

**FDA Virtual Town Hall Series –
Immediately in Effect Guidance on
Coronavirus (COVID-19) Diagnostic Tests Moderator: Irene Aihie
September 30, 2020
12:15 pm ET**

Coordinator: Today's conference call at this time your lines have been placed on listen-only for today's conference until the question-answer portion of our call. At which time you will be prompted to press star 1 on your touch-tone phone.

Please ensure that your line is unmuted and please record your name when prompted so that I may introduce you to ask your question.

Our conference is being recorded and if you have any objections you may disconnect at this time.

I will now turn the conference over to our host Ms. Irene Aihie. Ma'am, you may proceed.

Irene Aihie: Thank you. Hello, I am Irene Aihie of the CDRH's Office of Communication and Education.

Welcome to the FDA 28th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

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

Following opening remarks, we will open the line for your questions related to today's discussion.

Please remember that we are not able to respond to questions about specific submissions that might be under review.

Now, I give you, Toby.

Toby Lowe: Thanks, Irene. Thanks everyone, for joining us today. My update today is that, we updated the Web site that we have for the reference panel comparative data this is the reference panel that we have been sending out to test developers to characterize their LOD in comparison to other tests.

And we first published data two weeks ago and we just published some new data that's come in since that - the first batch where I believe we added somewhere around 20 to 25 new tests to the data that we posted there.

And now I'll turn it over to Timothy for his update.

Timothy Stenzel: Thank you, Toby. And thanks to all for joining us again today. The first thing I wanted to do is to give a shout out to those who are critical and so important for us to put on these weekly calls.

First of all, you're very familiar with Irene but her backup is Kemba. All of them get involved with transcribing this and then posting that.

Of course Toby and the operators and everyone else. There is a little bit of an Echo. I apologize for that.

Irene Aihie: Now you're better, Timothy.

Timothy Stenzel: Is that clear? Okay. Thanks.

Irene Aihie: Perfect. Good.

Toby Lowe: Sure thanks, Timothy.

Timothy Stenzel: So thanks. Thanks, Irene, Vickie, Kemba, everyone. Okay, I wanted to speak about the quality of EUA submission.

So it's important to have a complete, well-organized submission, including your validation protocols so we know that's how your validations were performed and whether or not those were accurately and correctly done.

Those are all important in order for us to move swiftly towards an authorization decision.

You know, our expert reviewers have expressed to me a growing frequency of getting bogged down with less than optimal submissions.

And they have spent valuable time working with these developers in trying to help. And the process, of course, has delayed review of other applications.

We're in a new phase now and we've authorized quite a few tests. And therefore we are going to take steps to correct the situation so that we can work through all submissions as quickly as possible.

So please take steps to have, you know, the best quality submissions. If you've already submitted and you want to update and make updates to it, please do.

And then when we have questions, please address them directly and clearly and as quickly and as completely as possible. So that we can work through those submissions with you and then move on to the others as quickly as possible.

So I thank you all in advance for help with this. And so with that, we'll turn it over to question and answers. Hello.

Coordinator: Your line is open.

Irene Aihie: Timothy are you there?

Timothy Stenzel: Yes.

Irene Aihie: We can hear you.

Timothy Stenzel: All right. Yes, moving to Q&A now if possible.

Coordinator: At this time, if you would like to ask a question, please press star 1 on your touch-tone phone.

Please ensure that your line is unmuted and please record your name when prompted, so that I may introduce you to ask your question.

Please stand by for questions. The first question is from (Savannah SP) your line is open.

(Savannah SP): Hello, this is (Savannah SP) with User Wise Consulting. I had a question about EMC compliance.

So in the molecular diagnostic template for commercial manufacturers, underneath the software validation section, the FDA recommends that manufacturers perform EMC testing to comply with IEC 60601-1-2.

We have a client who has tested for EMC through compliance with the IEC 61010 standards. Is it possible that the FDA would accept the IEC 61010 standard compliance instead of the IEC 60601 standard?

