

**FDA Virtual Town Hall Series #2–
Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
Moderator: Irene Aihie
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3:00 pm ET**

Coordinator: Welcome and thank you for standing by. 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 then the Number 1 on your phone to ask a question. I would like to inform all parties that today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference over to Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello. I am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's second in a series of virtual town hall meetings to help answer technical questions about the development and validation of test for SARS COV-2 and the updated policy on COVID-19 diagnostics policy for diagnostics test for coronavirus disease 2019 during the public health emergency.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in CDRH's Office of Product Evaluation and Quality will present an overview of the guidance. Following the brief presentation we will

open the line for your questions related to information provided during today's presentation. Now I give you Timothy.

Timothy Stenzel: Hello and welcome to our ongoing series of town hall meetings. We intend to do these weekly at this time until we've addressed all questions which may be a while. I am only going to introduce some brief remarks today. The guidance of 16th of March is available. I can address questions that are specific to that. We did cover it in detail last week.

I do want to point out a couple of things though that are of importance. First of all please continue to check out our Frequently Asked Questions page at the FDA. We update these regularly. We do send out notices when these updates occur and so we try to alert people that way. But I would save the tab and check it frequently. As these updates get more and more it is hard a little bit to track, you know, where those updates occur. So I will in these weekly addresses I will briefly point to where the updates are and when helpful I will give a little bit more detail.

So since last week there are updates to what laboratories are offering testing under Pathway A. Also there is an update to which states have chosen to authorize laboratories under Policy B. Also there are updates on what commercial manufacturers are distributing test kits under Policy C prior to submission. And then there's also an update to what serology assays are being offered under the policy in Policy D.

There's also an update on how we go about authorizing and stating when there is a point of care or near patient device. I did want to read through this because we get a lot of questions about that and have received a number of questions about that. And then I want to finish up after that with a discussion on serology testing and then we can jump into questions and answers.

“So under this when FDA authorize - authorizes a SARS CV test for use at the point of care does that mean it is CLEA waived?” That’s the FAQ question. The answer is the FDA does not CLEA categorize tests authorized under EUA. Instead the settings in which an EUA authorized test may be used are described in the Letter of Authorization. This Letter of Authorization by the way is available on our EUA authorization Web site under each test developer.

We note that the terms “Patient care settings outside of the clinical laboratory environment,” “near patient testing,” then “point of care,” in the UAs policy for diagnostic test for coronavirus and are generally - and generally refer to settings that are equipped with the instrumentation as needed and appropriately trained personnel necessary to perform the test and may include settings such as hospitals, physician offices, urgent care outreach clinics and temporary patient care settings. These terms generally do not apply to home specimen collection or at home testing unless otherwise specified.

Okay, I would like to say something about serology. And these are typically the serology tests that are listed under Policy D on our Frequently Asked Question page. These are typically rapid finger stick tests for IgG and IgM and IgM antibodies. The FDA we recognize that these types of devices have a critical place in the fight against coronavirus. These tests results should not be used alone to make a diagnosis but are helpful in identifying who may have already been infected and their immune status response.

The FDA’s diagnostics policy allows these tests to be used, and I have a quote, without FDA authorization as long as these tests are labeled appropriately, including a statement that they cannot be used as the sole basis for diagnosis or exclusion of infection. Results should be obtained and used in

complication with the healthcare provider. No at-home serology test are exempt meaning they need authorization from the FDA for the setting.

To date we have not in fact authorized a serology assay. That should change in the relatively near future though as some of these are - have begun coming through our EUA process. So be on the lookout for that. Also I would say that we are starting to hear complaints from a number of different sources that these rapid serology tests that are listed under Policy B under our frequently asked Web site that they're making claims that they are authorized by the FDA and that they can be used for diagnosis. Those seem to be not in line with our policy and when we find out about this we will be contacting those companies and correcting their misinformation. So hopefully that has clarified this policy around these - this particular non-EUA authorized category of test. And with that I turn back over to Irene and the operator to take questions. Thank you.

Irene Aihie: Thanks Timothy. (Jennifer) we'll now take questions from our participants.

Coordinator: Thank you. We will now begin the question and answer session. Please note that you will be allowed to ask one question at a time so if you would like to ask a question please press Star 1, unmute your phone and record your name clearly. If you need to withdraw your question please press Star 2. Again to ask a question please press Star 1 and it will take a few moments for questions to come through. Please standby.

Irene Aihie: And while the operator is getting the questions in queue, we did have a few questions come through via the chat and as you mentioned we'll only be taking questions by the phone, but while she gets folks into the queue, Timothy the first question that we had is does the lab need to validate each transport media or to CDC EUA test?

