

**FDA Virtual Town Hall Series –  
Immediately in Effect Guidance on  
Coronavirus (COVID-19) Diagnostic Tests Moderator: Irene Aihie  
October 14, 2020  
12:15 pm ET**

Coordinator: Welcome and thank you for standing by. Today's call is being recorded. If you have any objections you may disconnect at this time. All participants are in a listen-only mode until the question and answer period. At that time, you may press Star 1 on your phone to ask a question. I would now like to turn the conference over to Irene Aihie. 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 30th 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 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. Hi everyone. Thanks for joining us again this week. I've got a couple of announcements that I wanted to share with you and then we can open up the line for questions.

So the first thing I wanted to mention is last week in case folks didn't see it, we put out a letter to healthcare providers on recommendations on providing clear instructions to patients to self-collect an Anterior Nares Nasal sample in a healthcare setting for SARS CoV-2 testing.

So that walked through the importance of having appropriate directions for patients who are self-collecting so that we make sure that they get a good sample prior to that sample being sent into the lab. And we link in that letter to healthcare provider to a couple of examples of it and instructions that can be used that, you know, are available for public use so providers can use those if there are not other instructions that they already have available so encourage folks to take a look at that.

Along with that on the same day last week we also updated some of the FAQs related to swabs both in the testing supply FAQ section and the 3-D printed swabs FAQ section on the FAQ page. So take a look there for some updated information.

And then yesterday we issued an immediately in effect guidance on enforcing the - sorry titled, the Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests during the COVID-19 Public Health Emergency. We put this policy in place to help with the potential for shortages during the upcoming flu season since a lot of the flu and RSV tests use the same components as many of the SARS CoV-2 molecular assays.

So this policy will help expand access to certain FDA cleared molecular tests intended for detection and identification of flu viruses. And it includes those influenza tests that also detect and identify RSV. And so that was issued yesterday and is posted up on our Web site as well. And with those updates we can go ahead and open line for questions. Thanks.

Irene Aihie: Operator, we'll now take questions.

Coordinator: If you would like to ask a question press - if you like to ask a question press Star 1 from your phone, unmute your line and speak your name clearly when prompted. Again, if you would like to ask a question press Star 1. One moment as we wait for any questions. There are currently no questions in queue.

Irene Aihie: Operator can you get scripting one more time? I'm sure that we have questions folks are probably trying to get into the queue.

Coordinator: If you would like to ask a question, press Star 1 from your phone, unmute your line and speak your name clearly when prompted. Again, if you would like to ask a question press Star 1. One moment as we wait for any questions. Our first question comes from (Adam Beatty). Your line is now open.

(Adam Beatty): Hi. Yes, first off, thanks for everything you guys do. Just a quick question, what are some of the circumstances that might allow for one company to receive EAU excuse me, EUA approval after say six weeks versus other companies that are - have been waiting for well over 100 days? Thank you.

Dr. Timothy Stenzel: So we do have a triage system (Adam). If you think that triage system I mean or you think you're - where you are in the triage is not appropriate for your developed test, if you haven't already done so please communicate with

us. I know we have our - some sponsor specific, developer specific conversations going on. And we'll continue those to make sure that they're properly triaged.

And we clearly have stated recently that those EUAs submissions that require EUA authorization before they can be implemented like any sort of home collection, home tests of course, point-of-care tests, they can't be point-of-care unless we've reviewed and authorized and deemed it as point-of-care and then in addition those things that substantially add to the ability for our national response in terms of throughput, high throughput testing.

The other thing is, you know, those submissions that are incomplete may not be triaged higher on the list. So every submission in my direction has a contact within two weeks in the office. So if you want to check that your submission is complete you can ask that contact. You can also ask that contact to double check your triage status and make sure that they understand the features of your tests and how it might be a higher priority.

But, you know, from the beginning we've received over 2400 applications, EUA applications as of last month. We've authorized going on 300 tests. We've authorized over 200 amendments to EUA authorized tests and we've denied something on the order of 100 tests. So we are making decisions as soon as we can.

Those who have serology tests that are amendable for testing at NCI we are encouraging all developers to submit their tests to NCI. And we are - there is still a backlog although of those that we've prioritized at NCI, the backlog is shrinking and then once we get data from NCI we try to make our decision as quickly as possible. And obviously we share the NCI data with - that we

receive with the sponsor so hopefully that helps. And Toby I don't know if you want to add anything else?