Timothy Stenzel: So I would want to verify the standard that the entire center is moving to? I think it's the first one you mentioned that's in our templates.

You can double-check at the template's email address. But we are making that transition and understand that there are some opportunities to grow through that transition.

So there - we are flexible on dealing with potential deviations from what we'd like to adhere to and are open to alternate mitigations.

So and that can include labeling but when you get into the - it's important on a one-by-one basis to understand that and a granular level.

But obviously, we want if there are instruments - electrical instruments used, we want to make sure that no harm comes to users of those instruments.

(Savannah SP): Okay, that makes sense. Thank you.

Timothy Stenzel: All right. Thank you.

Coordinator: Our next question from (Shannon Clark). Your line is open.

(Shannon Clark): Hello, (Shannon Clark) also with User Wise consulting. There isn't currently a clear template that outlines home use testing for antibody lateral flow test kit.

Should we just go ahead and follow the antigen home-use instructions with testing of 100 users who are negative for COVID-19 in order to obtain an OTC designation or 30 users who are negative for COVID-19 if we're pursuing a prescription-only indication?

Timothy Stenzel: Well, that's certainly a good start. We're supportive of that. We are working on a template specifically for that.

And we have enough built up thoughts about that to be able to provide, via the templates email address, with some recommendations.

So if you reach out to the template's email address and ask for the home testing serology recommendations then one of our team members can assist you with the best possible and most up-to-date recommendations that we have.

(Shannon Clark): Great and do you have any concerns about testing only COVID negative individuals and displaying positive results to those individuals in order to test that scenario?

Timothy Stenzel: You know, overall we want to ensure that in the non-lab setting that accurate results are attained, accurate readings are obtained and accurate interpretations. Especially in the OTC (Over The Counter) where a clinician is not involved in the testing for those individuals.

So I would - I don't remember the details of the current recommendations for serology at home and therefore, you know, do request those recommendations.

And then if you have follow-up questions on those contexts, we can work through any potential alternatives.

(Shannon Clark): Okay, thank you.

Coordinator: Thank you. Next question, (Louis Perlmutter) your line is open.

(Perlmutter): Yes. Timothy and Toby thanks. Thanks for taking my call. Besides the biomax now from Abbott, is there any other rapid antigen tests been approved?

Timothy Stenzel: Yes. So we've authorized four I believe. The Binex to my knowledge is the only one authorized to date that doesn't require any instrument.

And certainly, there are more in development that won't require an instrument. Instruments in the area of rapid testing has been deployed for other respiratory

pathogens such as flu and RSV. And there can be obvious benefits in using an instrument in the current pandemic. And, you know, prior to this pandemic we also authorized non-instrumented rapids and continue to do so.

(Perlmutter): Yes, because I was thinking of the non-instrument tests. But just to go on is there anything been approved for saliva-based rapid antigen tests?

Timothy Stenzel: No, not yet. In our conversations with experts in the field, there is - has been some concern about the use of saliva-based rapids and the sensitivity given the fact that there's not an application and...

(Perlmutter): Yes, because it wouldn't be nice if you could. Yes, but I understand their concerns. And of course...

Timothy Stenzel: ...and we're, you know, at the end of the day, you know, data supporting use for those specific sample types will be reviewed. We don't make any, you know, preconceived decisions about this.

(Perlmutter): Right.

Timothy Stenzel: We're obviously into uncharted territory looking at saliva antigen for respiratory viruses. We've authorized it for a molecular test and - while I can't encourage it for antigen test specifically I'm not dissuading developers either.

Come with, you know, if you have ideas come to us. If you have data come to us.

(Perlmutter): Great. Okay, thanks for your answers.

Coordinator: Once again, if you would like to ask a question, please press star 1 on your touch-tone phone and record your name. We have a question from (Franco Calderon) your line is open.