Timothy Stenzel: So labs under our updated guidance are able to make such changes on their own to an EUA device. That could include their own EUA that they've attained if they're laboratory developed test or if they obtain an EUA kit from a manufacturing source. They are - we expect that they will do the appropriate validation before they implement those changes under a so-called bridging study. You can reach out to the FDA if you have any questions about that.

We do not ask for those bridging studies to be submitted to the FDA although if you do them and you think it might be useful to other labs and you wish to share that data and that information if you send that voluntarily to the FDA we will review that data and if we can put that on to our Frequently Asked Questions page based on the data that you generated we will in order to help all labs and perhaps only one lab really needs to do this.

But if it is something that is already on our Frequently Asked Questions page we view those as mix and match. And we thank CMS and CLEA who have updated through an announcement that they are allowing lab directors to make the decision about whether additional validation is needed in the case where the FDA has already listed these options on our Frequently Asked Questions page. So hopefully that addresses that question appropriately. Thank you.

Coordinator: Thank you. The first question over the phone comes from (Amanda Barton). Your line is now open.

(Amanda Barton): Hi. I was wondering if there is any updates as far as larger scale serology testing coming through the United States.

Timothy Stenzel: Hi (Amanda). We are very interested in that and we're talking to a number of developers and we're very eager to get such a platform into the United States

and that of course would come through the EUA authorization process. So something like that could happen in the relatively near future so stay tuned. Hello?

(Amanda Barton): Sorry, thank you very much. Sorry.

Timothy Stenzel: Okay it - does that address your question?

(Amanda Barton): Yes.

Timothy Stenzel: All right, thank you.

Coordinator: Thank you.

Irene Aihie: Operator we'll take our next call.

Coordinator: Thank you. The next question comes from (Brandt Mitler). Your line is now open.

(Brandt Mitler): Hello. I have a two-part question. Number one under Policy B once a manufacturer has notified you with all of the requisite information what are you calling your response? I realize it's not authorization. What are you calling the response and how can one track the progress of that notification? And number two if one or more foreign manufacturers were - are interested and they are in participating in a clinical trial at - of the validity and accuracy of these foreign tests in a US major medical school laboratory is there a contact officer person at the FDA that we can talk to?

Timothy Stenzel: Absolutely. We would welcome such a study in order to show if - which of these tests -- maybe all hopefully have high accuracy. And so I'll address the -

I think the second part of the question first. You can simply contact us at our email address for EUAs and that is cdrh-euatemplates, the word templates with an S at the end @fda.hhs.gov. And if you or someone else were to do such a study we would welcome it of course. We would if you want to discuss how best to maybe design such a study we'd be happy to give you our thoughts about that.

I would just say in general that we would expect to see a minimum for good testing of these devices a minimum of say 30 positive patients, positive with some obviously IgM alone some that are going to have IgM and IgG. The number of patients in the US now with only IgG is probably limited and we understand that and we wouldn't necessarily expect to see that. You know, that's a bare minimum. It would be nice if possible to get 30 IgMs and 30 IgGs and some of them can be overlapping.

The other general advice that we're giving for the validation of these kinds of devices is that it may be very difficult to get panels of immune serum. In particular we want to know if there's cross-reactivity with any non-SARS coronaviruses that normally circulate during respiratory season than perhaps other times of the year. There are four main types that we - I think we have listed in our - in one of our - in our templates and we would of course love to see immune serum against those in more than single isolates.

That would be the best test to know if the SARS COVID-2 rapid tests are specific for (Com) SARS CV2. But in the absence of that we are allowing developers to test a panel of at least 75 non-SARS CV patients who should be negative for antibodies against SARS CV2. We would expect to see as much variety in those negatives as possible and where possible know the immune status for some of the common respiratory viruses. So could you let me know if I've addressed all of your questions?

(Brandt Mitler): Yes the - only the first one was - thank you very much on that. The first part was what is this process that your - that we call or that you're calling after notification during this pending period where the manufacturer is waiting back to hear from you under Policy B?

Timothy Stenzel: Yes, so what we're doing is we're taking a look at their marketing materials and making sure that they fall appropriately under this policy and that they be following this policy and we try to turn that around quickly. And once we have made that decision and informed them we will issue them a number. That is not an EUA number as some have confused that. That is not EUA authorization number, but that is a number so that we can identify that device going forward in the future.

(Brandt Mitler): Thank you very much.

Timothy Stenzel: You're welcome.

Coordinator: The next question comes from (Chen Zang). Your line is now open.

(Chen Zang): Hello. Yes my question - hello. I think first I would like to say thank you to FDA reviewers and managers for your dedicated hard work during this time. I know a lot of people are working around the clock. Thank you. And my question is about Section D serological test. And so if the test use an instrument to measure like the flu resin signal or to make a detection should the instrument be listed separately as under its own instrument product code?

And my second question is we made minor changes to the package insert after notification like extending the shelf life and but no big changes like remove

the limitation language, not those big changes. Are we allowed to make changes to the package inserts after notification?