Toby Lowe: No, I think you covered it. Thanks.

Irene Aihie: We will take our next question.

Coordinator: Our next question comes from Laura Mazzola. Your line is now open.

Laura Mazzola: Hi. Thank you. Laura Mazzola with Halteres Associates. I have a question on the EUA template for self-collection kits. The prior template was coupled to an EUA test and I'm curious now if there's going to be a revision of that template specifically for use with an LDT which no longer requires emergency use authorization or what are your recommendations for sort of in-house kit for self-collection?

Dr. Timothy Stenzel: Yes, that's top of mind and top of list for us to provide some more clarity. And Toby knows but I'm just wanting her to help with that. Yes, no, we would encourage that if you can use an EUA authorized collection device that fits with your test and under the authorization of that collection device that that would be a great way to go.

If you've not got a home collection device that has been authorized then yes it's time - it's you know, it's something we want to engage in a conversation with you. Of course Gates Foundation and others have done significant work in this area and have provided right of reference for some data and some information and so we would like to leverage as much of that is possible when we look to authorize additional home collection.

But you bring up a great point and it's one that we're working through now so I can't give any high level - anything other than that as far as details go now. So do send us an email at our template or talk to your reviewer about this particular thing and we'll work through these things on a case by case basis. Toby do you have anything to add to that?

Toby Lowe: No I think that's a good overview of where we are. I think, you know, emailing the mailbox about your particular situation is a good first step at this point so that we can work through any issues with you directly.

Laura Mazzola: Okay great. Thanks very much for that.

Coordinator: Our next question comes from Lonnie Adelman.

Lonnie Adelman: Adelman for (iAssay). I've called in once before. We have a cloud connected device that is an open platform for reading scripts and recording the data automatically. A couple of weeks ago Tim you made a comment and we're still kind of confused. You have said that developers don't have to use an instrument that's been prior authorized. They could use whatever they want as long as it works so this is kind of different than what our prior understanding was.

We sent them an email. We got an email back. It was kind of cryptic to us. So we would if - this would open up things for us if we could actually get to - get the potential partners either starting at the end user and doing some testing, presenting the data. So I wanted to find out is it - is that really a change in policy where we wouldn't have to put our device onto somebody else's EUA in order to use it for testing?

Dr. Timothy Stenzel: Yes I think you're talking about a device that can read a lateral flow strip primarily a serology...

Lonnie Adelman: Correct.

Dr. Timothy Stenzel: ...strip.

Lonnie Adelman: Serology or antigen yes sir. It's correct.

Dr. Timothy Stenzel: Right, right. So certainly all the EUA authorized devices are posted on our FDA Web site and, you know, if they don't already have a device or if they're interested in adding a new device you can work with them. We are working on a template update and I hope it gets cleared.

We would like to open it up and make this as easy as possible for a scanning device to be used. And we're just waiting for the final sign off on that template update to provide some specifics on that.

In the interim we can provide our up to date recommendations about how to do that. It sounds like you've already tried that so if you - and if I was included on the email I apologize. I've - I get inundated with emails but...

Lonnie Adelman: Yes, I can understand that.

Dr. Timothy Stenzel: But I do want to open up this pathway. So you can, you know, reply and say you're a little confused and can you please copy Dr. Stenzel and get his input on this because I know I have some thoughts about this. I've, you know, I've reviewed them, some of the updates and I'm happy with it. So we can provide some elements of those current - that current thinking, not a

completed template but elements of it that we're - where we're comfortable giving you some recommendations on how to move forward.

Lonnie Adelman: What's the name of the template?

Dr. Timothy Stenzel: Well let's see, I don't remember this is an update to the serology template or an update to the direct antigen template or both. I forget.

Toby Lowe: Yes.

Dr. Timothy Stenzel: And...

Toby Lowe: I believe we're in the process of updating both of those.

Dr. Timothy Stenzel: Right. So I just don't remember where this additional information on how to work some more flexibly for providing, you know, an image system. But I wanted - and my desire was to make it as easy as possible for all developers and as easy possible for the paperwork and of what we do at the FDA to add something like your product to a test and have it be able to be used and EUA authorized.

Lonnie Adelman: Yes, that's great.

Dr. Timothy Stenzel: Watch for details on that.

