FDA Virtual Town Hall Series –
Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
Moderator: Irene Aihie
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Coordinator: Welcome, and thank you all 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 session of today's conference. 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: Hello, I'm Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's first in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV2, and the updated policy on COVID-19 diagnostics policy for diagnostics test for coronavirus disease 2019 - during the public health emergency. Today, Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs in the Office of the Center Director and Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in CDRH's Office of Product Evaluation and Quality -- both from CDRH -- will present an overview of the guidance. Following the brief

presentation, we will open the line for your questions related to the information provided during the presentation. Now I give you Elizabeth.

Elizabeth Hillebrenner: Thank you, Irene. And I wanted to thank all of the participants. At FDA, we really appreciate the great involvement from the community in working with us and working together to try to address this emergency to the best we are all able to as a team. And we do appreciate everyone's efforts and feel like we really are all in this together.

So as background for this presentation, first wanted to mention that of course we issued a guidance first on February 29 that described a policy regarding laboratories certified under CLIA to perform high complexity testing immediately using the tests they develop and validate while they go ahead and pursue an emergency use authorization. And this was in order to achieve more rapid testing capacity in the United States. This guidance was the subject of two previous webinars.

And today we want to talk about the guidance that was updated on March 16, 2020, which maintained that policy that we've already talked about with you and also introduces three additional policies. One is regarding states taking the responsibility for tests developed by certain labs in their state. Another is regarding manufacturers immediately distributing tests they validated while they pursue an EUA. And the last policy is regarding certain serology tests.

Like the guidance that was issued on February 29, the March 16 update is issued immediately in effect. FDA determined that prior public participation for this guidance was not feasible or appropriate given the public health emergency, and therefore issued the guidance without prior public comment. That said, the guidance does remain subject to comment in accordance with our good guidance practices.

Next slide, please. So the first policy in the guidance is just maintaining the policy from February 29. This is in Section A of the updated guidance, and it includes recommendations regarding validating a newly developed SARS - CoV2 test prior to clinical use, notifying FDA when clinical use of the validated test begins, and -- because this is a lab that it is certified under CLIA to perform high complexity testing that is developing and running their own text -- we're asking in this case that the lab confirms the first five positive and first five negative samples with an EUA authorized test.

We're also asking that the test report include a statement to the effect that the test has been validated, but independent review by FDA is not yet complete. We ask the lab to submit an EUA to FDA within 15 business days -- or three weeks -- of initiating testing. And here we're just talking about submitting that validation data that the lab said it had prior to initiating testing. So, three weeks to just put that into an email and send it to us.

Elizabeth Hillebrenner: All right. And just to wrap up the discussion of the policy for high complexity labs that are running their own LDTs, we also in the guidance outlined some steps to take if any specimens fail confirmatory testing --those five positives and five negative done with an EUA test -- or if upon receipt of the validation, FDA is unable to authorize the EUA.

Next slide, please. All right. Now, Section B of the new guidance outlines the new policy for state authorization of CLIA high complexity labs to perform testing without submitting an EUA to FDA. So this section includes recommendations for states or territories regarding optionally choosing to authorize labs within their state or territory to develop and perform a test for coronavirus under authority of its own state law, and under whatever process that state or territory establishes.

FDA will not be reviewing the process adopted by that state or territory, but we do expect that the oversight process would require laboratories to validate tests prior to use. FDA continues to believe that all tests need to be validated prior to clinical use.

This guidance also includes recommendations that the state or territory notify FDA if they choose to use this flexibility to expedite testing in their state or territory. And we also encourage laboratories within such states or territories to notify us as well when they start clinical testing under this policy.

Next slide, please. In Section C of the guidance we've outlined a new policy for commercial manufacture, development and distribution of tests prior to an EUA submission. So this policy really parallels the February 29 policy for LDTs for manufacturers in this case.

So again, the guidance includes recommendations regarding making sure the test is validated prior to clinical use, notifying FDA when distribution for clinical use of a validated test begins. In the case of the manufacturer, we ask that they post the instructions for use -- including a performance summary -- on their Web site, and indicate in the test report that the test has been validated but independent review by FDA is not yet complete.

And again in the situation we would ask for an EUA submitted to FDA within 15 business days of initiating distribution for clinical testing.

