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

Moderator: Talya Simpson
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Coordinator: Welcome and thank you for standing by. At this time all participants are on a listen-only mode. During the Q&A session, if you'd like to ask a question, you may press star, 1 on your phone. Today's call is being recorded. If you have any objections please disconnect at this time. I'd like to turn the call over to Ms. (Irene Aihie). You may begin.

(Irene Aihie): Thank you. Hello, this is (Ilene Aihie) of CDRH's Office of Communications and Education. Welcome to the FDA's sixth in a series of virtual town hall meetings to help 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 Radiologicial Health in the Office of Product Evaluation and Quality, and Sara Brenner, Associate Director for Medical Affairs, both from CDRH, who will provide a brief update. Following opening remarks we will open the line for your questions related to today's discussion. Now, I give you Timothy.

Timothy Stenzel: Hello, thanks for joining us again. I hope everybody's finding these town hall meetings productive. I look forward to another one today. We have many updates but it won't take me long, I think, to go through some of them. So we have many new EUAs authorized since last week.

We're recruiting four new serology authorizations. Please check our FDA EUA Authorization web page. Also we've made numerous updates in the last few weeks for the frequently asked questions, including a new extraction option, so that hopefully is welcome news.

Finally, an important update, is they may have a new serology pathway,called an umbrella, pathway for serology. This high level applies to serology tests that are submitted to the inter-agency test group.

Currently testing is the (unintelligible) at NCI, and those are companies that submit a serology monthly a rapid test that (unintelligible) they're able to come through their pathway. Two, this program testing is performed currently at NCI, and then if performance metrics are met then those tests have a pathway to authorization under this umbrella pathway.

So I will speak a little bit to the specifics of this pathway. If it's not publicly available yet it will shortly be publicly available . So, this is for - the devices that include in vitro diagnostics, SARS CoV-2 antibodies test, lateral flow or enzyme-linked immunosorbent assays, LFAs, lateral flow assays. That is a validation study performed at the NCI, or another government agency designated by the FDA and are confirmed by the FDA to meet the criteria set forth in the scope of this authorization letter.

Let me go through what those performance metrics are. All right, as performed by the NCI or another government agency designated by the FDA, using a well designed panel of at least 30 confirmed SARS CoV-2 antibodies positive, per each - and 30 per each immunoglobulin that tested (unintelligible) cracks, currently we're restricted with testing the IgM and IgG devices.

We'll say they're IG only or (PAN) or those thatIgM and IgG. And these are positive samples and then Ab antibody negative and/or pre-COVID-19 serum positive samples. Ten of negative samples must be confirmed to be HIV positive.

The data must demonstrate a minimum overall 90% positive percent agreement, otherwise commonly thought of as sensitivity, in an overall 95% negative percent agreement or otherwise normally considered specificity, for the test to report specifically IgM and IgG results or has the ability to report a (PAN) result.

A minimum of positive agreement for those tests that - test for and report out IgM and IgG as that for IgG there must be a minimum of 70% positive percent agreement with sensitivity of IgM and a minimum positive percent for IgG of 90%.

The data must also demonstrate no cross reactivity in the testing. So this program is now available to developers and they can protest by emailing us at the template's address. And with that I concluded my opening remarks and comments and unless Sara has something, I will open it up for questions. Thank you.

Sara Brenner: Thanks and this is Sara. I'll just remind folks that last week I discussed the lab data harmonization effort under a project called SHIELD at FDA in coordination with CDC and other federal partners. I believe there's a slide that is up or will be up on the WebEx providing that email address for more information: SHIELD-LabCodes@fda.hhs.gov.

Coordinator: The phone lines are now open for questions. If you would like to ask a question over the phone please press star, 1 and record your name. If you'd like to

withdraw your question press star, 2. One moment for the first question. There's a question in the queue from (Brant Lidger). Your line is now open.

(Brant Lidger): Hello Dr. Stenzel. Thank you for providing this opportunity. I think there was a question last week about a protocol for point of care testing with rapid diagnostic test kits, and the question had to do with whether you all wanted just demonstration with the ability to follow instructions, open the materials, follow the (unintelligible), a survey perhaps, or if it had to demonstrate the actual ability to get a true positive with a sample or a true negative.