((Crosstalk))

Toby Lowe: And if I could just add I think, you know, I'm recalling but I don't have it in front of me, I'm recalling the email question that you sent in as well. And I



think, you know, there may have been a little bit of confusion around, you know, stating that you can use any instrument as long as it works.

The intent there was just to make it clear that the instrument didn't need to have prior authorization before the emergency, you know, and that it didn't need to be a device that, you know, like a platform that we've seen before. You can bring in new platforms that we've never seen before during...

Lonnie Adelman: Yes.

Toby Lowe: ...the emergency for an EUA. And so as long as it works we would be, you know, we would be authorizing it under an EUA just like we would with, you know, with something that we're more familiar with.

Lonnie Adelman: Okay so that clarifies. So we're very interested in getting this in the hands of people. It's going to solve a lot of problems. We can prove it. We already have. And so this template will be updated - it sounds like it will be great.

I don't want to monopolize time. One question I haven't been able to figure out, how do we get this NCI panel for testing? We've looked, we've dug? How do we get it so we can do testing with it?

Dr. Timothy Stenzel: Yes. So unfortunately it's, you know, sourcing the serology samples in sufficient volume to support the NCI testing has been challenging enough. And though it was our desire early on in the process to source enough sample that we could support testing in NCI and make the panel available to developers who don't have a device that's amenable for testing at NCI but because of the challenges and sourcing that material in sufficient numbers and quantity and volumes we've been unable to meet that need at this point.

Lonnie Adelman: So if we want to try to get it and get in the queue who do we talk to?

Dr. Timothy Stenzel: Well the only thing that they're doing right now is they are accepting kits for primarily - well some ELISAs but primarily lateral flow devices to get in the...

Lonnie Adelman: Okay.

Dr. Timothy Stenzel: ...queue for testing at the NCI. So a device that scans such things wouldn't be something that we would test unless it already comes in validated with a specific device. And that's part of the care already...

Lonnie Adelman: Okay.

Dr. Timothy Stenzel: ...that's being submitted.

Lonnie Adelman: Okay.

Dr. Timothy Stenzel: All right?

Lonnie Adelman: All right thank you.

Coordinator: Our next question comes from (Kimberly Zunker). Your line is now open.

(Kimberly Zunker): Thank you. My question is about the new FAQ surrounding laboratory developed test EUAs stating that they will not be reviewed. I'm wondering if laboratories are still required to submit their EUA applications within 15 days of validation if they're not going to be reviewed?

Dr. Timothy Stenzel: Toby how do you want to handle that question?

Toby Lowe: That's an interesting question. So the guidance document I believe is what you're referring to. That was issued well before the HHS statement. And the FAQ that you're referring to. And, you know, as I'm sure you're aware, guidance documents are nonbinding. So the recommendations in the guidance were our recommendations at the time that that was issued.

And we, you know, as we've now said that we would, that we're generally not prioritizing review of LDTs and HHS has said that FDA will not require premarket review of LDTs the, you know, the current FAQ is, I would say, more current than the portion of the guidance the you're referring to. Tim I don't know if you want to add to that at all.

Dr. Timothy Stenzel: No but I think we've heard some and we are working on some additional clarification in the FAQs and this is a good question for us to potentially address. And as it appears there's a discordance between existing guidance and the FAQs. So thank you for bringing that to our attention.

Toby Lowe: Yes absolutely. Thank you.

Coordinator: Our next question comes from (Ashley Douglas). Your line is no open.

(Ashley Douglas): Hi there. Could you provide a little clarity on if you have an existing EUA for a high - with high throughput capacity and you want to add new AV if you're recommending an amendment to an existing EUA and is that a possible pathway?

Dr. Timothy Stenzel: That typically would be a new submission, a new test and not an update, unless you're going to sunset the other test, but even so it's probably for our

records best to keep that as a separate submission. And we've provided some pretty good recommendation in our molecular template for that.

I believe also the - we've authorized the first antigen, indirect antigen test with the panel. But I don't know that our current template is updated for our panel test that's obviously in the works as well to provide updated recommendation.

But if you have a direct antigen test and you want to move to a panel for those listening, just approach us and ask us for our current recommendations on how to do that. So yes so the short answer is I think that's best handled by a new submission and new assay and a new record of validation because even for SARS we would want to make sure that SARS is not impacted by the additional panel members that analyze that you're adding.

Toby Lowe: And I would just add that you can reference your previous submission. So if there are elements of your previous submission that are still relevant you would be able to reference that instead of providing it new.

