

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

Moderator: Irene Aihie
April 8, 2020
12:15 pm ET

Coordinator: Welcome and thank you for standing by. I would like to inform all participants that your lines have been placed on the listen-only mode until the question-and-answer session of today's call. Today's call is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the call over to Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello and I am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's third in a series of virtual town hall meetings to help answer technical questions about the development and validation of tech for SARS CV-2 during the public health emergency. Today Timothy Stenzel the Director of the Office of In Vitro Diagnostics and Radiological Health here in CDRH's Office of Product Evaluation and Quality will present an overview. Following brief remarks we will open lines for your questions related to information provided during the presentation. Now I give you Timothy.

Dr. Timothy Stenzel: Thank you Irene. Also joining me today is our Offices Chief Medical Director. That's Dr. Sara Brenner. She will be making some brief remarks and

addressing certain questions when they come up. So first of all here at the FDA we continue to work extremely hard to do our part to get the country back to normal as soon as possible. We are reviewing EUA applications as quickly as we can and as you see we continue to authorize them on a daily basis.

I wanted to address briefly serology tests. They are growing in importance for our response to this emergency in order to aid the determination of patient immunity and prior exposure. And as a result accurate testing is very important. We do continue to welcome all EUA submissions for serology tests both point-of-care and high volume central lab test development. We think both of these are going to be necessary to address the upcoming need in very high volumes.

Serology tests have been able to come to the market through different pathways. On our March 16 guidance either Pathway C or Pathway D. Many have come through the Pathway D where they notify the FDA that they have completed validation and then once there is a few exchanges to understand that everything is being addressed according to the guidance then those developers are - receive a confirmation message and are able to market in the US.

We've seen a huge number come into the US this way. There has been some concern about the accuracy of some of these tests. And so the FDA in collaboration with other agencies is standing up a volunteer - a voluntary interagency program to help address and verify error accuracy. Developers involuntarily participate in this program. They can send their point of care test kits and any instrumentation that might be needed to a central location. And we are putting together a panel of positive sera and plasma and negative

serum plasma in order to take a look at performance of these tests through an independent assessment.

If you are a developer and are interested in this program please send an email to our general EUA address. That is [cdrh-eua-templates](mailto:cdrh-eua-templates@fda.hhs.gov) with an S@fda.hhs.gov.

I am going to cover a few of the frequently asked questions in the past week. First I'm going to turn it over to Sara to cover a specific topic and then we'll open it up for questions and answers in an attempt to address your current needs under this emergency now and stimulate further development and further validation of tests and to address this emergency. So let me just pull up that.

All right, so there are general questions that we recently received having to do with what developers are required to do with regard to validating alternate supplies and reagents such as alternate viral transport medias, swabs or extraction reagents and instruments and PCR instruments. We do address this on our Frequently Asked page but we continue to get questions so I wanted to address this. So if you are a holder of an EUA authorization or have submitted an EUA and you're a laboratory you can simply do a bridging study with the alternate reagent or supply validate it to your standards into clear standards and then you can begin using that. You do not need to submit an amendment or an application to the FDA.

If you are using someone else's EUA authorized device you could do the same thing without submitting if you're a laboratory submit - and submit that you don't have to if you're a laboratory you don't need to submit anything to the FDA. However in both situations we would love to see the validation instrument validation data that you generated in order that it might be helpful

to others and with your position would like to add that alternate supplier reagent on to our Frequently Asked questions page. So it's not required to submit your data but we would love to see it. If you are a test manufacture and you have an alteration to your product yes that does require validation and it does require a submission to the FDA usually in the form of a supplement and we also work closely with you to address those additions as quickly as possible to make more options available.

Next set of questions that are recurring have to do with whether or not home collection is allowed and we have said that collection and/or home testing require a UA authorization. So if you are interested in this pathway please reach out to us at our general EUA address and we'll work with you to design the appropriate studies to ensure that home collection is safe and is accurate and that the shipping return to the laboratory is also considered and is validated so that we know that when the samples are returned to the laboratory accurate results are obtained and false negatives are avoided.

So we do welcome these. We do encourage these however we have stated that any EUA authorization is required. We are working with a number of developers now and hope to have some positive news in the near future with these amendments or these authorizations.