Next slide, please. Thank you. In Section D of the guidance we have outlined a new policy for either commercial manufacture or a laboratory development and use of serology test without an EUA. So the recommendations here include of course validating the newly developed serology tests that detects

antibodies to the coronavirus prior to clinical use, again, notifying FDA when clinical use of a validated test begins, and indicating in the test report information along the lines of the following.

The test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV2 infection or to inform infection status. Positive results may be due to past or present infection with non SARS-CoV2 coronavirus strains, such as a list of specific strains.

Next slide, please. So to summarize these different policies and bring out some of the highlights, the first three policies -- the one for LDTs, the one for state authorizations and the one for manufacturers -- are for any technology - molecular, antigen, antibody. The last policy for serology is specific to antibody test. In all cases we would expect tests to be validated prior to clinical use. That does not change.

In all cases we expect some form of notification so that we can maintain an awareness of the testing that's going on for this emergency response. In the case of Policy A for labs who are developing and running their own test, the notification would come from that lab. In the case of the state authorizations, we're asking for notification from the state, and we encourage notification from the labs as well.

In Policy C, we're looking for notification from the manufacturer who is distributing a validated test kit. And in Policy D for serology test we're looking for notification from the developer - be it a manufacture or high

complexity CLIA lab. The next column addresses whether or not an EUA from FDA is required.

In the case of an LDT developing a test and running it in their lab or a manufacturer in Policy C developing a test and distributing it for clinical use, we would like to see an EUA within three weeks of initiating testing or distribution. In the case of states taking responsibility (unintelligible) Policy B of LDTs in their state, an EUA to FDA is not required.

Similarly in the case of serology test -- whether they're developed by a manufacturer for distribution or a high complexity lab -- if they meet the recommendations outlined in the guidance, specifically that they're validated and that the labeling includes the recommended statements -- then an EUA to FDA is also not required. For LDTs -- whether they are being offered under Policy A or Policy B under their state authorities -- these policies only apply to high complexity labs.

In the case of the manufacturers who are distributing kids under Policy C or any developer who has a serology test under Policy D, if the tests are validated they could be used in a variety of different locations, including different types of clinical labs -- not necessarily only high complexity -- they could be used at the point of care under these policies provided the tests are validated for such use.

However they are not appropriate for home use within this policy. If a developer is interested in a home use test, we would ask that they work with us through the EUA process at this time.

Next slide, please. The guidance also includes recommendations for test validation. The recommendations for molecular testing remain the same as

those outlined in the February 29 guidance, but we've also included additional recommendations to address antigen and antibody tests as well.

So for all technologies, we would be looking for or recommend validation of clinical agreement and cross reactivity. For molecular and antigen tests, we recommend limit of detection studies. Fr molecular tests, we recommend inclusivity. For antigen tests, we recommended microbial interference studies. And for antibody tests we recommend class specificity.

Next slide, please. So this slide is intended to just give you some information about how to send in notifications or an EUA if that is something that you are pursuing. For a notification -- whether it's from a state or a lab or a manufacturer -- we ask that you use the mailbox cdrh-eua-templatesfda.hhs.gov and follow the recommendations in the guidance for the minimal information that we're looking for here.

And then for an EUA, we would ask that you submit that - normally an EUA, we would require submission to the document control center with certain requirements for how it's being submitted. Given the public health emergency that we are in right now, we have made a policy change just for this particular emergency, where we're accepting everything via email right now to oir-operations@fda.hhs.gov - we're trying to streamline things as much as possible for our submitters.

We do need to see the form 3514 - the link is provided here. And we recommend the EUA template, for which another link is provided.

Next slide, please. So I wanted to give you a status of where things stand as of yesterday evening So far in Policy A which have labs who have notified us they're running LDTs, we have 98 notifications. And those labs who have

agreed to us posting their names on the Web site are listed, and I have the links for you in the slide. We have four states who have notified us under Policy B. Again, those are listed in our FAQs online.

In Policy C, we have four manufacturers to have notified us that they are distributing kits. Again, those are available in the FAQs. And for Policy D, we have 12 developers who have notified us that they are distributing or using serology test. We also have 16 EUA authorizations, and these numbers are growing every day. We have more notifications and authorizations daily, so I encourage you to monitor through our Web site links here.