((Crosstalk))

Timothy Stenzel: Yes, yes you can if you've notified us under Policy D we would view the instrument that performs that testing as part of that - just as part of the policy and should be linked unless you want to come in for an EUA and then it would be a little bit different. And changes, minor changes to shelf life and things like that if there are performance differences for which we usually review package inserts prior to putting your name up on our Web site we would like to know if there's any performance changes. But minor changes such as shelf life do not need to be - we don't need to be notified about that. Hopefully that helps you out.

(Chen Zang): Thank you.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Hector Moldinaro). Your line is now open.

(Hector Moldinaro): Yes thank you so much. Thanks for the invitation and again I want to also acknowledge your guys' hard work, dedication and tireless efforts so thank you all for what you're doing.

Timothy Stenzel: You're welcome.

(Hector Moldinaro): So I work for SD Biosensor and I just wanted to clarify. So we have four different devices. We have one that's an immunofluorescence assay testing

quantitative. It is approved in Europe. It's been out for quite some time. So I'm also in the National Guard. I'm a part of the military for the last 24 years.

So I sent an email earlier when I was a commander or guardian in New York City in 9/11 and we had very limited resources. It would be really nice to get a lot of stuff in as quick as we could. So every night I hear Governor Cuomo saying that there is a shortage of tests and the national guards are exposed. So am I clear in that under the EUA policy D that we could bring our test in for military use?

Timothy Stenzel: So...

(Hector Moldinaro): What's the (unintelligible) needed?

((Crosstalk))

Timothy Stenzel: Go ahead.

(Hector Moldinaro): Yes so my question is what's needed and what are the steps to import tests from Korea?

Timothy Stenzel: Okay well first of all thank you for your service. Second let me just follow-up. So this is an IgG IgM that would fall under a serology test that would fall under Policy D?

(Hector Moldinaro): Yes so it's yes IgM IgG it's a dual FIA test.

((Crosstalk))

(Hector Moldinaro): It's - so it's basically the same as an HIV test which we also have that's widely used throughout the globally really. So what's the...

Timothy Stenzel: Yes, no I mean if you want to follow Pathway D you just, you know, you notify us and you label the test appropriately. Since you have - I think you mentioned CE mark in your remarks that you have CE mark for this you may have enough data to seek an EUA authorization and we'd invite you in. In the military setting what kind of setting would it be?

(Hector Moldinaro): So my concern is for all of the guard units that are mobilized now. So when I see them on TV these are young kids. Maybe they're - it's not going to affect them but they do have parents that are elderly. They have grandparents that are elderly. So at least having it for our first line leaders and the use for military to test these young...

((Crosstalk))

Timothy Stenzel: Okay. Well I would expect that you would have some sort of temporary healthcare facility that you would set up in such an environment and it would be covered under our thoughts of near patient testing that I explained first thing on the call which is on our FAQ page. We are not - at this point we do require EUA authorization for at-home use so and also the requirements are that a healthcare professional be involved in the testing with this Pathway D. So that's where if this testing is done and that sort of location it does need to be under the supervision of a health care professional.

(Hector Moldinaro): Yes, so for military use it would be under whether it's a physician assistant or a unit surgeon or something like that there would be...

((Crosstalk))

Timothy Stenzel: That sounds good to me.

(Hector Moldinaro): ... medics. Okay, so just follow Policy D and apply the...

Timothy Stenzel: Yes.

(Hector Moldinaro): ...the EUA authorization?

Timothy Stenzel: No, you just notify us and then you're allowed to import it. If you have any issues of importation reach back out to the notification email as I mentioned earlier and we will address those important issues as soon as we can.

(Hector Moldinaro): And how long roughly is the turnaround time for that authorization?

Timothy Stenzel: I don't know what the averages. Obviously we try to do all of these things as quickly as possible. We are quite busy and everybody's important. And we have a number of these devices already on our page so we're gratified that so much - so many EUAs have already been authorized and so many labs have notified us that they're doing their own LVT, so many companies have notified us that they intend to file EUAs and that they're on the market, et cetera.

So we have - we are working with hundreds of different developers right now and we have a great team and they're really dedicated. So if it's taking a little bit longer than you think, just send us another email, you know, to make sure that we haven't forgotten about you which we don't but don't hesitate to ping us again if you're not getting an adequate response time.

(Hector Moldinaro): Okay, great. Thank you very much -- appreciate it.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Sue Warner). Your line is now open.

(Sue Warner): Yes hello thank you. My question is related to Part D of the guidance as well. And my question is if a serological test is validated for whole blood can they be used for capillary blood?

Timothy Stenzel: Yes, what does the manufacturer's instructions for use say, just whole blood, not capillary?

(Sue Warner): Whole blood, correct.