We generally get a number of questions about when you hear back after you have submitted your EUA. If you are allowed be on the market with your test and do not require an EUA authorization before you can test in the way that you want we are triaging those that need our immediate attention. You can always reach out to us through the general EUA address or to - if you're going to sign the reviewer to reach out to your reviewer to get an update about where you stand.

We continue to get questions about what states are authorized to review tests from that state. You can check our Frequently Asked Questions page for an update but currently as far as I know there are six states Connecticut, Maryland, Mississippi, Nevada New York and Washington State and then there is a question about whether validation should be sent to the state or to the FDA. Of course even if your state is willing to authorize tests within your state you are always welcome to submit an EUA application to the FDA. And then Sara that kind of sums up what I was going to say in prepared remarks. Do you want to anything at this time or should we move into Q&A?

Dr. Sara Brenner: Yes, thanks Tim. This is Sara. I was just going to make a few comments on, brief comments on folks that have reached out regarding 3-D printing and additive manufacturing approaches to help address supply chain issues. I wanted to quickly point out that FDA has recognized that many stakeholders are interested in designing and producing 3-D printer devices and other types of and devices that are made through other nontraditional manufacturing methods as well.

So what we have done to try to accept different input from the community is form a partnership under an MOU with the Department of Veterans Affairs innovation ecosystem and the NIH 3-D print exchange to share data and coordinate on open source medical products for the COVID-19 response. So these agencies were working with closely as well with American made supervise resources that will help connect healthcare providers and 3-D printing organizations.

So we already have an FDA Q&A that's available on our Web site for 3-D printed medical devices including PPE, decontamination and reuse of respirators information, optimizing respirator decontamination and so on and so forth. So I would point you to our Web site for additional information on

engaging us and our sister agencies on those efforts. Also on a related note we've been made aware that there is a growing number of institutions from academic sector including universities and academic medical centers who are interested in contributing personnel expertise, resources and other things at their disposal across the country to try to address both local and national shortages. So we've engaged in dialogue at this point with the AAMCA AAU and APLU with regards to how we can all work together collectively across the university system as well to help address emerging challenges. Thank you.

Dr. Timothy Stenzel: Thank you Sara. Irene and the operator we're ready to take questions.

Coordinator: Thank you. As a reminder please limit yourself to one question. Our first question comes from (Daniel Simpson). Your line is open.

(Daniel Simpson): Yes hi. Thank you for taking my questions. My question is regarding a manufacturer that chooses to do Policy C for EUA of a serology kit. And if they have initial validation data that may not be complete do you recommend doing pre-EUA conversations with that data to understand what additional data FDA is requiring?

Dr. Timothy Stenzel: Well if they think they have a complete application they can put in a submission using the - I guess we don't have a template but if you send - if they send in an email to our general EUA templates we do have a fact sheet that we can provide to them. But if you do think you have a complete submission you can make a submission to our - to the submission email and we will all take a look at it and if there's anything missing we can look at - we can reach out back out to the developer. On the other hand you'll also be able to do that through the pre-EUA. So whatever pathway you think is most efficient for you we'll work with you on that.

(Daniel Simpson): Okay thank you very much.

Coordinator: Thank you. Our next question comes from (Heather). Your line is open.

(Heather): Hi there. This is (Heather) from Clinical Reference Laboratory and you may have already answered this so my apologies. But I was curious if we are looking at alternate sample types I'm guessing that a bridging study will not suffice and we will just need to work closely with you to design an appropriate study?

Dr. Timothy Stenzel: Yes that's a great question. So for any sample type that we've already authorized so whether it be NP swab, mid-turbinate, mid-turbinate self-collected and then healthcare increment nasal swab or a self-collected nasal swab in the healthcare environment nasopharyngeal swab or sputum I believe that's a complete list of what we've authorized so far.

We have seen some data with regard to a tongue swab and there are interested parties in saliva. Some of these alternate samples may not perform as well as others so at this time yes we would like to engage on - with the developer on an alternate sample type if it's not one of the ones that we've already authorized. If we've already authorized that sample type and you simply want to say switch swabs that's something that you can perform your own bridging study if you're it LDT developer or if you're altering an EUA authorized test and you don't need to submit that to the FDA. Did that address your question?

(Heather): Yes perfectly. Thank you very much.

Dr. Timothy Stenzel: Okay, and of course if it's a home collection or a home testing if that's the kind of development work you do yes we also want to authorize those for the EUA platform in process.