Could you expand a little on that? Since I think you also commented about demonstrating that the person doing it, say in this case a trained physician would be equal to a trained labratorian -- I think was the term that you used. I'm talking specifically now about the Rapid serology diagnostic test kits.

Timothy Stenzel: Yes. So, in general for a point of care type authorization, we will ask for lay-user studies. They're studies to demonstrate that a lay user can get accurate results when performed in that kind of setting onto those kind of conditions, with the kind of instructions that are provided with the test itself.

And ideally those would check for accuracy of the ability of the lay users to perform that testing. This is a required part of any new device that we haven't seen before to perform - that we haven't previously authorized for a point of care setting, for the ability to be designated as such as a point of care device.

I would also like to add that we've been working hard on serology template and they are very close to being done and the expectation is that they will be out at latest the end of this week but maybe sooner.

(Brant Lidger): Okay, just one clarification. You talked about lay users. So what does that mean

in terms of a - say, a physician using it at point of care, outside of a CLIA complex lab, say under a steady - say under a IRB? Is that appropriate to define point of care in that way?

Timothy Stenzel: So we have some broad language that covers near patient point of care and our FAQ page for point of care describes many of these. And I would have you refer to our frequently asked questions page for those environments. When we say lay user we are expecting that it is a healthcare professional of some sort, that it's - what we're demonstrating - what we're asking the developer to demonstrate is that a non-laboratory person, somebody that isn't trained in laboratory procedures maybe in a setting in a clinic where they don't normally perform tests as part of their all day long, every day activities, that, that kind of a user can get an accurate result with such a device. And two, it involves clear instructions, easy to do, easy to interpret, performance expectations.

(Brant Lidger): Thank you.

Timothy Stenzel: Next question.

Coordinator: Next question (William Chappa). Your line is open.

(Bill Chappa): Yes, this is (Bill Chappa) from a lab here in Grand Rapids. My question is kind of a general question. It deals with SARS CoV-2 PCR testing of asymptomatic individuals by nasopharyngeal collection in non-healthcare settings. Just wanted to see what the FDA's stance was on that, either a - for example, a workplace setting collection by a healthcare individual or the supervision of collection individual by a healthcare provider.

Timothy Stenzel: So, where would the test actually be performed?

(Bill Chappa): The test would actually be performed within a CLIA certified lab, just the collection process would be outside of there in asymptomatic individuals.

Timothy Stenzel: Okay. So as far as the collection by a healthcare professional, I'm not aware of any FDA regulations that stipulates when a healthcare professional is performing the swab. We obviously have authorized self collection but now not for nasopharyngeal swab. You specifically also asked about asymptomatic individuals.

(Bill Chappa): Yes.

Timothy Stenzel: Currently we have not authorized an EUA test that have claims for detection of SARS CoV-2 and molecular tests for asymptomatic individuals. If a manufacturer or a laboratory wishes to make a claim about the ability to accurately detect SARS CoV-2 in an asymptomatic population, that would require a submission for that specific claim and a study powered well enough to demonstrate the capability of detecting an asymptomatic person.

And we don't exactly know what the asymptomatic carrier prevalence is out there, so how many people you might have to test in order to detect that. However, if you're asking can you use any given EUA authorized molecular test, like a nasopharyngeal swab, and perform testing on an asymptomatic patient.

That is not something that we're going to say - best way to put it. This is - I think falls best under a currently listed frequently asked questions, where he had said that laboratories that received samples that aren't -- I forget the terminology.

That aren't validated, they can receive those samples, perform the testing, but they can also amend the reports saying if they have - know that it's an

asymptomatic individual, saying that their test hasn't been validated for an asymptomatic patient and that a negative result does not mean they don't have SARS CoV-2.

So, again, I think the important thing is, if a developer with a lab or a manufacturer wants to claim an asymptomatic sample type, that would require an EUA authorization.

(Bill Chappa): Perfect. Thank you for your time.

Coordinator: Again, if you would like to ask a question over the phone, please press star, 1 and record your name, and also please limit yourself to one question. Thank you. Please go ahead. Your line is now open.

Man: Yes, good afternoon. I have one question about the umbrella pathway that you mentioned. The NCI is going to be performing those tests. Is - I believe you mentioned this but I want to make sure -- the best avenue to get information about getting in that umbrella pathway is through the template's email. Is that correct, Tim? And you mentioned having a website open or something of that nature, aside from the template? Is that correct? Thank you for....