Dr. Timothy Stenzel: Yes.

(Ashley Douglas): Okay.

Dr. Timothy Stenzel: Yes, good point Toby although a lot changes right? A lot...

Toby Lowe: Yes.

Dr. Timothy Stenzel: ...can change with that.

(Ashley Douglas): Okay thank you.

Coordinator: Our next question comes from (Robert Datelio). Your line is now open.

(Robert Datelio): Hi Tim. Thanks for this. And actually my question was surrounding the self-test, the self-testing so it's been answered. But it's very - since I'm on here, hello. It's fascinating...

Dr. Timothy Stenzel: Hello.

(Robert Datelio): ...you had 2400 submissions. How many staff do you have in each one of the three groups approximately?

Dr. Timothy Stenzel: Not enough.

(Robert Datelio): You don't have enough. No, there's not enough people in government. I'm just wondering.

Dr. Timothy Stenzel: Yes and that includes both Pre-EUAs and EUAs. I think we have over 1000. Prior to our LDT decision we had over 1000 active EUA submissions still. And so we're working as hard.

We began the year the virology branch within DMD was about 25 people. We subsequently doubled it with direct reviewers bringing in other people from the office from the OPEC and from the agency we've hired. We've hired about 60 people in the office so far this year.

And then we are now adding additional staff from other areas of the office. So our direct reviewer numbers will be approximately 100 now with a large support staff behind them assisting in every way.

So it is - it has been very challenging. It is why we have utilized the notification pathway for nearly every type of submission except for some like home collection and home tests. So and for obviously for the point of care decisions.

So we've done our best to stay up and been flexible with our recommendations and guidances to deal with the volume so thanks for that question.

(Robert Datelio): Fascinating that, keep up the good work. Thanks very much.

Dr. Timothy Stenzel: Thank you.

Coordinator: Our next question comes from (Griffin Soriana). Your line is now open.

(Griffin Soriana): Hello. Thank you for taking my question. Just curious if the FDA has any updated position on the off-label use of antigen testing for asymptomatic screening given how forceful HHS was in requiring the model to resume the use of antigen testing in nursing homes for that purpose? Does the FDA have a position on this -- it's off label use and more importantly are you aware of any studies to measure the performance of the antigen testing in the asymptomatic population?

Dr. Timothy Stenzel: Yes, the data we've received -- and I can't go into all of it because much of it is confidential -- is mixed. Some studies seem to say that the viral levels at least as determined by cycle thresholds which is an imperfect way of determining virus thresholds or virus levels are similar in some cases and others very different. And we don't understand why that is.

So and when they're different the asymptomatic population usually has a lower viral load than the symptomatic population. And that could be from a variety of reasons as well.

And we make decisions based on data and since it's - since the data are unclear, the science is unclear now, it's difficult to sort of say make blanket recommendations about this. So we have asked developers if they want a claim for screening, specifically asymptomatic patients that they come in with data. We've given them large number of options for doing that and we've offered - obviously authorized some already and we're very interested in authorizing others.

You know, and typically, you know, we ask for a small number of patients who are known to be asymptomatic and do a comparison study from the test that's being submitted with another high sensitivity EUA authorized test and then there's also the ability to use bank samples.

There's also the ability to look at for where it's applicable to historical data where you have data from both types of patients and it shows comparable cycle thresholds. I'm trying to think of the other ways that we've been allowing a claim.

But we very clearly as stated in our FAQs and other communications that most of the IUs that we - writing in the IU and the instructions for use, indications for use, we've clearly stated those suspected of COVID-19. And that can be people who have symptoms but it can also be some - many patients who are without symptoms but...

(Griffin Soriana): Yes.

Dr. Timothy Stenzel: ...are known to have an exposure where you want to make sure they don't  
- they are carrying the virus.

And then there's purely sort of the screening. You know, you've got, you know, you just want to know say in some setting where you want to know if anybody in that population and you want to return individual results to them that screening, then, you know, you can come in with a submission for that claim if a submission is required, if you're primarily a kit. But also we have very clearly said that clinicians can order this off label.

There were some other challenges at the federal level with CLIA and CMS. They have issued a statement an FAQ that says you can do this and you can get reimbursed, and you can report and you're not going to get dinged by a CLIA inspection.