(Heather): All right, thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Autumn). Your line is open.

(Autumn): Hi there, thank you. I had a question regarding research components available for the development of test. I understand that the March 2020 FDA guidance indicates that CLIA laboratories they need to utilize RUO components for development of their assays. But similarly does apply to manufacturers and specifically instruments? So with the wide availability and cost benefits of RUO instrumentation is it possible for kit manufacturers to develop kits for use with RUO instruments?

Dr. Timothy Stenzel: Well that's a great question. Yes laboratories are able to utilize RUO components in their lab developed tests as RR manufacturers. Now typically - oh the excuse me, I'm going to put you on mute and cough. I just had a little allergy there I think. Typically outside of an emergency situation we would require more work for and an RUO instrument however under the emergency authorization Program we will work with developers, manufacturers to validate those instruments as well for use with their assays. Does that address your question?

(Autumn): So to follow-up would manufacturers be able to develop a test and make available that test while issuing an EUA within 15 days or would the FDA preferred to engage with those manufacturers before EUA issuance?

Dr. Timothy Stenzel: They - that's a great question. Yes, they can follow Pathway C, complete their validation and then within 15 business days submit that application. And as long as everything looks good we're good.

(Autumn): That answers my question. Thank you very much.

Dr. Timothy Stenzel: I would add though that there may be challenges once the EUA might come to an end. I don't expect that the emergency declaration will end anytime soon. However there is a provision in the EUA statues and regs that allows for specific technologies once they come through for a full authorization, normal authorization whether that's usually their de novo first and a 510K that there is an option for that particular type of device to be removed from the emergency declaration and require full submission. So as developers are developing this they should keep that in mind with regard to research use instrumentation but there may be a limit beyond an emergency in which they could use that other than labs that validate RUOs. They are potential pathways, it's just that it's good to talk to the FDA about those pathways ahead of time and be prepared for them. Okay, next question.

Coordinator: Your next question comes from (James). Your line is open.

(James): Hello.

Dr. Timothy Stenzel: Hello.

(James): Hi. My question is whether serology tests on the testing for the - of the FDA guidance can be used in labs with moderate complexity all we were (certificate)? I understand that FDA's statement in the FAQ Web site that these tests have not been reviewed by FDA and therefore theoretically they are high complexity by default however most of the serology tests are

designed to be used in public care that are not high complexity. And it was probably not the intention of the guidance to limit the use of serology tests in high complexity labs because the guidance does state that serology tests are less complex than molecular tests. So that's my question.

Dr. Timothy Stenzel: Yes, that's a great question and it's a challenging question and a challenging answer. So under the EUA authorizations we are not making CLIA class CLIA classifications as far as high, moderate or waived. And also if we do not authorize through the EUA process a test we cannot deem something to be CLIA waived which is an alternate pathway under the EUA provision. So all tests are typically thought to be or assumed to be high complexity tests unless through the EUA authorization process we deem them as moderately complex or waived.

This deeming is only something that's allowed under regs and statutes for tests that are authorized by the FDA. And so certainly it was not our intention to limit the use of these serology rapid serology tests that are otherwise designed to be used in a point-of-care setting. However because of the limits that we have in law it is the opinion of CMS that these can be performed in high complexity labs.

If a developer wishes to come through a full EUA authorization process with their point-of-care test that is always a pathway open and at that point if the test is appropriate for a patient or a point-of-care setting we can deem that test to be that category and make that clear in the labeling and that then allows the device to be used in a near patient point-of-care setting.

We are looking at potential alternate pathways to achieve the same end. I mentioned that we have an interagency effort to verify performance of these tests. We may have a pathway open through that that we're looking at. And

we encourage all serology point-of-care developers to participate. It's a voluntary program but that would be most helpful I think to everyone. Hopefully I answered your question...

(James): Yes.

((Crosstalk))

Dr. Timothy Stenzel: ...but maybe not in the way that you wanted.

(James): It's okay thank you. Just one quick follow question is when - do you know when the template for EUA serology test can be available?

Dr. Timothy Stenzel: So you can send us an email request at our EUA CDRH EUA email and we can provide you with a document that lays out what we think is - are the studies that are recommended and the manner in which to do them.. We are working on a template and as soon as we can we will post that.