Next slide, please. I did want to take a moment to talk about modifications. So as noted in the March 16 guidance, we do not intend to object to the use of a test without a new or amended EUA if the test is validated using a bridging study to an EUA authorized test.

So a lab can take an authorized test -- whether it's CDC's or somebody else -- make some changes to it -- whether it's a new platform, a new component -- and if they do the appropriate bridging study or rely on somebody else who has done a bridging sorry for that change, then they do not need to come in with an EUA or notification.

As noted in the guidance, we would like to see the validation data of that bridging study informally through an email to our CRH-EUA templates account. We would review that data, and if it does appear that it supports the modification, and if the laboratory or other entity who owns that data agrees to FDA sharing that information on our Web site, we would intend to update our Frequently Asked Questions site so that other labs can refer to that validation for their testing without having to conduct their own bridging study for the same modification.

So we're essentially looking to serve as a clearing house where if one entity is able to validate a particular tweak to an authorized test and they are willing to share that -- they don't have to share the raw data with the public, but if they're willing to allow others to leverage their findings -- we can serve as that clearing house, check that the data are good, and put it up on our Web site so that others can benefit and that everybody doesn't have to reinvent the wheel for every modification.

So right now on our Frequently Asked Questions Web site we have a list of potential alternatives for swab, transport media, RNA extraction, PCR instruments, and validation and control materials. We urge you to share whatever data that you have with us so that we can keep adding to our Frequently Asked Questions and help everybody out.

Next slide. The guidance also addresses manufacturer modifications to their own distributed kits. And here if a manufacturer has an EUA and they want to make a change, they can go ahead and implement that change when they send us the amendment for that change. They can go ahead and start implementing it right away while we do our review.

Next slide, please. This is just a list of resources. Our Frequently Asked Questions page, I would really encourage folks to check that out. We are updating it almost daily with new information. So please continue to monitor that. Of course there's a link to the guidance document, the general EUA guidance document, and our novel coronavirus Web page.

Next slide please. Okay, I seem to have lost my connection to WebEx so I - actually it looks like we're now turning it over to questions. So operator, if you could open the lines for questions, please?

Irene Aihie: Operator, are you there?

Coordinator: Can you hear me?

Irene Aihie: Is this the operator?

Coordinator: Yes, this is the operator. Can you hear me?

Irene Aihie: Yes, we can hear you. Are you there?

Coordinator: Okay, thank you. Yes, thank you. If you'd like to ask a question on the phone, please press Star-1. Please make sure your phone is unmuted and record your name to ask the question. Again that is Star-1 to ask a question. If you wish to withdraw your question, please press Star-2. One moment while we wait for questions to come in. Again, that is Star-1 to ask a question, unmute your phone and record your name.

One moment please. Our first question comes from (Crystal Nguyen). You may go ahead.

(Crystal Nguyen): Oh, thank you so much thank you for doing this. My question is regarding the serology test. So is there a template - I know there's a template for the molecular test for the EUA submission. Is there a template for the serology test? Can you hear me?

Timothy Stenzel: Elizabeth, you may know that. Yes, I can hear you.

Elizabeth Hillebrenner: Yes, we are working on a template, but we do not have one available at this time. The idea was with this policy that most people would

likely choose this policy and not actually come in with an EUA. So we have been focusing our efforts elsewhere. But we have one in development. If you have a serology test that you believe needs to come through the EUA process, I would encourage you to reach out through the template mailbox and we will be happy to help you.

(Crystal Nguyen): Okay, great. Thank you so much.

Timothy Stenzel: Yes, I would just add that most of the serology tests coming through now are IGGIGM, not for sole diagnosis, and a submission is not needed.

(Crystal Nguyen): Right. So as long as the notification is done. Quick question - what about - so the validation, can it be done by the manufacturer overseas? Like, let's say the manufacturer is in South Korea, and they have done the clinical study, can that be used?

Timothy Stenzel: Yes, it doesn't matter where the validation is done, just that a proper validation is done and that you notify the FDA and then you follow the other information in the guidance as far as labeling and the proper claims that you can make.

(Crystal Nguyen): I see. And then what about the registration? Do you know from - like the medical devices registration that has to be also done?