Timothy Stenzel: Yes, sure. So, you can ask to be part of that program by emailing the template's address. You'll be connected to that program and you will receive information about ship to and the number of tests that would be shipped to the location.

The umbrella pathway, is in the process, if it hasn't already been posted on the FDA website, is in the process of being posted. So, keep attention to the website to see all the details in this new pathway. And then the last question - what was the last part of that question?

Man: You got it actually. I asked if that was going to be a separate website or part of the - through the template, and I think you just explained it, that it will be noted on the FDA website. So thank you very much.

Timothy Stenzel: In addition there are more general serology templates that will be posted in the near future, hopefully by the end of the week but hopefully sooner than that.

Man: Great to hear. Thank you.

Coordinator: Next question's from (Sam Nelmy). Your line is now open.

(Sam Nelmy): Yes, I was wondering if you could share some perspective on the unintended consequences where pathway D manufacturers can sell easily in the US and have them administered by point of sale, (unintelligible) reputation, so when someone gets an EUA then suddenly they are required to be performed only in CLIA Labs.

They are also subject to the restrictions of reporting back to the FDA who's using them false positives and false negatives so that the companies with an actual EUA end up having most of their products be bought by foreign governments who are willing to use unemployment care to utilize any kind of gold standard of (unintelligible).

Timothy Stenzel: Sir, hang on. I want to make sure I'm answering your question. So first of all, those who notify us via pathway D are only deemed to be used in the US in a high-complexity lab. They are not to be used moderate complex or in point of care or home use in any way. In order to get those - that authorization, they must come in for an EUA authorization.

Also, in pathway D, those that have just notified us and have not been

authorized, they are formally not FDA authorized. And let's see, you had some other questions there I'm pretty sure. Oh, point of care. I just want comment on what it takes to be point of care.

So, if they want to be moderately complex for point of care, they come in - they demonstrate the performance in those settings and we can deem those as point of care, and then they can be used as point of care setting. But those not authorized for those settings and those that haven't notified us cannot deem those for use for those purposes.

(Sam Nelmy): So, my understanding is there's no enforcement mechanism then for pathway D. They can sell directly to point of care providers and they haven't necessarily covenanted that they're not going to. Whereas anyone with an EUA has - (unintelligible) EUA specifically (unintelligible) that they're not going to be used inside of complex laboratories and that they're going to report back everything to the FDA. So the restrictions on the EUA tests make them less attractive in the local market in the practical sense than those with (unintelligible) EUA.

Timothy Stenzel: So those that have simply notified us that they have validated their test through pathway D, they are allowed under a high complexity lab certificate, if that lab sets up, say a draw on a patient, that lab is allowed to do, under their high complexity Clia certificate, under their rules, to do (quote) "Point of care testing".

But if someone has simply notified us - a developer has notified us through pathway D, and they are selling into a point of care setting, that is not allowed, is not authorized. We have a fraud email on our FDA website, EUA website, you can send information about that and we will investigate and take action as appropriate.

And that said, email address is not easily available. You can always send something to our template email address. But if a developer is selling something into the point of care testing world, not under a high-complexity situation, they are not authorized to do that. We will investigate and we will take action as appropriate. Okay, next question.

Coordinator: Next question is from (Daniel). Your line is now open.

(Daniel: All right. Thanks Tim. I appreciate the weekly public information sharing session that you guys are doing. It's kind of a two-part question. Do you envision - what do you envision as the path forward indirect for (unintelligible) serology test kits. Currently it's only acceptable to use at high-complexity labs.

Some developed countries have gone as far as making these available for home use, if I understand correctly. When do you see FDA policy changing to allow utilization of these tests at, at least point of care level? That concerns me from a commercial standpoint, in my opinion could reduce the (RNG) effort in development or investment activity for these test kits.

So that's part one. The part two is, we've seen so many unverifiable claims by suppliers of serological tests, companies claiming their (unintelligible) application or (unintelligible) distribution notification has been submitted or is in progress, (unintelligible) transparency, could FDA maybe consider publishing the status of developers that have (unintelligible)? Of course, we can see you approved one, but more, I guess related to in progress or that have been rejected, so that we know which manufacturers or suppliers to focus on or consider (unintelligible)?