(James): Thank you.

Coordinator: Thank you. And as a reminder please limit yourself to one question. Our next question comes from (Jeff). Your line is open.

(Jeff): Hi. Yes, similar to the academics with resources that are looking to get plugged in I represent a group of roughly 150 lab technicians, lab IT people with both hospital lab and independent lab expertise. We're looking to get plugged in on a meaningful and voluntary basis. You know, we're now looking to sell you anything but we're just trying to get plugged in. You know, we can assist with test selection, test validations electronic reporting.

What's the best way to do that? I know you have the tool for academics to get involved. Is there a portal for those of us in industry that want to get involved?

Dr. Timothy Stenzel: Well we certainly welcome your - the opportunity to work with you and your great attitude to try to help on this. Sara do you want to address how to connect up with (Jeff)?

Dr. Sara Brenner: Yes, that's great. And thank you (Jeff) for volunteering this information. It might be most expedient if you would shoot me an email and we can pick up the conversation from there. Sara, S-A-R-A.brenner, B as in Blue, R-E-N-N-E-R@fda.hhs.gov.

(Jeff): Thank you.

((Crosstalk))

Coordinator: Thank you. Our next question comes from (Alice). Your line is open.

(Alice): Hi. Yes thank you. My question deals with the applicability of the tests that are currently available whether they be nasopharyngeal or serology testing about their applicability and validity on deceased patients since none of those kits have cateveric indications for use at this point?

Dr. Timothy Stenzel: That is correct. That is a question I'm going to take back and get prepared for. And (Alice) if you were to shoot us an email to our cdrh-eua-templates address we will answer you directly. and on the next call after we've been able to provide some advice and guidance we will respond more globally with an answer to that.

So it's a great question. I know we've authorized an Ebola test for such a situation but to my knowledge we have not specifically authorized that. If you're a lab that is using an EUA authorized device, you're and LDT lab you have the ability to validate that through some sort of bridging study or whatever validation that you think is worthy of that and no FDA submission is required for that particular application.

(Alice): Okay, thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Scott). Your line is open.

(Scott): Thank you. My question's already been answered.

Coordinator: Thank you. Our next question comes from (Jackie). Your line is open.

(Jackie): Hello? Is this...

Dr. Timothy Stenzel: Hi (Jackie).

(Jackie): Oh hi. Thank you. I work for ET healthcare and our product is a fast high-volume test that actually gives us (unintelligible) readout. We got the notification clearance under Pathway D but we would like to submit an EUA is a quantitative test. And if the EUA proficient under Policy D does not allow the serology test is a quantitative test do we have to just submit a five 10K to be a quantitative test on a COVID assay?

Dr. Timothy Stenzel: You're measuring IgG IgM quantitatively?

(Jackie): Yes.

Dr. Timothy Stenzel: Okay. And...

(Jackie): I - excuse me, sorry.

Dr. Timothy Stenzel: Oh that's okay. I'm - I think that is something that we can authorize if you want to submit something. That is - whether that's covered under that particular Pathway D I would want to double check for sure. So if you were to send an email to our cdrh-eua-templates address and ask that specific question I'd like to verify.

(Jackie): Okay.

Dr. Timothy Stenzel: And then once again once we've been able to address your specific question we can make that more broadly, that information more broadly available through one of our town hall meetings.

(Jackie): Okay, I asked that question and the answer was that FDA is not reviewing any quantitative tests at the moment.

Dr. Timothy Stenzel: Okay. Well ask them to contact - go back to that email address and asked them to bring me involved okay Timothy Stenzel. Ask them to involve me okay?

(Jackie): Oh, thank you so much Dr. Timothy Stenzel. Thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. As a reminder if you'd like to ask a question please press Star. If your question's already been asked and you'd like to remove yourself press Star 2. Our next question comes from (David). Your line is open.

David Grenache: Hi. Thank you. This is David Grenache out in TriCore Reference Labs at Albuquerque. FDA requests that antibody class specificity studies for serological testing performed. Are laboratories that are validating commercially available tests expected to do that or is that an expectation of the manufacturer? And I ask because some manufacturers have indicated they have not done that.

Dr. Timothy Stenzel: Yes. That is part of our guidance to manufacturers. And I am not necessarily up to speed on what our guidance is to say an LDT. And I would want to give you a very direct and transparent and clear answer to that David. Could you send an email to our EUA address and ask for me to be involved in answering that question and we'll get back to you really, really quickly.