Elizabeth Hillebrenner: Yes, if you notify us that you have a serology test, we will respond to you with information about registration and listing.

(Crystal Nguyen): Okay. Now that's for the distributor. How about the manufacturer in the other country? Do they - I assume that they have to go through the registration process and listing also?

Elizabeth Hillebrenner: Correct.

Timothy Stenzel: Once you - yes, correct. Once you notify us, we'll work with you and the manufacture to address all those concerns.

(Crystal Nguyen): Okay, got it. Thank you so much, guys. Thank you.

Coordinator: The next question comes from (Erica al Marati). You may go ahead.

(Erica al Marati): Thank you - thanks again, you guys, for doing this. My question also pertains to serology. Can you hear me? Hello?

Timothy Stenzel: Yes.

(Erica al Marati): Oh, great, sorry. I heard a buzz. My question also pertains to serology. The notification states that the devices can be distributed to labs or health care providers. How widely is health care providers defined? Specifically, can it be sent directly to doctors' offices to test their patients if they do or don't have a CLIA certificate? How does that work?

Timothy Stenzel: Elizabeth, do you have…

Elizabeth Hillebrenner: This policy does not change any of the CLIA requirements in our guidance. So the developer would have to make sure they're meeting whatever the requirements are.

(Erica al Marati): Okay. So it sounds like you can sell to a doctor who's operating under a CLIA-waived or CLIA-moderate certificate, but not a doctor that is not. Is that how we're defining that?

Timothy Stenzel: That sounds correct. If that really matters, send us a note at the templates email and we will follow up with (unintelligible).

(Erica al Marati): Yes, I asked that question specifically yesterday, but I understand you guys are up to your eyeballs with stuff. So if I don't hear back, I'll send another one. Thank you very much.

Timothy Stenzel: Well - yes, that - I'll tell our team to be on the alert for that question. Thanks.

(Erica al Marati): Thank you very much.

Coordinator: Our next question comes from (Michael Messerman Smith). You may go ahead.

(Michael Messerman Smith): Hi, thank you very much for doing what you're doing. I know you guys are really busy and I really appreciate expeditious and the updates that are coming through, and the clarity. My question is regarding the policy which was addressed in a previous question, but is there any guidance coming from the FDA to states regarding allowing CLIA waivers or activating - or some sort of process that is allowing the states to use ISO 17025 BSL-2 certified labs to be activated to expand capacity?

Timothy Stenzel: I think you're talking about non-CLIA accredited labs? Is that correct?

(Michael Messerman Smith): Yes, that's the question that I have, is with these - would it be possible for these labs to be activated? We're talking to my - I'm in California, and I work with an organization trying to network variety of CLIA/non-CLIA labs. And one of the circumstances that we might go to the state with is the procedures for activating non-CLIA labs or something like that. It's a work in

progress, but is that something that the FDA would be helping the states with or providing guidance to allow that to happen, given (unintelligible)…

Timothy Stenzel: Yes, it's actually not under the FDA's authority. It would be under CMS. And I know that a number of interested parties have approached CMS, so you may want to approach CMS with this question as well. My understanding is that there - that you could - and I can't speak for CMS, but one of the things you could ask for is if you have an existing laboratory CLIA license and you want to expand that to include additional personnel or space, you could potentially ask that question. I can't promise a response.

And then if you are a facility that would like to become a CLIA lab, you can make an application for that, and ask if that can't be expedited. So again, I cannot speak for CMS, but those are at least two potential pathways you might pursue in discussions with them. Hopefully that's helpful. But again, this is not under the FDA's authority about where the testing is done. That is CMS.

(Michael Messerman Smith): All right. Thank you very much.

Coordinator: Next call us from (Tom Sidebottom). You may go ahead.

(Tom Sidebottom): Thank you to the presenters and the information today. Very helpful, and appreciate the responsiveness and assistance from the email address and online. My question specifically is this. For foreign manufacturers that are registered and have an EUA or are developing an EUA, are the import processes aligned with getting the items through the courier hubs in a streamlined and efficient fashion?

Timothy Stenzel: Yes, we're working on that and aware of those issues. So if you encounter any problems, do send us an email at the templates email address and we will

endeavor to assist you. Elizabeth, do you have anything else to add? Not sure if Elizabeth's still on. She may have got kicked out. So hopefully that's helpful. But we are working through that with multiple parties now so that that's not an issue in getting into the United States.