Timothy Stenzel: Yes so capillary blood can obviously perform a little bit differently than a venipuncture sample for some devices. So if you're going to change the test in any way I would suggest that you do some sort of bridging study between venipuncture and capillary so that you can ensure yourself but the two tests will perform equivalently. That sort of bridging study is you're not required to submit that to the FDA for review and any sort of EUA authorization but again if you do that sort of study to update, you know, a sample type like that we would love to see that data voluntarily and in order to continue our assessment of the performance of these devices on the market.

(Sue Warner): Okay thank you.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Elliot Cowan). Your line is now open.

(Elliot Cowan): Hi thanks. Another Part D considering that it EUA isn't necessary for the IgM IgG test that are used - are the sole basis for clinical decision-making and the test is labeled like that, should the manufacture label be used for IVD use or if not what other labeling recommendations do you have?

Timothy Stenzel: We are allowing them to be marketed as IVDs in the United States so yes for IVD use is appropriate.

(Elliot Cowan): Got it, thank you.

Coordinator: Thank you. The next question comes from Chris Emery. Your line is now open.

Dr. Chris Emery: Dr. Chris Emery from Indiana University. Yesterday there were multiple media reports about an EUA authorization for body sphere that a rapid point of care test actually had been authorized. I'd just like some clarity on that because in this presentation it was stated that no serological assay has yet been authorized.

Timothy Stenzel: That is correct. We have not authorized any serological tests right now and the - if someone should be listed under our Pathway D list they should not be saying that it is EUA authorized. And we have heard about that complaint and they are following-up on that.

Dr. Chris Emery: Okay and just one more question because I'm a clinical pathologist and laboratorian. Can you give us perhaps any possible projection on when we might be seeing some of these applicants for EUAs actually authorized?

Timothy Stenzel: Yes, I'm hoping this week.

Dr. Chris Emery: Okay.

Timothy Stenzel: Maybe even today but no promises.

Dr. Chris Emery: Thank you.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from Dr. (Jonathan Wiener). Your line is now open.

Timothy Stenzel: Hello?

Coordinator: It looks like the line disconnected. The next question comes from (Eric Cabrins). Your line is now open.

(Eric Cabrins): Thank you so much for the sessions and for your leadership during this time. My question is can the FDA speak to the reporting expectations of positive diagnoses or presumptive positive diagnoses to the CDC and or state health agencies for the manufacture of an at home nucleic acid test that's paired with a mobile application connected to the cloud?

Timothy Stenzel: Okay so you're interested in an at-home test. Do you have such a test already produced and ready to be used?

(Eric Cabrins): We're in the process of development right now and have started the conversations with FDA.

Timothy Stenzel: Great, great. So again what are your specific questions because we certainly welcome this kind of development? We think that the appropriately - the appropriate testing in the home environment or self-testing is - will be a part a strong part of our response to coronavirus. So...

(Eric Cabrins): Okay.

Timothy Stenzel: ...can you just rephrase your question?

(Eric Cabrins): Yes thank you for your support. My question is regarding the reporting expectations of presumptive positive diagnoses. As the manufacturer of an at-home test it isn't clear how those laws apply to us.

Timothy Stenzel: Yes, okay so first of all the technology is it molecular?

(Eric Cabrins): Yes.

Timothy Stenzel: Okay.

(Eric Cabrins): Yes it's a nucleic acid test.

Timothy Stenzel: Nucleic acid test okay yes. Proteins or molecules too and nucleic acid is what I should say. You know, so part of this will depend on the performance of the assay. Is it - does it perform in comparison to a central already central lab already EUA authorized device or you can use one of the point of care already EUA authorized devices as a comparative tour. If you want to do that that would be ideal but it's not necessary. You can also follow our regular guidance and that's sufficient for this particular use.

In the in-home setting I'd also say that we are look at actual user safety. So if there's an instrument user safety is important. If there's any collection devices, user safety is also important whether it be the actual collection instrument or what's in the collection article. Those are all important questions.

If the performance is sufficient and if and they can be relied on the only real issue is how that result is reported back into the healthcare system. So perhaps you have some ideas that you want to share or thoughts or ask questions about but it's really how do you link a result that's obtained in-home use to an individual patient?

Now I have heard I think this is public knowledge that there are some telemedicine portals that are being proposed to be able to do this even under supervision and guidance of a clinician or a healthcare professional so that the testing is done appropriately, that the results are understood and can be interpreted by the healthcare professional. And do you have any follow-up questions on what I've said?

(Eric Cabrins): Yes this is very helpful. I think maybe in the interest of letting other people ask questions I'll follow-up with you and your team in our subsequent meetings but thank you very much for this information.

Timothy Stenzel: You're welcome, you're welcome.

Coordinator: Thank you. The next question comes from (Michael Roth). Your line is now open.