David Grenache: Absolutely, thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Nikki). Your line is open.

(Nikki): Good afternoon. We're representing some companies from a foreign manufacturer. And - or so different kits. Each of them have notified per Policy C, but they are not - obviously they don't have the EUA issued yet but there is - they have notified that they want to distribute and they're not showing up on the section of the Web page that shows the companies that have intended to distribute. So I'm wondering I just want to be sure that I'm understanding correctly that once someone notifies per Policy C notifies FDA of an intent to

distribute while they're preparing the EUA or while the EUA's being reviewed that it should show up under the FAQ page. Is that correct?

Dr. Timothy Stenzel: And this is a serology test or serology tests?

(Nikki): No it's a PRC test (unintelligible) test.

Dr. Timothy Stenzel: I'm sorry

(Nikki): I'm sorry it's the diagnostic test the...

Dr. Timothy Stenzel: Is it a molecular test?

(Nikki): Yes, sorry yes.

Dr. Timothy Stenzel: Yes. I don't know that we're posting those. And I forget. Let me pull up the FAQ page right now. We probably are. And I'm - I know that we're tracking them internally but I just do not remember...

(Nikki): Yes it's under the question that says what commercial manufacturing or distributing test kits under the policy outlined in Section 4C of the policy for diagnostic tests...

Dr. Timothy Stenzel: Yes, yes.

(Nikki): ...for coronavirus disease.

Dr. Timothy Stenzel: Yes, and we're listing those. So if we have not listed them yet please ping us at the EUA template and ask for them to be listed.

(Nikki): Okay, thank you.

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

(Peggy): Hello. Yes my question is regard - in regard to home use serology test. As you noted Timothy, they are not - there are no home use serology tests that have received an EUA. And my question is can states override that because I have heard of a company in New York creating test kits that then gets shipped across the country and then shipped back to them to do the testing but the collection is done at home. Is that allowed?

Dr. Timothy Stenzel: So that is also a great question. It has not been to our knowledge something that the states are doing. And I was not aware that New York was doing that. We of course are working with states who are able to authorize tests and we will reach out to New York about that. But we would ask that developers of home use test that they reach out to the FDA. And then if there's something that a state may be willing to do we can interact with that state to make a decision.

(Peggy): Okay thank you.

((Crosstalk))

Dr. Timothy Stenzel: (Unintelligible) halfway.

Coordinator: Thank you. Our next question comes from (Frank). Your line is open.

(Frank): Hi, thank you. Just as a follow-up on the serology question regarding CLIA complexity. We have a lot of people telling us kits are being distributed with the understanding that these are moderately complex that actually waived tests

when we know that there's only one test that's been approved and that is only approved for moderate use. Is there going to be any type of notification to alert that at least the doctors' offices that these kits are not being used in the proper settings?

Dr. Timothy Stenzel: Okay, we've point out some notifications already. I am not aware that we have said that they are currently high complexity. And so I will check into that and if we can we'll make that more public. It is on our FAQ page though already.

(Frank): Well and the FAQ page has on one, question one says that the test is waived and on the second question it says that it's high complexity. So a lot of people I think are getting confused because they look at the one answer and then they don't go any further to look into it.

Dr. Timothy Stenzel: I agree. We'll try to resolve the confusion on that Web site.

(Frank): It is a possible can we use third party approvals, a third-party review to review a submission for a serology test?

(Frank): Wow that is a fantastic question. That's the first time I've gotten that question. I do not know if we're using third parties for EUA. We - I will address that. I will look into that question on my next quick address which I have about three or four of a week now.

(Frank): Great, thank you.

Dr. Timothy Stenzel: I will include that in many of them and if we can update our Web site we'll do that okay. Well alternatively you can also go to the email address and

ask that specifically you get that specifically address but that's a great question.

(Frank): I'll do that. Thank you.

Coordinator: From (Abby), your line is open.

(Abby): Hello.

Dr. Timothy Stenzel: Hi.

(Abby): I was just curious I noticed that on the Frequently Asked Questions page the FDA is now recommending phosphate buffered saline pacifically over normal saline. Do you have data or bridging studies to show its superiority and if so do you have a specific formulation of PBS that you're recommending?