Tim Stenzel: Okay, so the two questions are, I think, point of care, the need for that, and

status of submissions of serology tests. So, we do make the serology tests that have been authorized clear - that have notified us but haven't been authorized clear.

We also have now made clear both the authorized and the notifications pathway what clinic or what clinical environment they can be tested in, whether it's high complexity or moderate complexity or point of care -- or what we call waved, with a W.

So, H, M or W. It is more challenging to provide updates other than that because that is oftentimes considered proprietary, confidential information. If a test is denied, authorization, if under the NCI umbrella pathway, that I mentioned earlier, if you do not meet the performance bar, they will be removed from the (unintelligible) and potential other further actions may be taken.

So those tests that may have been denied may be removed from the (unintelligible) list, and that will be out - that will be one way that we make this information public as soon as we make that decision. I hope that answered your question.

(Daniel): That did. And I guess maybe about the first part of the question, what the path forward may be.

Tim Stenzel: Yes. So, the pathway - if you come to us through our EUA template address, what the path forward may be. Yes, so the pathway, if you come to us through our EUA templates and ask what is required for a point-of-care validation, we will provide that to you. We are in the final stages of drafting the serology template, which will lay out these things a little bit more clearly for all to see, and will be posted publicly when they are signed off.

(Daniel): Okay, thanks.

Tim Stenzel: Our policy is that we will authorize point-of-care serology, and other point-of-care tests, if they meet the expectations in working with our reviewers for those applications. So, there is no prohibition about this - there is also no prohibition about home collections or home testing.

It's just that in the home collection, home testing situation, those require EUA authorizations. They require specific accuracy tests to be done, so that we know in those environments accurate results can be obtained -- and the same goes for the point-of-care setting. So it is policy that we will authorize these if the correct studies are performed and the accuracy is there that we can authorize them.

(Daniel): Thank you sir. Thank you.

Coordinator: Next question is from (Erica Tyberski). Your line is now open.

(Erica Tyberski): Thank you. In regards to home testing of agnostic of type of, I guess, type of sample, what would be the gold standard you should be comparing against for performance characteristics?

Tim Stenzel: So, what kind of test are you developing, because it depends -- whether it's molecular, whether it's serology, or whether it's a direct antigen test.

(Erica Tyberski): I'm working with...

Tim Stenzel: So, sort of at a high level, the performance expectations are the same as if they would be performed in high-complexity lab. We require for point of care, a lay-user study, or for home use a consumer study that demonstrates that in the

context of those other environments accurate results can still be obtained.

(Erica Stenzel): Okay. Thank you.

Coordinator: Next question is from Sara. Your line is now open.

Tim Stenzel: Hi Sara.

Coordinator: Next question is from (Alberto Genier). Your line is now open.

(Alberto Genier): Hi, the question is, if the FDA consider any antibody (unintelligible). That's number one, and then in any of those pathways to get the EUA approved, is the test needs to be performed any way with finger-stick or that is not being considered as part of point of care from home testing that would be - from my understanding, it would be done later?

Tim Stenzel: So two questions. One is Titer-based tests and the other is finger-stick tests?

(Alberto Genier): Yes.

Tim Stenzel: I believe we already authorized a lab - undeveloped test, a laboratory test in Mt. Sinai, that does the titer. We will consider authorization of the titer test. Obviously, that has different performance features that we want to make sure are accurate.

So, engage with our reviewers on EUA template sites. Right now the templates that we're working on now will not specifically show what's suggested or recommended development tests should be for titer or (unintelligible) qualitative or quantitative serology tests. So anything other than a qualitative test, engage with our reviewers on what would be required for that.

On the finger-sticks, so the templates will lay out a recommended pathway for demonstration of performance accuracy with the finger-stick. It being compared to another sample type that's been fully validated, like serum plasma or venipuncture whole blood.

(Alberto Genier): Okay, thank you.

Tim Stenzel: You're welcome.

Coordinator: Next question's from (Kay Jewel). Your line is now open.

(Kay Jewel): Hello. Thank you for all of this information. My question is about the umbrella pathway. In terms of what the cross-reactivity you're require - it's requiring a HIV. Will that replace - will they still have to also have do the cross-reactivity and the class specificity that's addressed in the March 16 policy?