(Michael Roth): Hi. Thank you very much for the time. A very simple question as you may have heard a number of us we're on the Webinar and heard nothing. So is this

going to be recorded and made available or can you possibly go over the opening remarks which none of us heard?

Timothy Stenzel: Really?

(Michael Roth): Yes really.

Timothy Stenzel: Operator are you on? Did we start recording from the beginning?

Coordinator: Yes sir. We have recorded from the beginning. There will be no audio heard over the WebEx however.

Timothy Stenzel: What do you mean by no audio over the WebEx?

Coordinator: During the live call there is no audio provided through joining the WebEx. It all needs - it is all provided by dialing in.

Timothy Stenzel: Oh calling in...

Coordinator: The recording will have both the audio and the WebEx together.

(Michael Roth): We'll honestly we - a number of us did dial-in and heard silence. We were on the WebEx and we heard silence and then somebody in the group in the chat provided a secondary dial-in number which is what I'm on now. And basically I got in at the very end of your remarks and I think a lot of people would very much like to hear your opening remarks...

Timothy Stenzel: I will go back...

(Michael Roth): ...because I think they answer a lot of questions.

Timothy Stenzel: Yes I'm sorry about that. There's a lot of people using these kind of sessions. So I will go through them again. Did you have any other questions while I have you on the line otherwise I will...

(Michael Roth): Well I don't want to waste anybody's time. I really wanted to hear the opening remarks because I...

Timothy Stenzel: Okay.

(Michael Roth): ...from what I heard on the tail end they were very salient.

Timothy Stenzel: Okay well let me just briefly go through their first remark and I won't go through all the updates to the FAQs but do check the FAQs. There have been updates since last week. One of those updates had to do with what we mean by near patient testing or point of care testing. We will note terms like patient care setting outside of the clinical laboratory environment or near patient testing or point of care in our EUA authorizations. And this generally refers to settings that where appropriately trained individuals are able to perform the tests and may include settings such as hospitals, physician offices, urgent care, outreach clinics and temporary patient care settings.

These terms generally do not apply to home collection, specimen collection or home testing unless otherwise specified. I also talked about the proper advertising and marketing of the rapid serology tests. These if they're under Policy D are not to be advertised as EUA authorized because they are not. They have not received FDA authorization. They should not be making these claims.

You can say that the FDA has allowed this to be marketed under Policy D. That would be very correct. And then let's see what was the other thing that I covered? I think those were the main things. But anyways it will be recorded and transcribed so you can check that later on if I missed anything that was of importance.

(Michael Roth): That would be great. A quick question about that did our pharmacies with proper personnel included in point of care?

Timothy Stenzel: Yes. But it's maybe a practice of medicine question. That's not something that's under the FDA jurisdiction.

(Michael Roth): Okay.

Timothy Stenzel: So look at your state laws.

(Michael Roth): Correct. Thank you very much and keep up the good work.

Timothy Stenzel: Thank you.

Coordinator: Thank you. The next question comes from (Becky Habert). Your line is now open.

(Becky Habert): Hi. So I work for a company in Canada. And we don't currently provide any FDA approved or cleared products. So we're working on a quality management system to prepare for eventual approval or clearance. But what I'm hoping you can help me out with is clarification on the description of the waived elements for the COVID-19 EUA. I've looked at a number of authorization letters and it seems that some elements of A20 are being waived.

And so I guess what specific sections of 21-CFR 820 does FDA expect to see from a company providing tests under the EUA?

Timothy Stenzel: Okay and so this would be something that would come in for this would be a lab developed test or this would be a manufactured test for distribution?

(Becky Habert): Kind of a mix I suppose. I mean we would be developing the test and then likely finding a lab partner in the US to actually...

Timothy Stenzel: Okay.

(Becky Habert): ...provide the test.

Timothy Stenzel: Okay. All right well that's you would potentially be described as a manufacturer.

(Becky Habert): Okay.

Timothy Stenzel: And may be held to if you're - it depends on how you develop and produce the test. If you're manufacturing the reagents and shipping them to a lab then you would be judged as a manufacturer. I am not actually up to speed on what parts of A20 are required under EUA. And I would suggest that you ask for a very good question to our cdrh-eua-templates email address.

(Becky Habert): Okay.

Timothy Stenzel: And I will actually learn something in the process as well about what we waive under EUAs.

(Becky Habert): Okay thanks very much.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Sarah Kalil). Your line - her line just disconnected. The next question comes from (Les Wilson). Thank you.

(Les Wilson): Thank you very much and I want - I send my appreciation for all your hard work. My question has to do with the serology test and does the FDA have a source or can you recommend a source of positive material that we could acquire for validation? And is there any restrictions in importing this positive material for QC validation?