(Franco Calderon): Thank you very much. Dr. Stenzel, I have a question regarding LOD for the antigen test and if you could also speak a little more about sensitivity and specificity.

I know regarding the LOD you've said a couple of times before that the focus should be on the overall clinical performance because there are no universal standards set for LOD. I would appreciate it.

Timothy Stenzel: Yes, so, you know, I think our expectations both for those that are prescribed tests for antigen and as well as those that are OTC, you know, and in the home environment, we've made, you know, recommendations for performance at least for sensitivity or PPA quite clear.

You know, that we would like to see at least 80% sensitivity for a single result compared to a high sensitivity molecular test at least during the period of time when an individual is considered to be infectious.

So, you know, that period is when we typically think, you know, after infection and when they begin to shed virus and perhaps the first five to seven days of shedding - and at least that's the period that I correlate with symptoms for those patients who do have symptoms.

We would like to see that, you know, overall that at least 80% sensitivity for that period. That's does mean that potentially during that period your test is missing 20% of people who could be infectious.

And then, you know, certainly we've heard arguments made in the public arena for authorizing much lower sensitivity tests, significantly below 50% and as low as 30%, or even lower.

And, you know, if a test misses more than 50% of the people who could be infected, we would have serious concerns about that kind of test.

Now we are open as Dr. (Shuren) and I expressed in the recent op-ed in The Hill to using serial testing. It's very possible that to test that individually might have performance below our recommendations say 70% PTA. That if used in serial testing, perhaps a two-pack, you know, two tests in a pack then would rely on testing twice the same individual twice over a set period of time. Maybe day one, day two, day one, day three, something like that.

And we've expressed, you know, very much flexibility to say, we can look at the combined performance of such a strategy. And if it does do an excellent job of hitting us, you know, a minimum recommendation then we could consider that for authorization.

So, we – however, we do think that the vast majority of people who are infective or should be infective, that is they have the ability to infect others.

We would want to see identified out for those individuals.

(Franco Calderon): Okay, thank you. Thank you for that if I may add a couple of related questions. So can you speak a little bit to the LOD?

I know in the past two, three calls you've said that LOD should not be so - much a big deal in antigen test rather the overall clinical performance?

And then the last one it's perhaps not something that you do but my test was developed and validated in China, okay, so we have data for that.

However, the biggest hurdle I'm having is finding a CLIA lab, whether it is private or public or an academic lab to conduct the U.S validation both analytical and clinical.

Does FDA provide any resources, recommendations for someone like me that's trying to do this?

I have the test. I can produce 300,000 of these a day but I do have the hurdle of the validation. Not being able to after multiple, multiple contacts to again public, private, academic institutions and everybody is extremely busy.

Timothy Stenzel: Yes, we have heard that there are some contract research organizations out there that have been very helpful to developers and we don't give out recommendations for how to use. But certainly, that's a pool of folks who can potentially help.

I think what you're probably talking about is doing the point of care study to demonstrate that non-laboratory users from the point of care settings can perform the test accurately.

And while we would love to see that work done in the United States, that's not a formal requirement. It is a requirement though to do that testing in English and perhaps even in Spanish.

I'd looked at the template because that's the US target population. So hopefully, that helps.

(Franco Calderon): Okay. So could you please clarify? So are you - am I misunderstanding when you say that the performance data that we already have for the test if it's presented in English and or Spanish could be acceptable or is that...

Timothy Stenzel: If you have done the point of care study...

(Franco Calderon): That is okay.

Timothy Stenzel: ...that is not in a laboratory - not in a laboratory with formally laboratory trained people. But if you've done it in a CLIA waived environment, with non-laboratory healthcare professionals.

So it's all in how the study was carried out in the target population because when we deem a test as CLIA waived, we expect that test will then be performed by non-laboratory users

Even these days by say, officials at schools and businesses who have never or even nursing homes who have never done this kind of testing before, and they have newly acquired a certificate or waiver from CMS CLIA.