Tim Stenzel: So the classic - or the other already open pathway for serological testing is still open. This new umbrella is a pathway that goes through NCI and other government agencies doing the testing from 30 positive and 80 negative samples. 10 of those negative samples will be HIV positive. And that's because there is some concern of potential cross-reactivity in HIV positive samples.

So those are specifically added to look at that. We assess that if performance is good on the 80 negative samples, basically above about 98% no specific additional cross-activity testing may need to be performed with specific potential cross-reacting agents.

However, if - in the usual pathways if performance falls below a level, we would ask for additional cross-reactivity testing to determine the reason why

specificity is lower than expected.

(Kay Jewel): Thank you. Thank you very much.

Coordinator: Next question's from (Mark Manuer). Your line is now open.

(Mark Manuer): Yes, these are terrific conferences, thank you. Wondering if you can detail some of the specifics regarding the serology tests, in particular potential cross-reactivities with other Coronavirus species or sort of what the threshold is there?

Tim Stenzel: Well, it's very minimum if any cross-reactivity is detected. It would have to be in the instructions reviews in the performance section. And if it reaches a certain level, a number of cross-reaction samples, that may be - that may impact a potential for a positive authorization. So, it's...

(Mark Manuer): I guess more simply put is, are the tests that are examined, are there panels of sera from other non-COVID-19 affected individuals that are not used in the screening process and as a parameter of either approval or not?

Tim Stenzel: There is not any sort of FDA panel, commercially available panel at this time, in hopes that, that could be happening. I've asked and I haven't checked whether our FAQ page lists potential providers of validation panels. For those providers of such panels, we have a process by which we engage firms, and if we feel it's something that we can make widely available to developers, as far as information goes, you can go to these providers, we will do that.

We have had some providers approach us and I asked that they be reviewed and we can post one on the FAQs if we haven't already. We would post them. However we do know some providers, and if you email us at EUA template, we

can at least give you contact information.

And if it's not on our FAQ page it would basically be information without any guarantee that - at this moment, that we've taken a look at them and we know that that's a good provider.

But I know that there are providers out there that are developing these panels and as soon as possible we'll make as many of them as possible, (unintelligible) FAQ page, and if we get to the point where we can specifically recommend something we will do that. We understand that is challenging to get these materials.

(Mark Manuer): Perfect, thank you.

Coordinator: The next question is from (Ted Riff). Your line is now open.

(Ted Riff): Hi, yes, thank you. Good afternoon. My question is for Dr. Brenner if she is still available, or, Tim, if you could answer. At a town hall...

Tim Stenzel: She's probably better answering almost anything.

(Ted Riff): At a town hall two weeks ago it was mentioned that an FDA recommendation pertaining to 3-D printing of nasopharyngeal swabs. I was wondering whether we will be seeing that document soon or if it's still in progress? And specifically during this public health emergency, will FDA expect the hospital to register a list of (unintelligible) as a manufacturer if it prints the swab only for the internal hospital use of its own patients?

Tim Stenzel: Go ahead Sara.

Sara Brenner: So those are great questions and I know we have discussed the issue of 3-D printed nasopharyngeal swabs and other types of swabs on this town hall call for many weeks now, so I thank everyone for their patience.

What I can share at this point is we most certainly are preparing formal information or guidance. I don't want to be too prescriptive of what form it will take, but we are working on, what I believe the community will find to be very informative based on the questions that have come in so far.

And then there's a process that we go through internally to have that verbiage cleared, it will probably be out of our office this week and moving up through the necessary channels with posting hopefully as early as next week.

I'm not making that promise but we certainly have been striving to get all of this information together and presented to the public as quickly as we can, because I know there are many, many questions and many people trying to address shortages through these very creative manufacturing means. So that's one thing I'll say.

The two other points on that. One is that we do intend to have an open discussion, a town hall- like forum, where folks who are interested in a dialogue with FDA and other federal partners can join in sort of an open-dialogue and those of you who have reached out by email following this town halls would certainly be welcome and any others would be welcome as well. So we're shooting to get that conversation set up and broadcast to the appropriate parties at some point next week. Again, thanks for your patience and stay tuned.

The last piece on this and related to that is our internal team, which includes subject matter experts, policy folks, regulatory experts, legal folks, the whole gamut, we've been following the literature closely, including data that has been

submitted to us for analysis and data that's been submitted to federal partners, including NIH and VA, too as, I believe most folks know we have an interagency partnership with -- on 3-D printing and additive manufacturing.

