymptomatic in this context so the molecular, I mean, I'm sorry, the antigen template says 30 positives, 30 negatives, there's nothing the asymptomatic is up to you I guess, up to the developer if they want to make an asymptomatic claim then they flip into all of this discussion that we've been having on asymptomatic; do I have that right so those are the two questions.

Timothy Stenzel: Yes, so first is we did at least update the antigen template to have point of care equivalent of CLIA waiver recommendations for an EUA and so those studies including user studies are in the template now so I would refer you to that template which is posted on our the Website for this is the in vitro diagnostic EUAs FDA Website and we have all our templates listed there and that would be the antigen template.

For point of care tests, for antigen tests, well moderately-complex, high-complexity as well, the - just one second, I think here this - so for I lost the question as I was thinking. Can you ask your question again?

(Jessica Washerman): Oh, well just about the POC validation studies ...

Timothy Stenzel: Asymptomatic, right, asymptomatic was the question, right, but also POC so I've got people who are texting me and telling me things and so it was a little bit distracting I'm looking at what they're writing me but I thought we had recommendations under a template for point of care.

(Jessica Washerman): No, you don't, you don't on the antigen one but you've always said go to the molecular, look at that, I don't know, but it was most just...

((Crosstalk))

Timothy Stenzel: You're right, we don't. I have look at the new version ...

(Jessica Washerman): Well, it's (unintelligible).

Timothy Stenzel: ...and cleared it of the template that has it in there. We have and so it's very, very similar to the molecular, there's a couple of points on both on asymptomatic and how do you finish your point-of-care studies that I do want to update you with our current thinking and it will show up in the new template updates and that is while point-of-care tests, we really want to see how it performs prospectively in the point-of-care setting.

In order to speed access to point-of-care tests that haven't been previously cleared or authorized for other antigens not SARS and to get these new tests that haven't been seen before by the Agency on the market, we are allowing for you to supplement prospective patients in the point-of-care with banked samples that work with you and your technology.

There is going to be a post-market, post-authorization commitment to complete the prospective portions of the point-of-care studies and there are certain ways that we want you to, you know, add those banked samples into the testing that's done in a point-of-care setting for the authorization and then with asymptomatic we have very clearly stated in our Website that physicians can, clinicians who place orders for tests, can place an off-label order for a test to be used in an asymptomatic individual even though there isn't a claim for that particular test and we are encouraging those that are using those tests to perform the test on those individuals and report-out those results.

If a test developer wants specifically to say that our test is validated for asymptomatic individual, then we want to see the data for that and we want to be able to post the validation data in the EUA summary or IFU so...

(Jessica Washerman): So for all those, the antigens all of which got CLIA waiver, they all had submitted basically the molecular template POC data?

Timothy Stenzel: Well, they interacted with our team and our team gave them feedback so the team, now if you send in an e-mail, usually through a pre-EUA request, they can now give you the feedback on what to do for point of care. What do we recommend that our current thinking is for point-of-care validation. I've given them authorization to go ahead and give you an e-mail response which should happen very quickly after you send an e-mail to our template's e-mail address.

(Jessica Washerman): Okay, thank you.

Coordinator: And our next question is from (Bolivar Markovich). Your line is open.

(Bolivar Markovich): Yes, my question is very simple. If you know that anybody has tried to test vaginal fluids at home test self collection of system together with HPV and pap test because that would be an excellent model for home testing and for post symptomatic patient screening? COVID, HPV and pap test?

Timothy Stenzel: So you want to combine SARS and PAP testing into one? It's not something that we've authorized and it certainly isn't a common respiratory virus sample type, vaginal fluid, you know, in general if you have data to support that sample type, we can't really argue with data.

Just realize that each PD testing, molecular testing is a PMA-level authorization in the U.S. and that is quite an extensive validation so that would certainly you know, entail a lot of discussion. The other thing is

depending on the actual test type, we've authorized quite a few saliva sample types for testing and that is certainly something that's very readily available.

And easily collected at home and doesn't require swabs, doesn't require, you know, VTM which can be in short supply, and obviously we've authorized patient self-collection at home with proper validation of of saliva test so again, we're open to what developers develop.

There are certain practical pathways that might be easier for a test developer than others. Always open and especially if there's data. I just want to give you a couple of my thoughts there.

(Bolivar Markovich): Well, thank you very much for the information because we have some data that could be perceived as for combined testing and we'll speak with you about the data and will ask you more so thank you. It is possible and I will reply to continue these discussions with more data we'll have. Thanks.

Timothy Stenzel: All right, thank you.

Coordinator: And there are no more questions at this time and I'd like to turn the call to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learning Webpage at www.fda.gov/training/cdrhlearn by Tuesday, September 22nd. If you have additional questions about today's presentation, please e-mail cdhr-eua-templates@fda.hhs.gov.

As always, we appreciate your feedback. Following the conclusion of today's presentation, please complete a short 13-question survey about your FDA

CDRH virtual town hall experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's wide discussion. Again thank you for participating and this concludes today's discussion.

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

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