The specific issue that I know was seen in Nevada and many other nursing homes recently and certainly whenever there's a complaint about say a false positive, we look at those complaints and we do an investigation as required and determine whether or not there's a device issue.

Then the challenge is that in those populations it doesn't even matter what particular test, whether it's authorized for asymptomatic testing or not, no test is perfect, no test is 100% specific. And so if you have - and that includes molecular tests by the way. Those are not 100% specific. They may be very high, maybe even higher than direct antigen tests but they're not 100% specific. That's sort of impossible to reach.

And so when you have a very low incident population of positive results the chance of having a false positive is very high. And therefore if it matters whether that's a true positive or not whether it's in somebody who's staffing



the nursing home or it's a healthcare worker in another environment or it's an actual patient that you're interested in knowing when the population you're looking at is very low incident you want to double check that result.

So I would send it off for a different orthogonal test. This is very clearly stated in the current CDC FAQs and our guidance and it applies not to just to direct antigen tests but also to all tests.

And just to go back and just talk about this a little bit, so if you have a test that is 99% specific that is a fixed number. It doesn't matter what the incidence is in the population. It means on average one out of every 100 negative patients will test positive with that test. And I think most people would agree that a 99% specific test is pretty high.

So, if you suddenly have a population that has significantly less than 1% incidence of true positive results it means that there will be more false positives than true positives. And I think that's where - what Nevada saw. And it, you know, and dealing with that, you know, it can be a challenge granted. But it is nothing wrong with the test, it's nothing wrong with the test method. It's nothing wrong with what the test was labeled to do given that the federal government, CMS, CDC and the FDA have said it's okay to use the device off label when you have a clinician prescribe this test.

So that's a very long answer but I think it's very important. Now the testing that is able to be done in these populations is very important because my understanding of the Nevada data other data is that you are identifying true positives that you - in their faster fashion than you might have otherwise. So I personally view that as a very important public health tool. And Toby I don't know if you had anything to add to that.

Toby Lowe: I think you - you've covered all of it. Yes.

(Griffin Soriana): Great thank you.

Coordinator: Our next question comes from (Tom Slavic). Your line is now open.

(Tom Slavic): Thanks. I'd like to confirm my understanding of the options for a company that wishes to market the VTM. There seem to be three separate ways to go. First is that the VTM notification pathway is sufficient to be able to market swap collection kits that include a transport tube with VTM.

The second is that there's an EUA template for saliva collection kits to be used for the SARS CoV-2 only. And the third is that a 510(k) is required for potential broader use of a saliva collection kit. Is that a correct understanding?

Dr. Timothy Stenzel: That sounds pretty good to me but, you know, Toby has been focusing on this a little bit more than me. So Toby you want to address that?

Toby Lowe: Sure. So yes you - what you've outlined sounds pretty much correct. The - so what - when you're saying that there's a, you know, EUA for saliva collection devices we don't actually have a template specific to saliva collection devices. We have authorized EUAs for two, I believe saliva collection devices at this point. Those are standalone collection devices. They are not home collection kits.

We have also authorized several home collection kits that include there are some that are saliva and some that are nasal swabs. And for VTM separately we do have the immediately in effect guidance.

So many swabs are Class 1 exempt if it's just the swab and the transport media is what bumps it up to needing the 510(k). So generally those do need 510(k) and we are not generally looking at EUAs for transport media specifically because we do have the - this guidance document out with the policy that allows for enforcement discretion for the 510(k)'s that are required for that transport media.

So if you want to use and to so to market transport media during the public health emergency you can take a look at that policy and the guidance and that is not limited to SARS CoV-2 testing. That is for the distribution of transport media during the public health emergency but it is for more broad testing for molecular testing I believe. I'd have to look at the exact language in the guidance. So...

Dr. Timothy Stenzel: Yes, yes...

Toby Lowe: ...that - hopefully...

Dr. Timothy Stenzel: ...yes very clearly.

Toby Lowe: ...that does clarify a little bit there for you.

Dr. Timothy Stenzel: Yes Toby good point about the VTM guidance. Some people have thought it only applies to SARS and it doesn't. It is broad in the pandemic. And I don't know if the new IE for flu and other respiratory pathogens you want to discuss its relevance to this question at all either. You can check just check that out as well.

Toby Lowe: Sure. So the new guidance about flu is sort of the flip side of the transport media guidance. So the transport media guidance talks about the

manufacturers of the transport media and their need for a 510(k) and their ability to use this policy to distribute without a 510(k) during the emergency.