And so there are many experts across FDA our agency partners who are trying to stay ahead of the curve with regards to what's being manufactured and advertised and marketed and used out in the field.

So, in coordinating with those folks and stakeholders that have reached out to FDA and other parts of the government, we're looking for a sort of harmonized way that we can all work together safely and get products out there that are going to be effective and safe, and then also where that fits into our regulatory framework given that these traditionally have been class 1 exempt devices.

To your question about registration enlisting, I'm not sure that we have a definitive answer on that yet, but it is something that will go into the guidance or information that we put out. We definitely are aware of that issue and that question.

(Ted Riff): Thank you for your answer and I really appreciate all the work you and everyone at FDA have been doing -- and for these town halls. Thank you so much.

Coordinator: Next question's from (Rita Coda). Your line is now open.

(Rita Coda): Hi Dr. Stenzel. Thank you so much for your time and answering all these questions. They've been really helpful. I just wanted to know, what is the FDA recommendation on recording quantitative results for serological tests, for IgG and IgM?

Tim Stenzel: Quantitative results for IgM and IgG. So, Tim, first of all. Thank you. This is a question that's for our expert review staff. I know that a - you know, a straight sort of Titer has given determination that's pretty straightforward. But if you're going to do quantitative testing there's some additional considerations and development and performance evaluation of those, and I would defer to them. Our template's address is a perfect way to ask that question.

(Rita Coda): Okay, thank you.

Coordinator: Next question is from Sara. Your line is now open.

(Sara): Hi, good afternoon. Can you hear me?

Tim Stenzel: Yes.

(Sara): Hi, thank you for holding these town halls and describing this new umbrella policy. I've got a general question about pathway D and the serology test. Is that (unintelligible) considering that all of these tests will either need (EUA) in the future or some other FDA approval besides just the notification?

Tim Stenzel: So, that consideration is being thought about right now, and there may be something in the works in the near future to address that question. So, I would have to defer until that can - the deliberations are completed and we're able to make something public about that. We do understand the concern out there about at least some of these tests to pathway D.

(Sara): I completely understand. Thank you. So, just one quick follow-up. So are you suggesting then that once the serology test templates go out, then we can start preparing that EUA through the serology template?

Tim Stenzel: So, you can email still to the template email address and ask what is required for serology tests- today, now -- however, those templates will be made public in short order, and will provide much more clarification on our recommendation for validation of those tests.

(Sara) Wonderful. Thank you so much. I really appreciate it.

Coordinator: Next question is from (Tom Hahersh). Your line is now open.

(Tom Hahersh): Yes, thank you very much for your transparency on these weekly meetings. I appreciate it as I'm sure everybody else on the lines do also. I'm specifically addressing the serology testing and even more specific the lateral flow test. You've opened up the call with a very nice pathway forward for the validation for the EUA and submission guidelines for the lateral flow test as a device, but has there been any considerations of looking at digitizing those results through a device that may be agnostic to the vendor to pick up those lateral flow tests and enable epidemiological review of the data and other sorting of that data. Has there been any pathway forward for a device validation -- instrument device?

Tim Stenzel: Yes. So we're totally open to such devices. There are already such devices for other respiratory diseases on the market that allow the recording of non-identifiable information and uploading for public health surveillance type activities. So we're totally open to that and as long as the technology works, is accurate, then we'll authorize that.

There's a number of different ways you can go about that. I would just state though that there could be considerations or concerns about things that are - can otherwise be visually read rather than, say, read by some other means, like fluorescence, that are - where the detectors are measuring something other than

a visual read, and its thing like lighting and how dark the bands are and things like that, and whether or not the device you're using to record the results is uniform in the marketplace.

So, an application might be very valuable but if it's able to be used - able to utilize a number of different devices, smartphone, if the camera performance, for example, doesn't have resolution, the differential ways of handle the lighting, things like that. So our expert team would evaluate the technology that you're interested in developing and using in this way, to make sure that an accurate result is recorded by such a device.

(Tom Hahersh): Very good. Thank you very much.

Coordinator: Next question is from (Brad Fox). Your line is now open.