And then finally, and I want to wrap up these questions because I have a feeling there is more questions from callers.

Is LOD, you know, probably many outside the FDA have made more deal of LOD than we do.

First of all, if there's not an easy way to harmonize how LODs experiments are performed. It's very hard for us to assess individual LOD determinations. We do require it. We expect you to do it but it is a lesser review item than for

actual clinical study performance. That is, what is your sensitivity, and what is your specificity?

And then if you are, you know, want to do things like home testing, or point of care testing and you've done the appropriate study to show accuracy in both settings as well.

But thank you for your question, the opportunity to address some of those.

(Franco Calderon): Thank you.

Timothy Stenzel: We will need to move on.

Coordinator: Thank you. The next question comes from (Sheree Kaushik) your line is open.

(Sheree Kaushik): Hey, Tim and Toby thank you for taking these calls and taking the town hall every week and taking our questions.

Timothy, basically I wanted to ask a question about the issue of the quality of submission that you raised. Could you elaborate on - when you said you needed validation protocols - did you guys actually want to see the protocol before it's implemented or?

I mean, the way I've been doing my submissions is to actually get a clinical trial report or analytical validation report that briefly describes the protocol. Could you give us some examples of what you want us to give you for making the submissions better?

Timothy Stenzel: Yes, in a perfect world, you know, where you're you doing pre-sub or Q-sub or in the case of EUAs or pre-EUAs and we have a lot of time which we don't.

We don't have the time or resources to give as much feedback as we would love - which is why we provide templates that provide very, hopefully very clear recommendations on study designs and expectations.

When we receive the data - if we just receive the data and we don't receive information about how the studies were carried out, it's sometimes hard for us to assess, you know, whether this directly applies to the review.

So if your summary of how you did this is clear enough and our team doesn't have questions then we're fine.

We just want to very clearly understand, you know, what were the requirements you set on the study and what are the inclusion-exclusion criteria, the settings, the type of users, all that is very important for us to understanding the performance and being able to make a decision as quickly as possible. Hopefully, that clears things up.

(Sheree Kaushik): Yes it does. Thank you very much.

Coordinator: The question comes from (Tom Slovak). Your line is open.

(Tom Slovak): Yes, I would like some advice on what is the most appropriate product code to use for the saliva collection kit with VTM and also a swab collection kit with VTM. I've seen an amazing range of different code used.

Timothy Stenzel: I'm not going to be able to provide you with those codes but we have experts on the team who can. I don't know if Toby has some at hand. The important (unintelligible).

Toby Lowe: I don't know off the top of my head, but if you email via the mailbox we can get you some answers on that.

(Tom Slovak): Thank you very much.

Coordinator: Thank you. The next question comes from (Annie Bell), your line is open.

(Annie Bell): Hi thanks. Two questions related to the serology template for manufacturers. Are there any limitations on using archive samples for a semi-quantitative serology test?

Timothy Stenzel: You know, we are working on our recommendations for semi-quant and quant neutralizing antibodies.

I think our thinking is advanced enough that if you ask that question to our templates email box we can respond and without checking with - double-checking with the team on what they would like.

We I will just say generally, we try to be as flexible as possible with archived samples in order to speed development and speed access to technologies.

(Annie Bell): Okay, great. And then one other question on the same template. Are there - does it have to be more than one lot used in the robustness study or can one lot of reagent be validated?

Timothy Stenzel: It depends. By and large, we have been not asking for that for EUA. There are specific examples though in situations where we may.

(Annie Bell): Can you give an example where you might ask for that?

Timothy Stenzel: Yes, I mean, I would say that it's uncommon but it happens. And I would actually, you know, I think it's best to handle that on a case by case basis.

But if you have any concerns about anything that's asked and you think it's not least burdensome you can get ahold of me through the templates email and give me specifics.

(Annie Bell): Okay. Sure. And specifically for stability will more than one lot be required?