Timothy Stenzel: So obviously negatives in the United States should still be easily obtained especially if they are banked from prior to the epidemic. We are aware that our - there are foreign suppliers of panels of serologies that would be appropriate for this however we don't necessarily know the quality of that. So we would certainly look to you to ensure that the quality of these panels is good and accurate for what you intend for it to do.

If you were to have any trouble importing those do let us know at our cdrh-eua-templates address and we will work with you on any potential import issues so that you can do this validation. We are reaching out to a number of entities in the United States in order to facilitate the collection and development of panels of immune serum for SARS COV-2. This is actually an interagency effort now involving CDC, BARDA, ASPR and the FDA. And we are in the beginning stages of this work and so I can't report any success at the moment but we will be updating our Frequently Asked Questions page with regard to resources that could be used.

In the interim I know that there is at least one lab in New York that has begun offering a test probably because New York is one of the states that can authorize their own SARS CV tests. So there may be others in New York that are under this or when we are able to authorize the serology test whether that's an LDT or a manufactured test that could - anybody who utilizes that test or that testing service could potentially identify such immune serum.

(Les Wilson): And so you're saying that I need to keep in touch with the - your Frequently Asked Questions page and when you have anything like that posted it would be there. Is that correct?

Timothy Stenzel: Yes exactly. We're looking at how we can develop panels that could potentially share with developers and/or labs that could do that testing as a third party. So we are in the initial planning stages of how to roll that out and initial discussions but this is a large federal effort at this time.

(Les Wilson): Thank you very much and once again great job.

Timothy Stenzel: Thank you.

Coordinator: Thank you. The next question comes from (Mark Coudier). Your line is now open.

(Mark Coudier): Hi. My question is actually in regards to the part D Pathway. I think a lot of us in the laboratory community are curious how thoroughly this validation data submitted by manufacturers is being evaluated by the FDA. And what measures are in place to ensure that were not going to see any manufacturing quality control issues that cause significant damage in Spain and Italy with regard to inconsistent products and citizens offices performing it without any experience in monitoring such quality?

Timothy Stenzel: Yes, no that's a very excellent question. We came up with this pathway to expedite tests that were not for sole diagnosis to get onto the market. We have a parallel path where there is a full EUA authorization review that's open to these developers. And we would encourage them to come through that pathway. But for the time being they cannot claim FDA authorization. We are solely allowing them to be marketed. So I would urge those that buy these tests is to do some sort of verification of the performance. That's not required but I think it's only wise.

We are aware of the Spanish situation and particularly the business insider article. And it's why we are currently standing up this federal effort. We hope and we have already begun inviting these serology test providers to come in voluntarily to undergo a third party validation program. We are just in the beginning stages of that. Once that program is up and running and we are able to verify the performance that are stated in their package inserts we will make that information publicly known.

(Mark Coudier): I totally understand and agree with that. I think the problem is, is that is assuming that these are being marketed, purchased and performed by laboratory personnel and unfortunately we're seeing in our community that's not the case, that they're being aggressively marketed to small physicians' offices. There is no technical laboratory expertise and the physicians are essentially unboxing, running and taking it as gospel and I think that's really scary.

Timothy Stenzel: Thank you for sharing your concerns. They're not necessarily unwarranted and it's why we're standing up this effort right now. If you hear of any false claims or if you hear of any absolute performance issues we will - we would

like to hear about that and you can send it to us at our cdrh-eua-templates email address. And we will absolutely investigate complaints of that sort.

(Mark Coudier): All right thank you.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. The next question comes from (Sarah Kalil). Your line is now open.

(Sarah Kalil): Thank you very much. Can you hear me? Hello, can you hear me?

Coordinator: Yes, we can hear you.

(Sarah Kalil): Excellent thank you. My last time I got cut off. I have a two-part question on sample collection. And the first part is does the FDA have any data on the acceptability of a saliva sample for detecting SARS CV2? Hello?

Coordinator: Excuse me I have joined Tim back to the call. Thank you.

Timothy Stenzel: Hello everyone, sorry about that technical issue. Somehow I was knocked off the call and then I couldn't call back in because there's too many people on this call which is a good problem to have. Anyways I'll take additional questions in the time remaining.

(Sarah Kalil): Great Tim. This is (Sarah Kalil). And first thanks to you and your colleagues at the FDA. The response has been amazing. I represent industry. And so my first question and it's actually a two-part question first is does the FDA have any data on the acceptability of saliva as a sample type for detecting SARS CV2?

Timothy Stenzel: We've been - I presume you mean by nucleic acid methods?

(Sarah Kalil): Yes thank you.

Timothy Stenzel: Okay. So we have developers both for serology. You can, you know, do things like IgA in saliva but we have quite a bit of interest in other sample types for nucleic acid-based testing. We in the United healthcare group study which I still don't know if it's been published yet we looked at what was it tongue swab which may simulate somewhat saliva or it may not because there's not a whole lot of volume there and more volume of saliva make a difference. But anyways in that comparison there was not good correlation between the cycle thresholds of the tongue sampling and a swab and the nasopharyngeal comparator. There was actually no correlation to CT. So we became a little bit concerned at least with the tongue swab.