And then the flu guidance talks about the regulatory requirements for the manufacture of the flu test themselves and the ability for them to use this policy to expand the use of their flu test to use these other transport media that may not have been included in their 510(k) initially.

(Tom Slavic): Okay thanks. And I think you've confused me a little bit. If someone wants to mark a swab collection kit that includes transport tube with VTM is a notification pathway sufficient or do they have to apply for 510(k)? That's the part that I'd be trying to...

Toby Lowe: The notification pathway would be available for them. Sorry about that. That was confusing there.

(Tom Slavic): Okay great. Thank you very much for this clarification.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Troy More). Your line is now open.

(Troy More): Hi. Thank you for taking my call. I have a - it's a two-part question regarding the announcement around the LDTs last week. There wasn't a time - so we have a submission in, and I was curious if there's greater clarification on the timing of receiving notifications of whether the review is going to proceed or be declined based on a determination of an LDT status.

Dr. Timothy Stenzel: Yes, so we've reached out to a number of LDT developers and let them know already. But that process is not complete and if you want to check on it you can send an email to your contact...

(Troy More): Okay.

Dr. Timothy Stenzel: ...whether that's a contact within the office or a reviewer or you can use our templates email address as well and we'll attempt, you know, we're engaging in dialogue with some to make that determination. And that's on a case by case basis so that may take us a little bit more time to work through them.

(Troy More): Yes and I guess that was the second part of my question was we have a pool based methodology 25 samples or more using the next generation sequencing readout. And I do note there's a stratification on, you know, things that would clearly fall on the LDT bucket and things that would not or do you guys have any clarification on that?

Dr. Timothy Stenzel: Yes we're doing our best right now and we're working through that very important question. And as I said earlier, I think we're going to work on some additional FAQs to post to make this a little bit more clear and transparent. But for now I think it's best to, you know, this be handled on a case by case basis so we can give you the very best of feedback and recommendations and answers that we can tailor to your use.

(Troy More): Okay that's - and I've certainly heard you loud and clear about the overwhelming number of submissions that you guys have received and I really appreciate the effort you guys are putting in to this.

Dr. Timothy Stenzel: So well these kinds of questions we try to handle very quickly. So it - this is not part of submission review. If you're coming and you say, you know, do we fall under this new FAQ for LDTs and you're not - you're going to choose not to review it that's a straightforward or a seemingly straightforward question that we want to respond to as quickly as possible and that's what I've directed the office to do.

And we're - and we are engaging with - obviously with numerous discussions. So that's not something that you're going to - that I am asking - that I'm expecting that you're going to have to wait a long time for a response. We want to get back to you as quickly as possible on that and that's what we're doing. And Toby's thankfully is heading up the response team here and making sure that we're getting back to developers as soon as possible.

Toby Lowe: Yes those types of questions...

(Troy More): Okay.

Toby Lowe: ...we usually get back to you - to folks within a day or two. We just like to make sure that we have all of the information specific to your question before we give an answer just so that we can make sure that we're responding appropriately for your specific situation.

(Troy More): Yes, no that's - well just note that I - I mean, I know this is a complicated submission with pooling and sequencing and such, but I mean, we've had it in for six weeks and haven't gotten any feedback and we've posed those questions through the templates and was told they were going into the queue. But and that's been more than a week ago so, you know, any guidance there that could get me a response I'd appreciate it.

Dr. Timothy Stenzel: Well I think coming in with a direct question of and do I fall under the new policy for LDTs or not and very simple. And if you don't get a response in 24 to 48 hours ask to bring me, Tim Stenzel into the conversation and - or Toby.

Toby Lowe: Yes.

Dr. Timothy Stenzel: And we'll get you a response absolutely as fast as we can.

Toby Lowe: Yes you can also...

(Troy More): Yes. And we're trying to be patient. We realize there's a high workload there so but I will follow-up.

Toby Lowe: You can also specifically ask for the link to be sent to me. It is very possible that it's on my plate since I was out last week.

(Troy More): Sure, no problem. Okay well thank you very much for the guidance. I really appreciate it.

Coordinator: Our next question comes from (Daniel Rock). Your line is now open.

(Daniel Rock): Hi. Thank you Dr. Stenzel and Toby for organizing this. So we have been developing an antigen test and meant for home use. And we have two development tests as far as kit design. A color metric assay with enclosed containers as well as a flow-through kit also with enclosed containers.