Timothy Stenzel: That is a great question. I don't know the answer to that off top of my head for EUAs.

(Annie Bell): Okay.

Timothy Stenzel: I know I defer to the template and our team for that. But in general, I don't believe so. But I'm happy to double-check with our teams.

(Annie Bell): Okay. Thank you for your help.

Coordinator: Thank you and our next question comes from (Sean Gamel). Your line is open.

(Sean Gamel): Good morning, Dr. Stenzel. Good morning, Toby. Thank you for taking the call.

I represent a high complex accredited laboratory - a single laboratory located in Carlsbad, California.

We submitted our EUA to the high throughput of 20,000 specimens per day PCR assay. Our EUA has been under review for a little bit over three and a half months.

To your question - to your comment earlier we did address questions from the agency on software validation provided that additional information. And we've answered all of the FDA questions pertaining to our EUA application.

At this time, we're still awaiting an EUA approval or response from FDA for any outstanding items. Understanding that our application has been under review for three and a half months, we are confident we've answered all questions. Can you provide an estimate of when an EUA approval should be anticipated if our organization is confident that we've addressed all of the agency's questions in our EUA applications?

Timothy Stenzel: Yes, so we don't address specific applications on the open call. If I haven't already been approached by you or a representative of the developer, I often get the mails and then do look into them and as soon as I get back, I get them back.

But if I haven't been brought in to your knowledge, you can send an email to the template's email address and I can look into the specifics of the situation.

Of course, we do allow the guidance for those that require an EUA but where there's an allowance for the launch of that test prior to authorization to the guidance, we allow that pathway very specifically in view of we are dealing with volumes applications...

(Sean Gamel): Yes.

Timothy Stenzel: ...and we didn't want to delay access.

(Sean Gamel): Yes, Dr. Stenzel thank you. Our company is listed on the FDA website. It is a high complexity CLIA laboratory offering testing. However, you know, the state is currently not EUA authorized.

And so I know the question has been asked before callers we understand the great number of applications. But on behalf of the organization, we're just looking for an estimate of when we should anticipate our final response from the agency so.

Timothy Stenzel: If you contact me with the name of the organization and the submission by somebody who has the authority to communicate with us then I will - and through the templates email address ask for Tim Stenzel and they'll get that over to me and we'll look into and we'll provide a specific answer.

(Sean Gamel): Great. Dr. Stenzel. Yes, I'm the point of contact on our EUA application and I will forward an email via the templates address and send in the question.

Timothy Stenzel: Thank you.

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

(Jeff Gray): Hi, this is (Jeff Gray) from GrowTech. Thanks, again very much for having these meetings. Very helpful.

Question. Over the last couple of meetings, you said that you still had not had any submission for an at-home POC virus test. Is that still true? And then the question is why do you think that is? I guess I'm looking for your opinion there.

Timothy Stenzel: That's still true to my knowledge. We had a home non-lab test template out there for a while. We certainly engaged with a number of parties. I've certainly personally encouraged a number of developers to advance their programs. I don't know. Honestly, I don't know.

(Jeff Gray): So if you - I'm just looking to learn here. Do you think it's a market reason or regulatory reason or a reimbursement reason?

Timothy Stenzel: When something goes OTC I don't believe there's reimbursement. It's a patient out-of-pocket sort of testing, or it's whatever entity is doing the testing out of their pocket to my knowledge. But I would refer you to CMS with regard to any specifics about reimbursement for that.

(Jeff Gray): Okay.

Timothy Stenzel: If somethings by prescription, typically it is covered. We clearly allow prescription tests to be performed in the home and we've authorized those for other non-COVID tests for home use by prescription.

And anyway, we're very open to it. We're very open to working with developers. We've provided, you know, recommendations for validation. So we're open for business.

(Jeff Gray): Okay, thanks. Sorry. One other question kind of a tactical one. If one submits a pre-EUA submission and gets on a kind of a EUA track if you will -- and then if largely the EUA program goes away or something changes are submissions already in the queue are going to be approached with the EUA or how do you see that?