(Tom Sidebottom): Okay, great. Thank you very much. Appreciate you taking the time for the question today.

Timothy Stenzel: You're welcome.

Coordinator: Next question comes from (Ken Yao). You may go ahead.

(Ken Yao): Hi. Questions regarding - I'm working at a CLIA-certified lab and I would like to purchase the EUA kit and reagents to perform, but I don't have the approved piece of equipment. So I do have other equipment can be used. Is it the same validation procedures, like reporting the first five or comparing the first five positive and first five negative with an EUA-approved test result?

Timothy Stenzel: So as Elizabeth explained, you're welcome to share the data the bridging study data, but if you're using an EUA authorized kit and you're validating it for a new piece of equipment, as long as everything validates well, go ahead and do that.

Since it is - you are validating something new, it wouldn't hurt to go ahead and just confirm the first five positives and first five negatives with someone else who is already set up and using a completely EUA-authorized assay as a check. But I don't know - I wouldn't say right here and now that it's required. Yes, if you were developing your own LBT from scratch and doing it, that's clearly something that we want you to do.

But I would not require it for you using an EUA-authorized test. If you want to voluntarily share that validation data with us -- as Elizabeth mentioned -- we'll make that available to more folks if everything looks good. So hopefully that answers your question. Thank you.

(Ken Yao): Thank you.

Coordinator: Next question comes from (Charlene Yao). You may go ahead. Hello? Please check your mute button. Okay, our next…

Timothy Stenzel: Hello?

Coordinator: Hello, is there anyone on this line?

Timothy Stenzel: This is just Tim.

Coordinator: Okay, Tim. Just a second, let me go to the next one, because this person's not answering us. So one moment please. Our next question comes from (Luiz Furlan). You may go ahead.

(Luiz Furlan): Yes, hello. I have a - first I want to thank you for doing this. It was very helpful. I want to ask about the serology test. Maybe I misunderstood, but I think if the person said earlier that the initial intent was for serology tests to not go through EUA, and that was the reason why there was no template. But I'm a bit confused because section D seems to be about that.

Timothy Stenzel: Yes, so there's two different pathways for serology tests. One is just notify and don't submit an EUA - and that's for a test where you are just reporting the presence of IGG or IGM antibody. If you wish to make a claim as a sole diagnostic, then we would want you to come in to the EUA process.

So if you look for that section - and I'm not sure if I can pull it up right now quickly. There is a section where it's just notifying us. See if I can - I'm pulling that up now. Yes, so commercial manufacturing development distribution for use of a serology test without an EUA. It's Section D. So if you follow everything in Section D, you do not need to come in with an EUA.

(Luiz Furlan): Okay. And then - that's just CLIA, and I just use it in my lab. Is that it?

Timothy Stenzel: Well, if you are purchasing such a serology test that follows under D and then and that company has notified us and is following it, you are not required to do an EUA. It's just for the developers of this - or if you're a lab that's developing such a serology test, yes, and making just these claims, then you don't have to come in with an EUA.

(Luiz Furlan): Okay. And if I have a client who's a commercial manufacturer of such a serology test, is that the same - that seems to be what Section D is for.

Timothy Stenzel: Yes, if they're just going to claim the presence or absence of IGG and IGM for coronavirus -- for SARS-CoV2 -- then this is a pathway that they can use, and no template is needed.

(Luiz Furlan): Excellent, thank you. I have a small comment in closing. The electronic invite that I received did not have a link for the slides. So I did all this without slides. It was only phone number availability. So if you can perhaps provide more guidance in the next update of the FAQ for how to connect with full visuals for the next one of these, that would be great.

Timothy Stenzel: Oh, for the next town hall? Okay, yes, thank you.

(Luiz Furlan): Thank you so much.

Coordinator: Our next question comes from (Jackie Chou). You may go ahead.

(Jackie Chou): Hi. We are a commercial manufacturer for an IGM and IGG serologic test, and we plan to pursue the Policy D, which is notification path first .But can we upgrade it to Policy C -- which is the EUA path -- after we get the notification clear? Because the data is pretty much for - yes.