(Brad Fox): Hi there. Some of your information on the swabs have been answered but specifically I'm referring to the CDC recommendation for which type of swab should be used, the NP or NF swab and does the FDA have any thoughts or recommendations, especially as it might apply down the road for asymptomatic people, for instance, large organizations which will want to test people that are asymptomatic before their return to work, so differences between the two swabs. Is there an FDA preference, the CDC recommendations that they would prefer the NP over the NF, any thoughts on that?

Tim Stenzel: So first of all I would defer to - those kinds of recommendations, as far as what the CDC perceives is being important to the CDC. I think at the same time we all realize that performance, depending on the interval, a weekly NP swab on people who might be considering going back to work, other options are being considered out there for them, could be challenging from a number of standpoints. One of them is that NP swabs might not be readily available, the

supply issues.

Second is, anybody who has had an NP swab will know - and I have as a volunteer - they are very uncomfortable and enduring that on a weekly basis could be challenging to people. So, this is an extremely challenging question. What is the - about testing asymptomatic people, and in certain situations like returning to work, this obviously is a very important question, and exactly how this should be done is still an unknown scientifically.

Is there nasal swabs as effective as an NP swab? I think more data could be collected on that and we can see - I guess, from our standpoint, if a claim is going to be made, we want that claim to be supported by data for one type of swab or another. Exactly how labs utilize their tests for this situation is perhaps something that the FDA may not specify unless their making a claim.

But we are working on a communication. It may just be an update to our FAQ page about this specific topic. So we'll be as transparent and forthcoming as we can, but we realize - and we hope that you realize that this is a very challenging topic.

(Brad Fox): Yes, and I really appreciate that. Some of the new tests that have come out on NF swabs and I was just curious if the FDA has been doing effectiveness testing between the two types of swabs or if that is something that will be done in the future?

Tim Stenzel: So there are some studies that have been done out there showing the differences between nasal swabs determinant and NP swabs, and then there are some developers who have done some of that work as well. Going forward as we know that there are now patients available to do these studies, comparisons between the different swab types sensitivities for detection would be important.

I think it's generally wise if you're going to do interior hairs that you swab both sides of the nose.

But if you're going to do studies be sure that you properly randomize how you swab for say comparison testing different devices, different tests, different molecular tests, go forward potentially direct antigen test. And then if you also obtain another sample type like (unintelligible) or a nasopharyngeal, you also take that into account as you randomize the sample collection.

So you don't always take the nasopharyngeal swab first. You randomize whether you do that first versus another site, like (nares). So, I don't think we have definitive evidence yet about how much performance you might lose going from a nasopharyngeal to a (nares), even bilateral nares, even at a healthcare group study was pretty well done, but the numbers maybe could be added to with other studies. But it did show that there is a potential small drop off in sensitivities when you go from nasopharyngeal to (anterior) nasal swab.

(Brad Fox): Okay, thank you so much for - it is a challenging question. So thank you for your comments.

Tim Stenzel: You're welcome.

Coordinator: The last question we have time for today is from (Kevin Boykin). Your line is now open.

(Kevin Boykin): Hey, Tim, thanks for holding these calls. They have been very informative. I work for a specimen collection kidney company, focusing on getting supplies out to clinicians for the collection of these samples, and we're trying to address the shortage in media. I know you guys had some conversations around how you can address some of this on the FAQ page, but has there been any talks

around (unintelligible) in EAU or (unintelligible) page for additional media that could be used for the collection?

Tim Stenzel: I think we would be open to an EUA. We have been working with certain entities who have come forward to us on plans that they have to manufacture (VTM) and distribute it. So, some of them are copying these on CDC formula and they've come forward to us and we've worked with them on a plan to do that and allow them to do that.

One of the important features of (VTM) is (unintelligible), whether it be (VTM) or say (unintelligible) important factor. We realize this is a great unmet need and we are thinking about what we might do to make (progress) on this. But for now you can simply send us an email to the template's email address and we will work with you one on one to address any concerns that we have about what you might want.

(Kevin Boykin): All right. Thank you, Tim.

Coordinator: And I'd like to turn the call back over to Ms. Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie and we appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the (CDRH) web page at www.fda.gov\training\cdrhlearn by Monday, May 4.

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-CRH virtual town hall experience. The survey can be found at www.fda.gov\cdrhwebinar, immediately following the

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

Coordinator: This concludes today's call. Thank you for your participation. You may disconnect at this time. Speakers please standby.

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