Timothy Stenzel: I'm sorry can you ask that question again?

(Jeff Gray): Sure. If you make a submission under an assumption that you're going for a EUA and you're partway through that track If then the EUA program goes away -- will you phase it out and still approach people who already have submissions on the EUA still consider them for EUA or goes away? It's just done that's it. Whoever's in the queue doesn't matter.

Timothy Stenzel: Yes, that's a really excellent question. And I don't have an answer. I'm not sure if Toby does, either.

I mean certainly, you know, we have a number of open emergency authorizations from prior emergencies still and we have not closed those down from an agency perspective.

We would support a very amenable transition plan so that those that have developed tests that could, you know, help out here.

So, you know, for those that have already been authorized, there's a question for them. Specifically, I don't have a ready answer for those that have submitted but hadn't been authorized.

Except to say that it's from our perspective we want to have a smooth transition and we want to give all developers who want to make that transition in general sufficient time to convert.

(Jeff Gray): Okay, thanks very much, again, for having this. Appreciate it.

Coordinator: Our next question is from (Patrice Milo). Your line is open.

(Patrice Milo): Thank you very much. This is (Patrice Milo) from Pine Trees' health. And I'm interested in your perspective relative to surveillance testing.

And what is your guidance on point of care molecular tests being used for currently unmet surveillance testing needs in settings such as schools and in conducting that how should results be properly reported and acted upon?

And how should our test be labeled as such for example, for research use only?

Timothy Stenzel: Yes, we've gotten some inquiries about that. Toby, are you up to responding to this question?

Toby Lowe: Sure. So I think, you know, it's important to take a look at our website where we discussed surveillance testing and what surveillance testing is.

You'll want to make sure that, you know, that you're - the intent of your testing is true surveillance and not screening.

And then we have indicated on our website that FDA does not actually regulate surveillance testing if it truly is surveillance testing.

So then we would recommend that you also take a look at the resources that CMS has put out about surveillance testing and about ensuring that you have the appropriate CLIA certification as necessary for the testing that you're doing.

And then I believe that the CDC has also put out some recommendations regarding reporting and calling out the differences between surveillance and screening and diagnostic testing.

(Patrice Milo): Great, thank you very much.

Coordinator: Our next question comes from (Kaduna Moody Benpat). Your line is open.

(Kaduna Benpat): Hello, good afternoon. Can you hear me?

Timothy Stenzel: Yes.

(Kaduna Benpat): Thank you for taking my call. I greatly appreciate the town hall and your clarifications.

Earlier you mentioned the quality of the submission. I have a question regarding that.

When the review is being done currently does it mean that the earlier submissions have gone through a more lenient review and now the submissions under review are being reviewed with more rigor?

Is that the - It is the same format it is being done and because of the time if the submission quality is better then the review can go faster. Can you just clarify, please?

Timothy Stenzel: Yes, no in general our review process hasn't changed.

It's just earlier on when there were fewer submissions, we were trying to be as helpful as possible and perhaps taking more time than we can afford now on a given submission.

So and sometimes there, you know, we will ask for information and there's some dialogue about the necessity of getting that information.

And because of the volume, and because of our desire to work through all the submissions as quickly as possible.

We want to shorten those conversations, make them as brief as possible, and asking developers to help us get the information that we need to make as quick a decision as possible.

(Kaduna Benpat): I mean, does that mean that the people who submitted earlier because of the early mover advantage did they get away with less stringency compared to the bar is higher now for review?

Timothy Stenzel: No, not at all. Our expectations or recommendations as far as performance goes do not change.

What I'm saying is that if a submission has issues and they're not quickly addressed, we may triage those to the lower priority while we move on to the next.

So we would encourage developers when we ask a question to be succinct, quick, clear and provide the information because otherwise, we're going to have to move on to the next submission. In all fairness to other developers.