I do not know if a higher volume of saliva would work better. We do have parties who are interested in going forward with saliva tests. Because it is a new anatomical site we would want to do for any LDTs or any manufactured tests we would want to have an EUA amendment to review that data before we authorize it. And then obviously once we make saliva available as a reliable sample type from an anatomical site then we can make that widely known. Hopefully that addresses your question.

(Sarah Kalil): Sure it does. And I think that if the agency could provide guidance to industry that desires to collaborate on that it would be wonderful because that's certainly opens up a number of possibilities with sample collection. The second part is on the subject of sample collection and in the case of a nasopharyngeal sample if the agency were to agree to a home setting sample collection is there a feeling that that would have to be observed via

telemedicine? You know, what is the sentiment on the nasopharyngeal sample collection in a remote setting?

Timothy Stenzel: Yes that's a great question. Have you ever had a nasopharyngeal sample performed on you?

(Sarah Kalil): I haven't but some of my colleagues have described it and I do understand that it's highly uncomfortable, hard to inflict upon yourself and so that really raises the question of would it need to be observed from a telemedicine perspective?

Timothy Stenzel: It's not the - I mean of course if someone comes in with data and says that patients can do this and they have no on results but I don't I would advise against it. There - I think there is - there's danger of self-harm or from someone else doing it improperly. Also it tends to make patients sneeze and cough which could...

(Sarah Kalil): Right.

Timothy Stenzel: ...make, you know, infectivity increase. So we have already seen data that says the interior nasal swab particularly the only swab that has been validated in that in a (unintelligible) site right now is the round foam swab. We know of others who are validating other swabs that could be used for interior nasal but I think in the home care setting if someone wants to pursue that, an interior nasal swab in both nostrils need to be sampled. And then, you know, if it's a simple safe device, that's something that in the home setting that we want to take a look at.

But the United Health study already demonstrated that interior nasal swab could be self-collected. So that's not approved. What we are looking for is on

home collection at this point for something like that because that is the media that's used, is it safe for the home environment? And is a sample that is returned from a home setting through a shipping is it intact so that you have no false negatives from that transport of that.

And if it uses - happens to use media that's already been FDA cleared for such transport then maybe that isn't needed but it's usually typically a simple in lab bench study to demonstrate that the temperatures that the sample may be exposed to near the LOD of the assay with a sufficient replicates that you can demonstrate adequate performance from a shipment from the home setting.

(Sarah Kalil): Terrific, that's incredibly helpful. Thank you Timothy.

Timothy Stenzel: You're welcome.

(Sarah Kalil): The next question comes from (Erika Almardi). Your line is now open.

(Erika Almardi): Hi. Thank you and thank you Tim for holding these. Getting back to serology there, two related questions. One is you spoke of an EUA for home use and that's on the forefront is there an FDA template for EUAs from the serology side or do we just use our best knowledge of how to do that? And then related to that if you wanted to go the EUA route for a professional use that would take you beyond the notification. Is there a template for that or would they be the same or how would one go from a notified serology to an EUA?

Timothy Stenzel: Yes that's a great question. So home use serologies introduce some additional variables that are important to demonstrate safety her.

(Erika Almardi): No absolutely. I was just asking. I don't want to take up everyone else's time so...

Timothy Stenzel: But I do want to - I think it's important to say that how you collect the sample which is usually a blood sample, I mean this isn't necessarily performed routinely by anybody other than maybe a diabetic.

(Erika Almardi): Right.

Timothy Stenzel: And then the use of such a device that's intended for healthcare setting and the reading of it is not usually intended for the home use and we are open to it. There are clinician observed methodologies in the home they could be called upon. And I would urge you to consider those and to reach out through our email address to ask about how you might design and market such a device and do the study to show that consumers, lay users with simple instructions and perhaps in the right situations, you know, under observation can perform these testings - testing at home.

(Erika Almardi): Okay, but as of today there is no prescribed templates for that?

Timothy Stenzel: No, we haven't been approached by multiple developers in this area. And the other thing is how does a patient interpret the result too? So that's why it's really important for a clinician, healthcare provider to be involved in that part of the assay as well.

(Erika Almardi): Okay great. Thanks very much.

Coordinator: And our last question comes from (Marade Oxu). Your line is now open.

(Marade Oxu): Hello. Hi.

Timothy Stenzel: (Unintelligible).

((Crosstalk))

(Marade Oxu): First of all I want to thank you so much from the bottom of my heart for everything you guys have been doing since this unfortunate have started happening. I have a couple of questions. I'm going to try my best to summarize it.