Timothy Stenzel: Yes, if you want to follow - if you want to notify - if you're just claiming IGG and IGM detection and you're following the guidance under Section D, but you also want to get a formal EUA authorization, you can come through Policy C. Okay? And submit for EUA.

(Jackie Chou): Okay. And then the start time - the 15 days completion date, is it from when we submit the first thing EUA? So we fill out the template and then we have 15 days to send the data, but we already get all the data from the notification. So (unintelligible)…

Timothy Stenzel: If you want to follow Pathway C, you can simply notify us that you're following that pathway. Then you have 15 business days to submit your EUA package. All the while, you can stay on the market as long as you follow the guidance on your Pathway C - which is you post your package insert along with your performance.

(Jackie Chou): Okay. This is very helpful. Thank you for everything that you do. Thanks.

Timothy Stenzel: You're welcome.

Coordinator: The next call comes from (Fasita). You may go ahead.

(Fasita): Yes, thank you so much for your time. Again my question is also related to the serology tests that are being imported into the United States from outside. Are these products - can these products be imported easily, or will there be any questions if you have already sent the notification to the FDA? Do we need to show any evidence for getting the product inside?

Timothy Stenzel: Are you acting as an importer?

(Fasita): Yes, as an importer and distributor in the United States.

Timothy Stenzel: Okay. Right. So if you encounter - once either you or the manufacturer notifies us that you intend to market in the United States under Policy D, then we'll work with you to work through all those import issues.

(Fasita): Okay. And as soon as they send the notification, we are able to bring the product in to the United States and distribute?

Timothy Stenzel: Yes. But if there are additional notifications of border control and customs, then in order for them to be not held up, we'll work with you.

(Fasita): We have to work with you. Okay. So it's better for us to wait until we clear that up with you?

Timothy Stenzel: No. It's - you can go ahead and notify, and in real time, let's work through those issues. So you notify us, and then in your notification you can ask - and what additional do we need to do to ensure that the products can be imported into the United States?

(Fasita): Okay. That's what we didn't do. We sent the notification, but we did not ask that question. Okay, so I will follow up with that question.

Timothy Stenzel: All right, thank you.

(Fasita): I have one more question, and I don't know if it's the right place to ask it, but it has to do with the Medicare codes for this type of test. Would you have any guidance on that, or you know that?

Timothy Stenzel: No, that's again not in our purview. I would defer to CMS or one of the carriers on that.

(Fasita): Okay, great.

Timothy Stenzel: Or one of the professional societies.

(Fasita): CMS, okay. And just one last request - all the questions -- the very good questions asked by everyone -- will they be posted on the FAQs for everybody?

Timothy Stenzel: The questions on this call - this call will be transcribed, and so all the questions and answers will also be transcribed. But they will not be on the FAQ page. But through the mechanism to obtain the transcript from this call, this will be provided you in writing, yes.

(Fasita): The answer I was looking for I guess is about the CLIA (unintelligible) several people asked, the plan for distributing this serology kit to the CLIA (unintelligible) labs, if it's allowed or not. That is really my specific question.

Timothy Stenzel: If it's CLIA-waivable, then yes. But it does need to be a lab that can that's accredited to handle CLIA-waived tests.

Coordinator: The next caller is (David Schutten). You may go ahead.

(David Schutten): Thank you. So under the guidance, we're not allowed to say that an IGG/IGM serological tests is CLIA-waived. But we've had questions from physicians asking -- who are capable of running CLIA-waived -- whether they are allowed to use the test. But it's not labeled as CLIA-waived, which a similar test would probably be labeled that way. Is there any advice to the physicians that we can give them to assure them that they're not going to be penalized for using these tests?

Timothy Stenzel: That is an absolutely great question, which I will take offline and bring to our experts. The CLIA-waived decisions are made in our office -- the Office of In Vitro Diagnostics at the FDA -- so we have the expertise to address that question. And I will ask that we can post this up on the FAQ page as soon as possible.

(David Schutten): Thank you.

Coordinator: Next question comes from (Peter van Hoering). You may go ahead.

(Peter van Hoering): Can you hear me?

Irene Aihie: Yes, we can hear you.