(Kaduna Benpat): Thank you. Greatly appreciate your comments.

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

(Gustavo): Hello, my name is (Gustavo). Can you hear me?

Timothy Stenzel: Yes, we can.

(Gustavo): Oh, good afternoon to everybody and I want to thank you for this town hall meeting. I think it's a great idea.

I'm looking forward to hearing some of the previous ones to be a little bit better informed.

My question is regarding a real-time PCR machine it's made by A Chinese company called (unintelligible) and the model is a plan 96P.

It appears on a EUA IFU of a Korean company and I would like to know if there's another way to use that machine for other tests that have an EUA.

Timothy Stenzel: So we're open to whatever instrument a developer wants to use, as long as it works.

And if we have already authorized an instrument, obviously, we've had a chance to try and understand its performance at least with regard to the bars that we've set for EUA applications, which are much, much lower than our standard application.

And we do waive significant quality system requirements to make that - to allow that to happen.

And so if you see something that has been utilized already in EUA authorization, it's - you can certainly ask if there are any issues with that of our staff but, you know, in all likelihood we wouldn't have authorized unless

we have sufficient confidence in both the test and the platform as well, so, you know.

But we don't negotiate, you know, terms or we provide typically, intermediary services.

So feel free to reach out to any other developer of any technology in our space that you feel would be beneficial in your own program.

(Gustavo): Okay, so I understood that if the equipment was authorized for test XYZ, it can be used and validated for another test that also, has a EUA?

Timothy Stenzel: We wouldn't prohibit it unless as I said, if it performed once already with one developer, it's likely to perform again, for anybody else.

It's not a requirement. I mean, it's not a requirement for developers to use only instruments that we use for which we've allowed authorization for in developers' submissions.

You don't have to use something that's been previously authorized. You can use whatever you want, as long as it performs well and meets our expectations.

(Gustavo): And my next question is regarding the expansion. The EUA says to use (unintelligible) expansion regions and we would like to know if it's possible to use another expansion region that is EUA approved.

Timothy Stenzel: Yes, that's a question that I'm just not aware of that I would understand enough at this point, it sounds very specific.

So for those kinds of specific questions, I think it's best to go to our template's email address.

But again, we're open to whatever technology that works, whatever extraction technology that works, and it doesn't have to be previously authorized. As long as it works.

(Gustavo): Great. Well, thanks a lot that answers my questions.

Timothy Stenzel: You are welcome.

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

(Dwayne): Hi, thank you so much for hosting these town halls as others have stated. It has been very, very helpful.

My question is in relation to the process of the notification pathway for commercial manufacturers of serological tests.

After the manufacturer has sent in the notification to the template's email address could you just go over the process that occurs prior to the testing listed on the FAQ page, and what the usual timeframe is for that process?

And I know timeframes are really difficult for you to speak to. But if you can just give a little bit more information about that process, I really appreciate it.

Timothy Stenzel: Yes. So something comes into our email template box or wherever the particular box that comes into.

We do, you know, a quick vetting of that request. And then usually, within two business days, you should receive information back and confirmation of your request, and hopefully, if there are no issues, you know, confirmation that you know, the submission has been received and accepted.

And then it goes to the web service folks who post that as soon as they can.

So if there's a delay beyond two business days and you're receiving word back about whether your notification request was allowed then I would ping them again, email them again and ask for updates as soon as possible.

(Dwayne): Okay, thank you very much. It's very helpful.

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

(Cyad): Hi, Timothy. Can you guys hear me okay?

Timothy Stenzel: Yes.

(Cyad): Great. Thanks for taking the call. I know we're running out of time here. So we'll just get right to the point.

I had a question about the website, where you list the IVD authorized test?

It seems for recent approvals; you have to expand the date EUA for an issued order to get at the detailed information where previously it was at a top-level and that's great.

