

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

**Moderator: Kemba Ford
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Coordinator: Welcome and thank you for standing by. I'd like to inform all participants that today's call is being recorded. If you have any objections you may disconnect at this time. You have been placed in listen-only mode until the question-and-answer session of today's call. At that time if you would like to ask a question, please press star 1. And please make sure that your phone is unmuted, and record your name clearly when prompted, so I may announce you for your question. Thank you. And I would now like to turn the call over to your host, Ms. Kemba Ford. Thank you, ma'am. You may begin.

Kemba Ford: Thank you, Missy. Hello, I am Kemba Ford of CDRH's Office of Communication and Education. Welcome to the FDA's 13th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during this public health emergency.

Today, Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health, and the Office of Product Evaluation and Quality, and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, all from CDRH, will provide a brief update.

Following opening remarks, we will open the line for your questions related to today's discussion. Please remember that we are not able to respond to questions about specific submissions that may be under review. I would now turn the call over to Timothy.

Timothy Stenzel: Hello everyone and thanks for joining us again. And I appreciate what everybody is doing to help in this current emergency. And we are going to do our best to address your questions today, and going forward, as well, as we have in the past.

So there are a number of updates that both I and Toby Lowe will make today. You're probably aware that we made updates to the molecular EUA template, to include information about recommendations for validation of asymptomatic testing. If that is a claim that you want to make about your tests or assay. As well as for pooling. And that's pooling samples so that you might test more samples with given reagents.

So obviously we're interested that accurate testing still occurs in those situations. And we do want to make it clear that EUAs are required for pooling and authorizations. And they are also required if you want to make a claim about the ability of your test or assay to detect asymptomatic viral positive patients. And obviously this applies mainly to molecular tests. But it could apply to direct antigen tests as well.

Second, all that, if you are in a lab that's running a commercial test that's been authorized, and want to add either asymptomatic or pooling, you can work with the commercial test manufacturer. We are encouraging, obviously, those kit manufacturers to submit a EUA Amendment for these. If we can facilitate you working with the commercial manufacturer to add these additional

claims, we will do our part to do that.

You can submit your own EUA if the manufacturer gives you Right of Reference to do so. It's just a simple, brief memo that says the agency can refer to data the manufacturer has filed when they review your validation data for pooling or asymptomatic.

It has been our experience that most, if not all, manufacturers are very open to doing this for their customers. But we can't make that 100% assuring.

Next, you may have seen press that we have revoked the Chembio Serology test. As we have worked with Serology developers in this emergency and pandemic, we have gained additional knowledge. We have raised the bar on the expectation for Serology performance. And Chembio unfortunately, was no longer able to meet that bar in subsequent evaluation. And so we have moved to revoke their authorization.

As with all tests that have been removed from the notification list, the majority of those are, of course, if you've looked at that, are Serology tests. If you have inventory, we recommend that you reach out to the FDA if you are not interested in discarding that material. And if, of course, the developer hasn't asked you to do that.

So we're working with all developers to appropriately triage inventory that may still be in the field. But if you feel like you've validated that and it's performing well in your hand, I've had that question before. Let's have a one-on-one dialogue. So you can reach out to our EUA Template email address.

Next is that if you're a developer and you're having trouble getting clinical specimens to do your validation work, I'd like to refer you to our FAQ page

where there's information about validation material. More and more vendors are able to provide validation material for you. You can also look at our list of EUA authorized LDTs, and consider reaching out to any of those labs to see if they are able to provide any remnants of leftover specimens for your validation work.

In this pandemic and emergency I've seen, you know, lots of folks pool resources. Get together and help one another. And that's - and we're so appreciative of that. And of course, any sort of IRB requirements should be followed and adhered to in that situation.

Finally, for my talking points, before I turn it over to Toby, and before we open it up for questions, we have seen unprecedented volumes of submissions. Our Expert Team is working very hard, long days. We want all -- and this is at my direction within the office -- we want EUA submissions. This doesn't apply to pre-EUAs necessarily. But to EUA submissions where the application is complete, all data is there, and it's ready for us to review it.

I want a directive that all EUA submissions should be assigned a contact within our office within two weeks of receipt. Now I've heard some, at least one-offs, where this hasn't happened. And we're going to correct that. And as part of that correction, if you're in that situation I'd like you to reach out through our EUA Template email address, to me, Timothy Stenzel.