(Peter van Hoering): Okay. So, this has been partially addressed but we're coming from a non-CLIA laboratory side and wondering about the activation side. I know right now the plan is to potentially purchase the Thermo Fisher kit for real-time

PCR to do the clinical diagnostics testing for the virus. But as we're not a CLIA-certified laboratory, I was wondering - is there any discussion about potentially relaxing some of the requirements to help enable and activate the non-CLIA-accredited laboratories?

Timothy Stenzel: So again, that is not something under the FDA's authority, but it's fully under CMS's authority. One pathway you can do -- if you can't work with another existing CLIA lab to have your operation run under their license by some mechanism -- is to actually apply for a CLIA license for your facility.

(Peter van Hoering): Okay. And what is the typical turnaround time to acquire the CLIA license and certification? Because I know time is of the essence.

Timothy Stenzel: It is. I'm under the impression that it's not long. But I would defer to CMS on what the turnaround time is here.

(Peter van Hoering): Okay. We'll reach out to them. Thank you.

Timothy Stenzel: Yes, you're welcome.

Coordinator: The next question comes from (Denise Ghast), and please limit to one question.

(Denise Ghast): Oh, well, I was going to make it a two part question does that count? I know the FDA has come out with multiple sample (unintelligible) and you keep adding to the list of things that could take place. Are we to assume that the FDA has done any kind of validation on those? Because I get the feeling when you say that some of those may not have good RNA return and if so when you say that you want five positive, five negative for that first group, are we to

assume that that should be each specimen type, and using the different kinds of media and swabs?

Timothy Stenzel: Yes. First on the five and five question - we didn't really go down to that granularity. But it wouldn't hurt to - so we said first five positive and five negative. So I would follow that advice. And then - I mean, certainly if you had any questions about whether that applied to a more challenging specimen, you could do that as well.

But I would assume that any new specimen type that is not listed as allowed on our FAQ page, that you would do a validation for, and then you would have validation data that would support the use of that sample type. I would say that we've tried to be very clear on the FAQ page as far as sample types, and where there is insufficient data to recommend something, we made that clear.

But as of late on Monday night -- very late -- we updated it to say that while nasopharyngeal or NP swabs are still the preferred swab of choice, you can now do mid-turbinate and anterior nares -- or the lower nose -- in addition. And those appear to us to be -- looking at study data, which is not public yet, but which United Health Group will hopefully publish very soon -- looks equivalent in performance to nasopharyngeal swabs.

So we do make these decisions based on scientific - sound science and data when we have it, and the literature when the literature is appropriate.

(Denise Ghast): Okay, thank you. That really helps.

Elizabeth Hillebrenner: I would add to that that the mid-turbinate and nares locations are for symptomatic patients.

Timothy Stenzel: Yes, thank you, Elizabeth.

(Denise Ghast): Thank you. Appreciate it. And thank you for holding these town halls. Very helpful.

Coordinator: The next question comes from (Anthony Nguyen). Please limit yourself to one question.

(Anthony Nguyen): Hello. Just a quick clarification question. So in California we have a lot of biotech labs in companies that are interested in developing these diagnostic tests. So how do we know which lab can go to the state and which can go to the FDA directly, given the guidance that was updated on March 16?

Timothy Stenzel: Well, you could come in through our templates email and ask if your state has that, but your state should provide that information to labs in the state. Well, they can provide that to labs in your state. We don't specify that. But if you have any questions about whether your state is doing that, just send an email to us at the templates email address and we'll let you know.

Elizabeth Hillebrenner: And we are posting the states that have notified us under Policy B . We are posting that in our FAQs. I believe so far it's New York, Washington state, Nevada and Maryland. But the link to that is in the presentation, and so you can monitor that Web page. And as more states notify us, we will add it to our FAQs so that everybody is clear about which states have opted into Policy B.

Coordinator: Thank you. That will be the end of the question and answers. Ms. Irene Aihie will now take over the call again. Thank you.

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 Learn Web page at www.fda.gov/training/cdrhlearn by Tuesday, March 31. If you have additional questions about today's presentation, please email cdrh-eua-templates@fda.hhs.gov - and as always we appreciate your feedback.

Following the conclusion of today's presentation, please complete a short 13-question survey about your FDA CDHR 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: You may now disconnect. Thank you all for participating, and have a wonderful rest of your day.

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