My question is more around the authorized setting listing. For one of the recent authorizations on September 24, for an Cepheid that's on a public database - I'm not asking for anything private.

It seems like there's a point of care IFU as well as a lab test IFU but the authorized setting listing is only listing H and not the W.

Previously when I saw authorizations for point of care that also had lab tests there was an authorized setting listing with H and W and I'm wondering if this is a new nomenclature, or if we're still going to be able to sort on H and W in terms of authorized setting.

Perhaps this was a glitch. I don't know or if something changed?

Toby Lowe: I would double-check. Try refreshing your page and maybe clearing your cache because I'm looking at it right now. And it does show H and W for me.

(Cyad): Okay. Okay, perfect.

Timothy Stenzel: Yes, I have just double-checked that in both for their stars test and for their panel testing including flu and RSV it does list all 3 designations.

(Cyad): Okay. I was looking specifically at the September 24 authorization. That's great.

If that sticks. That's wonderful. And it's just a glitch that was on my computer. So thank you for clearing that up.

Coordinator: Our next question is from (Shawnee Fernando). Your line is open.

(Shawnee Fernando): Actually, my question got answered during the previous clarification so thank you.

Coordinator: Thank you, ma'am.

Timothy Stenzel: You're Welcome.

Coordinator: We move on to (Laura D'Angelo). Your line is open.

(Laura D'Angelo): Thank you and thank you guys obviously, for all the work that you've been doing. It's really appreciated.

I have two questions but I'll be very quick. Can you elaborate just briefly on the transition you mentioned versus, you know, is this an impending regulatory transition, or is it just kind of like the passage of time and a little more attention to detail?

I know that we have - we are expecting some new templates and some updates including, you know, antibody lateral flow home use.

But is this transition kind of a regulatory thing or is it kind of more of an attitude? Is there any formal announcement?

Timothy Stenzel: So we are working on guidance that obviously has to be cleared within the US government before it's posted on a transition path.

You know, and as soon as that can be finalized and posted it will, I can't - I'm not in control of when that gets posted.

But we certainly anticipate the question and we have for a while and the potential concern.

We don't want to over minimize the concern but it is and as I stated and others have stated our desire to have a very reasonable transition period from EUA authorization to full authorization.

(Laura D'Angelo): Okay, so when you said earlier that we're in kind of a new phase now that was just kind of a general thought.

Timothy Stenzel: That had to do with, you know, our ability to spend as much individual time with the developer as we may have had in the past or taken in the past.

It had nothing to do with the transition and everything to do with the fact that as the number of submissions is growing, our desire to get through them as fast as possible.

And now that we have a lot more templates and recommendations for validations and very clear recommendations and expectations, we think that due to that work that our conversations with individual developers can be much more efficient.

And that will help us speed through the applications.

(Laura D'Angelo): Okay, that makes sense. And then just super quick and I understand if you guys say anything kind of too strongly about it, but just status update on international LOD standards that's still kind of in the hopper with PCR coming first followed by antibody and antigen.

Timothy Stenzel: And they're all being worked on. We're not the main drivers. The FDA is not the main driver but we're at the table.

My understanding is those are still targeting towards the end of this year, to make those available.

(Laura D'Angelo): Good and all the work that you're putting in over that (unintelligible) and, you know, in general, thank you.

Timothy Stenzel: You are welcome.

Coordinator: Thank you. That was our last question. I will now turn the conference back over to our host Irene Aihie. You may proceed, ma'am.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Today's presentation and transcripts will be made available on the CDRH learn web page@www.fda.gov/training/cdrhlearn by Friday, October 9.

If you have additional questions about today's presentation, please email cdrh-eua-templates@fda.hhs.gov.

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

The survey can be found@www.fda.gov/cdrhwebinars immediately following the conclusion of today's live discussion.

Again, thank you for participating. This concludes today's discussion.

Coordinator: This does conclude today's conference call. We thank you all for participating.
You may now disconnect and have a great rest of your day.

END