Just ask to have that email directed to me. And I will be ensuring personally, that you get assigned a contact within our office, that you can ask about status and get updates on a regular basis.

So again, I'm going to step up and do that, to make sure that all are going assignments within two weeks. For those that received that, and send an

email, I'll be working to get those caught up as soon as possible. And I will work on that, as fast and as soon as possible. So with that, I will turn it over to Toby for her opening remarks.

Toby Lowe: Thanks, Tim. Hi everyone. Thanks for joining us today. I just wanted to give a quick update. As many of you may have noticed, our EUA page has been restructured. While this may be a little bit shocking at first, we hope that the restructuring will ultimately make it easier to find what you're looking for.

Previously on the Device EUA page, all device EUAs were on the same Web page which may have made it difficult to find what you were looking for. And specifically to find the IVD section. And all of the tests were grouped together in a single table.

So this restructuring has created a standalone COVID-19 EUA Medical Device page with separate pages for each device type. So IVD EUAs now have their own page. If you had bookmarked the direct link to the IVD section of the EUA page previously, that should redirect you to the new IVD page.

[Post meeting clarification: the old link to the IVD section does not redirect to the new page. The link to the new COVID-19 IVD EUA page is:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>]

And then on the IVD page, now the EUAs are broken out into separate tables so that it will be easier to distinguish between authorizations for molecular tests, antigen tests, Serology, and so on.

So we hope that this will make things more streamlined and easier to find what you're looking for. If you have trouble with the page or if you notice anything that looks not correct, please reach out - you can reach out to me

directly, or you can reach out through the EUA mailbox. And they'll get that over to me. And we absolutely want to correct anything that we may not have gotten quite right with this restructuring. And (unintelligible), if you have any feedback also on things that might be helpful, we'd love to hear that.

And then another update is we just this morning posted a new FAQ on laboratory reporting requirements. This ties to the HHS guidance that was posted a couple of weeks ago, that I think we mentioned last week on the town hall regarding laboratory data reporting requirements. Set up a new FAQ that points over to the HHS Web page - or the HHS announcement, rather.

And then as Tim mentioned, with the new templates that were posted yesterday that included information on asymptomatic testing and pooling, we also updated the FAQ page with new questions regarding that. So there are three new questions. Actually, one updated question and two new ones, regarding asymptomatic testing and surveillance testing.

So we hope that those are helpful for you as well. And that's all I have today. We can open it up for questions now.

Coordinator: Yes, ma'am it is now time for the question and answer session of today's call. If you would like to ask a question, please press star 1. Please make sure that your phone is unmuted and record your name clearly when prompted. First question comes from Shannon Clark. Your line is open.

Shannon Clark: Hello, hello this is Shannon Clark. Can you hear me?

Toby Lowe: Yes, we can.

Timothy Stenzel: Yes, we can. Hi Shannon.

Shannon Clark: Yes, this Shannon with UserWise Consulting. We're experts in human factors and usability testing. So we've been doing a whole bunch of home use, usability validation testing. And my question for you is about the FDA's perception of (unintelligible) related to reporting of data.

So say you have this serological test kit, will you prove that it's extremely safe to be used at the home. But does the FDA still have kind of hang ups related to making sure that those results get reported? And would you require some sort of home use platform to ensure reportability any infection?

Timothy Stenzel: Yes, that is the ask in this emergency is that positive results and (unintelligible) negative results get reported. So we are open to how that can be accomplished. And we realize that in the home, in a non-healthcare or other non-healthcare facility situation where there is not a direct role of a clinician for a healthcare worker in seeing the test results and interpreting them. That there is going to be a challenge in meeting that important element.

But we are open to various ways of doing that. And willing to work with developers on how that gets accomplished. Toby, did you have anything to add?

Shannon Clark: Are you open to relying on layperson to report, or is that out of the question?

Timothy Stenzel: No, I think there are possible ways of doing that. We would like to see a proposal on how that might be accomplished. And like I said, we're open to various ways of doing that. But we can't ignore that important element.

Toby Lowe: Right. And I would encourage you to take a look at the HHS guidance on reporting that was published. Because that does actually have a little bit of

information about tests that are performed entirely in the home.

Shannon Clark: Perfect. Thanks so much.