Dr. Timothy Stenzel: I think we provided a couple vendors with a PBS and/or an equivalent if I'm correct. Normal saline will work it's just that our thoughts are that if a buffered saline could be used that that is probably preferable but normal saline is still allowed.

(Abby): Okay, we did have - we're a manufacturer and we had some of our customers say that their saline studies weren't as efficient as their PBSF. So I did know if you had a recommended formulation. But I'll look at those ones that you have listed.

Dr. Timothy Stenzel: Okay.

(Abby): Okay, thank you.

Dr. Timothy Stenzel: Thank you.

Coordinator: Thank you. Our next question comes from (Margot). Your line is open.

(Margot Enright): Hi. This is (Margot Enright) PTS diagnostics. In my question is if two subsidiaries of the same larger company, two smaller subsidiary desire to market the same or similar test do both of them need to file an EUA followed-up by the 510K or just one of them file it?

Dr. Timothy Stenzel: Well is at the same test or different?

(Margot Enright): It's one is manufactured outside the US and the other will be manufactured in the US. So there's different manufacturing sites and the raw materials may come from different sources.

Dr. Timothy Stenzel: Can - oh that's interesting. I'm not aware of listing two manufacturers. That's best addressed to our templates email address to be certain. I don't see necessarily issues. We would again, you're going to seek EUA authorization for these?

(Margot Enright): Yes, one of them is already - one of the subsidiaries has already filed and...

Dr. Timothy Stenzel: Okay.

(Margot Enright): ...our subsidiary has not filed. And our question was since typically you can only have one 510K on the same product is at the same as for an EUA or is the - does the difference in the manufacturing site being US and having different source of raw materials does that make it a different product and should we file our own EUA?

Dr. Timothy Stenzel: You know, I don't know the best answer to that. I mean I would think that there would be easy routes to go through if it's the same design manufactured in separate places. It actually may just be a paper question of who's the legal manufacturer. If it needs to be two different EUA's the one entity can refer to the data in the first entity's package and basically submit a shell is what I'm thinking. But I would want to confirm all of that with our staff.

(Margot Enright): Okay thank you.

Dr. Timothy Stenzel: You're welcome.

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

(Brandt): Hi. First I want to thank the people who man the 24/7 helpline. They are uniformly helpful and patient and great. I want to go back to follow-up on (Frank)'s questions about serology tests. Just to be perfectly clear if we look at the (Selex) EUA and now apply this statement to all of those under the notification arm it says testing is limited to the laboratory certified under CLIA. So is it fair to say that if you're in the notification arm and you have a test kit it can only be used in laboratories, that a physician cannot get the blood and do the test and interpret the test for the patient unless the physician is in a laboratory or associated with the laboratory certified as moderate or high complexity?

And in another part I was informed that -- and I just want to verify -- capillary blood finger sticks are not allowed. And is that put anywhere in big bold type you cannot use finger sticks? Thank you.

Dr. Timothy Stenzel: Okay, well regarding the single EUA authorization for serology that we've granted that was designated by us as suitable for a moderate or high

complexity environment but not a CLIA waived environment so we did not deem it as waived. It's my understanding the CMS requires a certificate no matter where the testing is performed even if it is a CLIA waived test there must be a certificate of CLIA waiver in order for the test to be performed even a CLIA waived designated test to be performed in that setting. And so that is coming, that's our understanding what CMS opinion is on this. I would refer any questions to them though on this.

As far as capillary, so going back to the notification path for serology test that could potentially be used in point of care and could potentially have capillary. It is because we again because we have not authorize these under an EUA we cannot deem them as CLIA's and therefore they revert to high complexity tests. And as far as the use of capillary is concerned capillary or finger stick blood as long as tests are validated and for capillary they could be used even in a high complexity type environment.

A high complexity lab could set up a finger stick station to be able to do these tests under their high complexity certificate. Again these test should be validated for capillary. If a developer wants to have a point-of-care test for serology or another test - well it would be serology here. We utilize a finger stick. That's an acceptable sample type as long as it's been validated and then be used in that CLIA waived environment and we authorize it, we review the data and we are able presumably we're able to deem it as a CLIA waived test. So hopefully that address your question.

(Brandt): Thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Kevin). Your line is open.

Dr. Timothy Stenzel: Hey (Kevin).