First one is that you mentioned about the Policy C on Frequently Asked Questions on your Web site. And I'm actually checking out your Web site right now and I have been checking it for the past couple of weeks. And how often does that section get upgraded updated because there's a company -- I'm not going to give name at all of course. There's a company they received DUI authorization on March 26 last week. And that company's name still on that Frequently Asked Questions section. It's not been updated at all.

Timothy Stenzel: So okay so they previously notified us and it's they're - are they notified of the EUA page as well?

(Marade Oxu): Yes, yes on the UA page the date shows March 26 they received it but on the Frequently Asked Questions the company's name still there saying that FDA I cannot read it right now. The FDA has not reviewed the valuation of this test or these manufacturers or issued EUA for these manufacturers and there's a name there. But same manufacturer that received EUA on March 26 last week.

Timothy Stenzel: Okay, thank you for pointing out that error. I'll alert our Web folks and they'll make that correction. Thank you.

(Marade Oxu): Sure, sure okay. Real quick, second one is, I'm curious about the product called Q as in Question, Jay as in James, R as in Richard. Does that mean that this product has been EUA approved?

Timothy Stenzel: Those product codes have to do with the type of a device and the analytes. And it specifies our regulation that we follow. So it simply is a way for us to classify devices so that they are reviewed by the correct experts within our office and they are all handled equivalently as far as FDA regulations go.

(Marade Oxu): I see okay I have noticed but I was just wondering what it means. Last one is that it's a general question I'm trying to understand this timeframe. Once the manufacturer - under again the question is under Policy C. Once the commercial testing kits manufacturer does all their verification and validation through their own clinical evaluations, clinical trials and officially submits to you guys their EUA application from that timeframe how long does the FDA have to approve this manufacturing testing kit? Is that 15 days business days or 15 calendar days?

Timothy Stenzel: So the 15 business days are the time between the manufacturer notifying the FDA and when they need to - the deadline for what they need to submit the application to the FDA for EUA review. Because we have listed that manufacturer on our Web site already there is - and you've been able to be on the market for three weeks before we've even seen the package...

(Marade Oxu): Yes.

Timothy Stenzel: ...there's a benefit to that. We are typically not in a rush to review that package. We will take a high level review to make sure that there's nothing that looks like it may be incorrect. Once we receive it you should receive a notification that we've received it and that we have begun our review. And if

you have not heard from us you can stay on the market but we do to the quick high level review to make sure that there are no showstoppers.

And then we try to do it as quickly as possible. And we are getting some of those out but they are going a little bit longer than our normal EUA pathway where a company has expressed or we've expressed the need to do the authorization upfront. But now that companies can notify us we feel the pressure of our review other than a high-level review when we receive it is off so that we can appropriately use the resources in the best possible way.

(Marade Oxu): Oh I see. So there's no would you say timeframe for the notification you're saying pretty much?

Timothy Stenzel: So yes once we receive the EUA package we do not have a clock. Our normal - just so you know our normal 510K clock and that's in this situation with novel coronas the first...

(Marade Oxu): Yes.

Timothy Stenzel: ...submission would actually be a de novo submission and I believe that may be 180 days of FDA time. But for our following that de novo 510Ks have a 90 day clock.

Of course for our non-coronavirus applications right now there may be some developers out there that are wondering what we're doing with those. We obviously are - it's all hands on deck addressing...

(Marade Oxu): Yes.

Timothy Stenzel: ...coronavirus. And unless that there is some urgent unmet need equivalent to this emergency there may be some delays in the reviews of those non-coronavirus applications. We just - it's an opportune time to say giving people a heads up and we hope that they are understanding of that situation.

(Marade Oxu): I see. I understand, okay. It was just again I'm not here to give any names but there was just a specific question about this specific company. I mean they're pretty much on their Web site already doing what you guys are required them to do mentioning all these 100% specificity on 100% quality everything else. And they have been selling all around the world and they have all the CE mark and they already submitted all their clinical successful evaluation, verification, validation with your help with your guidance already on March 20th and still no response from you guys. And I was wondering when would that be...

Timothy Stenzel: If you - so has this company notified us through Policy C and have they listed on the Web site? Hello? Am I knocked off again? No?

Coordinator: No. No that caller has been disconnected sorry.

Timothy Stenzel: Okay. Well anyway if you have questions about any sort and you haven't been able to ask your question please submit them to cdrh.eua.template@fda.hhs.gov. Thank you so much, appreciate everybody participating on this and again we'll meet again in a week. Thank you.

Irene Aihie: Thank you everyone. This is Irene Aihie and we do appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn webpage@www.fda.gov/training/cdrhlearn by Monday, April 6. If you have

any additional questions about today's presentation please use the email cdreh-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/cdrh Webinar 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. You may disconnect at this time.

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