Coordinator: Thank you. And I forgot to mention, please also limit yourself to one question. Thank you. Next question comes Paul Barto. Your line is open.

Paul Barto: Yes, good afternoon every. This is Paul Barto calling in from McKesson. I'm interested to know, you had announced that there was a consortium between the NIH, CDC, and others, in the initial round of results from the analysis of multiple products that had been sent in, was released a month or so ago. I'm curious to know when the second round or just the next wave results will be released to the public.

Timothy Stenzel: So this is the NCI testing for serology tests?

Paul Barto: Yes, thank you. That is - you are correct.

Timothy Stenzel: So as soon after we make a regulatory decision, whether that is in favor, or whether that is a denial, we will make that information and final report available as soon as it passes our QC checks to make sure that it's absolutely - cross all our Ts and dot all our Is. So that's an ongoing basis. We don't handle that in tranches. So those are updated as they become available.

Paul Barto: Understood. Thank you.

Timothy Stenzel: I would also say that most developers are within a few days of those tests now being finalized. But they'll receive those results, so you can always talk to the test developers, as well.

Paul Barto: Okay, thank you.

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

(Sean McHugh): Good afternoon. (Sean McHugh) calling on behalf of (McHugh) and Son Holding Company. One question, two parts. My first question was, I was asking if you guys could clarify the approval process? As if it's first-come, first-serve.

And then piggybacking off that, you guys being on the front lines of everything, I was wondering if you guys had an idea or vision of what the best practices would be when wide-scale testing would be rolled out, i.e., like dental offices or at-home testing.

And I just wanted to leave it with, thank you guys for your commitment to stopping the spread here of this novel Coronavirus. Thank you.

Timothy Stenzel: And you're welcome. I'll take the second question first. So we were very interested in authorizing a point of care test and a home-use test. The home-use test, the other settings other than healthcare that situations would also apply. So it could be schools, it could be, you know, places of employment, shopping centers, whatever.

They all fit within what we call the home bucket, because a healthcare worker, potentially based on the authorization, may not be directly involved.

And then, yes again, point of care. So - and it bears upon your first question. So we have a priority now because we have so many applications. And also because we have the notification pathways. So users can - or developers can notify us of viral detections and serology tests. Can notify us that they've

finished their validation. And can then go ahead and distribute or offer the test. And they have a time limit to get the EUA application into us.

And unless we say stop, during that EUA review process, they can continue to market and perform testing. As long as all the other guidance is followed.

So because of that, it allows us to focus on those applications that are deemed to be of the greatest public health importance. Currently, those are point-of-care tests. And I would say it's challenging for us. There are so many people interested in - developers interested in having a point-of-care claim.

What I've directed the office to do is, if there is data to review for a point-of-care, whether it's complete or it's on a rolling basis where we're seeing data. That we make data review of point-of-care tests, the priority.

If someone - now with the home collection and other areas, we have given some guidance on point-of-care testing studies. So that information should be out there and developers should know what to do. So what we're really triaging here is that when we have data to review pertaining to a high priority such as point-of-care, that we receive that.

However, if there is no directly linked point-of-care data like if it's a serology and it's going to be a finger stick, we don't have finger stick, and we don't flex studies. If we don't have the user studies. If we don't have any of that sort of point-of-care related data, that application, unfortunately, cannot be triaged to the high priority bucket right now.

We still want to be responsive as fast as we can on questions and things like that. As far as the review goes of the data, and (unintelligible) that relative to that. You know, if it's a - you know, if the data is basically for a serology test

that's a moderately complex, non-complex environment, for something that might otherwise be point-of-care, it is prioritized into that sort of priority. Which is lower than the point-of-care, up to authorized point-of-care devices. The other - and that was for molecular. Obviously for antigen, as well, the point-of-care.

The other high priority bucket is those tests that are automated in the high throughput. And that should be relatively straightforward to explain. As those testing platforms that can generate a lot of test results in a short amount of time, allows us to expand the testing capability.

And so those tests can also, and its potential performance issues that might be seen with those platforms, they are allowed to get into the market via the notification pathway. But they can have a greater impact as well, obviously.

So those are going to be a higher priority. Again, if it's a full submission - all the data is there, it's a high priority. If they're submitting data prior to their full EUA submission, we also ask - have also directed our reviewers to provide feedback on the validation data on a rolling basis.