(Kevin): I'm with a kit packing company called PAP Tech. And as you know there's a shortage of UTM around the country. I'm just wondering what is the FDA's stance on bringing in UTM from a foreign manufacturer that may not be listed or registered. Is there any kind of fast track process that we could get this authorized to bring it in?

Dr. Timothy Stenzel: That is a great question. If you have a vendor in mind and you want to have us make this determination if you send in that to our EUA templates address we will route that to the team that is working on alternate ETM sources. And also they aid in importation of such and they can address this question specifically.

(Kevin): Okay thank you so much.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Next question comes from (Ethan). Your line is open.

(Ethan): Yes, it's a follow-up question from a previous caller. So my question is if we use the serology test at an appropriate site - I'm out here in California working with the local public health trying to expand increasing our ability to have more testing sites. Will we be able to use telehealth for the physician consult given that the serology tests are least for the ones that are not EUA are approved to be used for diagnosis? You know, I'm just kind of concerned how we can kind of increase our resources and also limit exposure?

Dr. Timothy Stenzel: So we have not yet authorize the serology test as a sole basis of diagnosis.

There are scientific challenges with that although if a developer wants to pursue that we will certainly engage in conversation. But obviously before antibodies are developed to SARS CV-2 the patient can be infected and that also antibody tend - antibodies tend to persist for long after an infection. And so they can be antibody positive but be completely cleared of the virus.

As far as telehealth or alternate sites or home use if something is within - is deemed as CLIA waived because it has been authorized by the FDA and it can be used therefore in a CLIA waived setting it that setting is going to be staffed by health care folks who are able to perform that testing. Usually telehealth would be used in more of the home situation and those as we stated before require EUA authorization for a home-based test. We are very open to a home-based serology test. The important factors are, you know, how easy for this a patient, untrained patient to perform the testing? How easy is it to them to read the test results and how easy is it for them to interpret those results?

Now for a typical rapid serology test there's questions in each of those places and also we do look at safety. But we are very open to telehealth especially with a video link to assist patients in performing a serology test at home, reading the results of the serology test and then also interpreting the results for what it means. Hopefully that addresses your question.

(Ethan): Thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Mehti). Your line is open.

(Mehti): Yes hi. Firstly, thanks for your time, your efforts and all the great info you're providing. This is really useful. If I heard it correctly you mentioned that you're porting a panel of positive and negative plasma together. Is there something that the serology assay developers are going to have access to or this is for FDA to try the kits that developers are submitting?

Dr. Timothy Stenzel: So this is an interagency program involving multiple agencies. We are collaborating on this. The first priority is to be able to collect enough of these samples to be able to test at a central lab various tests that can be sent to this facility. If you're willing to participate you can email us at their EUA templates address and volunteer to be a part of that. We are hoping that there will be enough remaining plasma and/or sera to develop panels that we could send to developers. So at this point it's probably best to stay tuned. If there is such panels that can be shipped to developers we will make that publicly known.

(Mehti): Right, thank you.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our next question comes from (Marcos). Your line is open.

(Marcos Lopez): Hi. My name is (Marcos Lopez). My question is about the serology test specifically the ones that are just going through the notification step. The thing is I'm representing a couple of clinical labs and I don't know if you guys are aware but here in Puerto Rico we have noticed that a whole bunch of different distributors not even related to the medical field are bringing a whole bunch of the serology test. And since we have a really big shortage of the molecular testing now we have a whole bunch of companies selling different serology tests.

Thing is that my question is we know that we have a whole bunch of companies that have been selling kits in Puerto Rico since the beginning of March. However what we are - the situation that we have is that if those companies have not been notified to FDA by that time since and the clinical labs already have this testing and they were issuing reports and things like that to people and we even have some positive patients do we need to go to those patients again and tell them, "Hey, your report isn't invalid because probably this company has, you know, did not notify FDA and it was not - the company was not allowed to commercialize the kit by that date?" And I mean the follow-up will be can you tell us the exact date that each of the companies were notified or okay to commercialize the serological test through this route in the Web site or something? Hello?

Dr. Sara Brenner: Hello? Tim, are you there?

(Marcos Lopez): Tim?

Dr. Sara Brenner: Operator are you there?

Coordinator: Excuse me this is the operator.

((Crosstalk))

Coordinator: It looks like his line is disconnected. I will give him a call back moment please.