Originally, we had assumed that is a traditional lateral flow design similar to an at home pregnancy test was a desirable kit design because, you know,

fairly available. And thus far from the sensitivity data we have our color metric assay test has proven to have higher sensitivity.

And so given that and provided we put together a rigorous feasibility study with the protocol that you authorized, FDA authorizes before conducting a feasibility study are you keen on authorizing under EUA an at home antigen test with color metric assay kit design? And secondly are you keen to authorize a flow-through kit also with enclosed containers as a kit design?

Dr. Timothy Stenzel: I'm not sure I know what the color metric is. You know, those color line that disappears and/or comes up on the depending on the function on the strip. What's the flow-through device? Is this just an electronic readout of a, you know, some of the over-the-counter flow devices that have a reader attached? I'm not sure I understand by the flow-through aspect...

(Daniel Rock): Sure.

Dr. Timothy Stenzel: ...of your question.

(Daniel Rock): Yes so...

Dr. Timothy Stenzel: You mean by flow-through?

(Daniel Rock): The flow-through kit design is nitrocellulose test strip where reagents are poured over and flowing through the test strip to enhance a visible change on the test strip that's visible to a human eye.

Dr. Timothy Stenzel: Yes no...

((Crosstalk))



(Daniel Rock): And the color (unintelligible).

Dr. Timothy Stenzel: ...I was confusing with you. So by color metric you mean on the spot where the sample is put down there's a color change if the target is there versus the flow-through strip where you put sample on one end and you read out down the strip after liquid has flowed through device?

(Daniel Rock): The and the color metric assay in the context of your question is without a test strip. It's a reagent...

Dr. Timothy Stenzel: Right.

(Daniel Rock): ...that changes color and an enclosed vial and this is a saliva based test I should've mentioned yes.

Dr. Timothy Stenzel: Yes so there's, you know, there's the three main things that we look for. So let me just, you know, at a high level say absolutely we're totally supportive of authorizing home tests and home direct antigen tests. And in fact I've, you know, well I've noted on previous calls here that we haven't received a submission for a home test whether it be molecular or direct antigen where we can even review to authorize so that's why I continue to encourage it.

I've also let our staff know that I would be very interested in authorizing a good home test as soon as possible. So they know when they see one if it's good that we want to do our best to get that authorized the soonest possible.

I've looked at various developers for SARS tests in both these categories that you have talked about. And it doesn't really matter the readout method as long

as it can be clearly understood by the home user and then the results clearly interpreted...

(Daniel Rock): Yes, okay.

Dr. Timothy Stenzel: ...and they read the test as being positive negative or didn't work invalid.

And then do they know what the results of that test means, you know, positive what does that mean, if negative what does it mean, if invalid what does it mean. And that the performance is such that we're now missing more than overall in whatever scheme you use you could have two tests that they use, day one, day two, day one day three, that we are able to detect the vast majority of home users that are have - are shedding virus that could potentially infect others.

I usually talk about the first five to seven days of shedding of virus in a newly infected patient. That may overlap symptoms or not. It doesn't really matter. That's what we're looking for. We want to see - we don't want to miss we don't want to miss 50% or more clearly of people who could transmit the virus to somebody else.

And we've set the bar at 80% I think that's pretty good. It's still means that we could be missing 20% of patients who could infect others. And going lower than that seems not the right thing to do. So but we will work with developers if they have different schemes so basically serial testing schemes are amenable if they're successful in getting that sensitivity PPA to a level that consumers and others can have confidence in a result.

If it's negative then it's most likely negative. If it's positive there most likely and positive. That's really important okay?

(Daniel Rock): Okay thank you.

Coordinator: Our next question comes from (Ted Liss). Your line is now open.

(Ted Liss): Hi. Thank you for taking this call and for the opportunity to ask questions. My question pertains to EUAs that are for tests that require a physician prescription and a test that do not. And what are FDA's considerations when considering either and how would - are they different with regard to the information that you would expect to receive from developer?

Dr. Timothy Stenzel: Yes so obviously under prescription well, you know, everything essentially, I don't think we've authorize the nonprescription test yet for an EUA. And the reason for that is we can lower the bar a little bit when a clinician is involved because that's a mitigation of risk.

They - if they're involved then they can assess the clinical situation and assess whether a positive is sounds right or a negative sounds right and instead of a patient or a consumer being left entirely on their own and not having the relevant medical background to make an assessment.

So when it's OTC we generally expect the bar to be a little bit higher. So for direct antigen test for example in an OTC where someone can just go to a drugstore and pick it up off the shelf, go to a cashier or self-check out, you know, go home and test and not have any interaction with a medical professional at all we expect that the PPA or sensitivity for such a device is 90% for like a direct antigen test.

But if it's by prescription our bar of 80% is sufficient because that additional loss of sensitivity if a clinician's involved we know that they can assess the situation and get repeat testing if warranted.

(Ted Liss): Okay thank you for taking the...

((Crosstalk))

Toby Lowe: And this is also discussed in the home test template a little bit there is some discussion about prescription versus nonprescription because as Tim was saying, you know, it's important that for nonprescription test the user needs to be able to identify that that's the correct test for them to take. They need to be able to perform the test themselves and get the results and interpret the results themselves. So those are all factors that we look at.

(Ted Liss): Thank you.

Coordinator: Our last question comes from Christie Bergerson. Your line is now open.

Christie Bergerson: Hi Tim, hi Toby. Thank you for taking my call. This is Christie Bergerson from Exponent Consulting Invitro Diagnostic Division and we were looking on your FAQ page about dry swab. And it says the shipping and stability data for the dry swab was provided and accepted by Quantigen but the usability was not, and needs to be assessed for each EUA.

However the next sentence after that says that the FDA still needs to review the clinical data on dry swab transport to understand the impact of test validity. Those sentences were last updated in May. Do you consider dry or direct swabs as an approved sample type at this point or is the usability data the only data that's needed or do you think the bridging studies would be necessary between wet and dry swabs?

Dr. Timothy Stenzel: Well the limitation in that study -- Gates was involved with is that there was - there wasn't a resuspension protocol of the dry swab. It was the collection and transport of that swab data was provided there. Also a universal sort of instructions for use wasn't provided with that and tested.

You know, the usability study is relatively easy to do. So the only other that I'm aware of -- (Toby) may know differently -- is that when for a test, you know, given a test that a dry swab is going to be used, is that swab adequately resuspended, you get the viral material off that swab adequately and you get an accurate swab from the result - from that setting?

So that's the wet lab piece that's missing from that particular study. And so we do ask developers to develop and validate the resuspension method and make sure that they're getting good results from that dry swab. Toby, do you have anything to add to that?

Toby Lowe: No, that's exactly what I would've said.

Christie Bergerson: Thank you. So does that mean that dry swabs are an approved sample type or do we need the bridging study between wet and dry swabs?

Dr. Timothy Stenzel: I'm not sure I totally understand the question. So you can add dry swabs if you validate the resuspension. There are different ways to validate that resuspension obviously. But we are not requiring a bridging study to a wet swab for a dry swab.

Christie Bergerson: Okay perfect.

((Crosstalk))

Toby Lowe: It would be authorized with specific sample types. And so if you're looking to include dry swabs in your authorization, we would want to see that validation.

Dr. Timothy Stenzel: Yes we need to understand the test performance if it's something that requires an EUA and not just, you know, and not just say oh we have a test and we don't have to test a sample type, no. This is one where, you know, for something requires an EUA authorization where any, you know, any authorization for some sample type is issued based on actual clinical study data positive -- minimum positive and negative.

And then if you're adding a dry swab like a home collection to it then - and then that's where we don't need to see that clinical study data for that dry swab. We just need to make sure that the resuspension works. Good point of clarification Toby.

Christie Bergerson: Okay excellent. Thank you all very much.

Toby Lowe: Yes, thank you.

Irene Aihie: I believe that was our last question. Thank you. This is Irene Aihie and we appreciate your participation and thoughtful questions. 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 Thursday, October 22. If you have additional questions about today's presentation, please email [cdrh-eua-templates@fda.hhs.gov](mailto:cdrh-eua-templates@fda.hhs.gov). Again that's [cdrh-eua-templates@fda.hhs.gov](mailto: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 at [www.fda.gov/cdrhWebinar](http://www.fda.gov/cdrhWebinar) immediately following the conclusion of today's

live discussion. Again, thank you for participating and this concludes today's discussion.

Coordinator: Thank you for your participation in today's conference. You may disconnect at this time.

END