Dr. Sara Brenner: Thank you.

(Marcos Lopez): Okay.

Dr. Sara Brenner: This is Sara. I can pick up for a minute until Tim is able to rejoin us. So that is an excellent question and a very challenging couple of questions and we're working as quickly as we can with our partner agencies to try to figure out how to assist with essentially figuring out which serology test will be best for folks and with the realization that many have already been rolled out.

(Marcos Lopez): Yes, but the thing is what we really want to do I mean we already issue a whole bunch of reports.

Dr. Sara Brenner: Yes.

(Marcos Lopez): But what we really want to know is that, you know, we know that some of the companies because now there is a big situation in Puerto Rico going on about companies that were not related to (unintelligible) that were bring in this test to Puerto Rico.

Dr. Sara Brenner: Yes.

(Marcos Lopez): And we know or we suspect that probably some of this test are were brought into Puerto Rico and they were not tests that are already from - or companies that already notify FDA by the date we were - they were purchased by clinical labs. So the question will be, you know, can we get in the Web site that they - that this company were okay to start commercializing the test in the US? And the second will be should we - I mean if we check that the company the kit was sold before the notification okay that will be like an illegal thing probably not related to the company manufacturing the kit but for to - these other people that are...

Dr. Timothy Stenzel: This is Tim. I'm back on. Can you hear me?

(Marcos Lopez): Yes.

Dr. Sara Brenner: Yes, we can hear you Tim. So there...

((Crosstalk))

Dr. Sara Brenner: ...was a question and a related question on serology tests that rolled out in Puerto Rico starting in early March that had not notified the FDA.

Dr. Timothy Stenzel: Yes.

Dr. Sara Brenner: So how to handle those results that...

Dr. Timothy Stenzel: Yes.

Dr. Sara Brenner: ...have already been reported to patients?

Dr. Timothy Stenzel: Yes, that's an off-line question I think. So if you send an email to cdrh-eua-template at...

(Marcos Lopez): Okay.

Dr. Timothy Stenzel: ...fda.hhs.gov with that question and ask that, I or Sara be involved will work with you to resolve that issue okay?

(Marcos Lopez): Thank you. Thank you, appreciate it.

Dr. Timothy Stenzel: You're welcome.

Coordinator: Thank you. Our last question comes from (James). Your line is open.

(James): Yes hi. I have a question also on serology Pathway D looking at the opportunity to set up a US-based production facility. And I noticed in the - one of the recent approved EUAs that the GNPs were waived. And I was wondering if there was further clarification on what that meant or will there be further guidance issued on that?

Dr. Timothy Stenzel: Yes, so under an EUA to waive any of the GNP requirements. One important element that must be retained is that you have a complaint handling system and adverse reporting, adverse event reporting so that your monitoring the performance of your tests on the market and if there are issues and you're required to report from the FDA that you do report in a timely way to the FDA.

If you look at any of the decision statements on our FDA Authorization Page you will see what provisions are waived. I don't have them off the top of my head but if you look at those you will see what provision of GNP and CFRs are waived in an emergency situation. And if that doesn't address your question well enough you can come back to our EUA templates address and we'll answer any further questions.

(James): Thank you. I also was wondering if you guys have sources for bulk COVID-19 protein antigen for the serology test? Is that an effort being pursued by government agencies with a private partnership?

Dr. Timothy Stenzel: So I know that we are trying to obtain some of those for our own internal interagency work but at this time we don't have plans to distribute that. Those are usually proprietary. I know that there is at least one entity out there that is publicly announced that they are willing to transfer their serology tests to

others so you can certainly look at those public announcements and reach out to them.

(James): Thank you.

Dr. Timothy Stenzel: And if you - and I don't want to publicly state their names just because I want to be fair to everybody so okay?

(James): All right.

Dr. Timothy Stenzel: All right.

Coordinator: Thank you. That was our last question. Irene I'll pass it back to you.

Irene Aihie: Thank you. This is Irene Aihie and we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Monday, April 13. If you have additional questions about today's presentation please email cdrh-edu-templates@fda.hhs.gov.

As always we appreciate your feedback. Following the conclusion of today's presentation please complete a short 13 question survey about your FDA CDRH Virtual Town Hall experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live discussion. Again thank you for participating in this concludes today's discussion.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

END