However, we get you know, someone comes in because we want to actually (unintelligible) platform. We want to get feedback on the - any required feedback on how to develop that assay. But really, the point where something gets triaged into a higher priority bucket is going to have data to review.

And then let's see, are there other categories? Yes, the final category is anything that requires EUA authorization and can't be on the market otherwise until they get EUA authorized. So that would be, home collection, home testing, and now we would add pooling.

We do allow EUA authorized assays to - of there's no specific limitation. As far as testing of asymptomatic populations, that as long as there is a healthcare order, that we are asking labs to go ahead and test those samples and report out the results.

So we feel like at least for the time being, asymptomatic testing is allowed. And we're working - we'll work as fast as we can on those that wish to make the claim, that their tests can be utilized for asymptomatic categories.

So that does leave a larger number of applications that are not prioritized. And again, as long as they can be on the market and we don't any concerns about our initial review of that package. About it staying on the market, then we feel like we're prioritizing our resources for the interest of public health.

And we will get to those applications as soon as possible. I would say that all things being equal, which they aren't usually. (Unintelligible) is not usually in this pandemic. We could -- and I've directed the office -- if all things being equal, that first come first served is what I want for the office to do.

And however, it may be that an application needs some work before it can be finally reviewed. And as we're waiting for additional comments, someone that might have come in later, if it's a complete package, one that we can make a decision on, that may be prioritized over the other. Because if it's ready to be authorized, we don't want to delay on that. And with that, I will turn it over to Toby for anything that you might want to add, Toby.

Toby Lowe: Thanks, Tim. I think you covered that very well. So I don't think I have anything to add at this point.

Timothy Stenzel: Okay, thank you. Next question?

Coordinator: Yes, sir. Next question comes from Lonnie. Your line is open.

Lonnie Adelman: Hi, Lonnie Adelman from iAssay. We don't have a EUA with a shared provider yet, for our reader, it seems to be working pretty well.

My question is if we could supply a leader in an environment other than the high complexity, and we also can show that we can do a finger stick accurately in an environment like assisted living or maybe home or return to work, is that possibly a mechanism for reducing the need for a high complexity lab use for serology?

Timothy Stenzel: So that's a great question. Is your device something that would still be something your reader that would, you know, be utilized within a healthcare facility? Or would it be potential home use?

Lonnie Adelman: It could be used anywhere. We also have a link to the Cloud, so all the data is stored up there for review anywhere in the portal. So it's really a universal solution.

Timothy Stenzel: So we are very open to anything that can reduce risk or mitigate risk, and improve the safety profile, reduce the risk profile, and aid the labs, healthcare workers, and consumer, or patients at home in non-healthcare settings to be able to get an (unintelligible) at all.

Is your reader, just to give you, while you're on the call, specific feedback, something that would be amenable maybe to a lateral flow strip? Is it a strip use?

Lonnie Adelman: Yes. Yes, it's right now focused on strips.

Timothy Stenzel: Okay. So obviously the majority of strip assays, if not all, are in the serology category right now. So we've authorized some. Those that are authorized are on our Web site. We have not authorized the point-of-care serology test. And this could help them achieve that.

And then also there's the notification list of a serology test. So you could certainly - those are all public. And so you can reach out to those firms and offer your device as a potential work collaborative, working together relationship.

The required studies for point-of-care of home use would still be required, even if there is a device involved. So those studies are still, you know, usability studies, accuracy studies, and the flex study would all be in accordance.

But as you heard a previous caller, if you go outside of the healthcare setting, and you want to be able to make a result available to public health authorities, it sounds like your technology could aid in that. So we're supportive of that. You know you can use the list on our FDA Web site as one to reach out to developers directly. Okay.

Lonnie Adelman: And who would I engage at the FDA? How do I send in an official request or something to let them know what we're doing, and see if we can help reduce the requirement for the high complexity lab use for serology?

Timothy Stenzel: Yes, so it's hard to - technology in the absence of a test, right? So we don't know if you're going to (unintelligible) test unless it comes in with the test. So we would ask you to link up with one or more test developers and gather...

Man: Okay.

Timothy Stenzel: ...together for (unintelligible) with information about your device in conjunction with their (unintelligible).

Man: So what do we do with before we submit all the data just start engaging with the FDA and say this is what we're planning on doing or do we do that as part of the application to be the reader along with their script?

Timothy Stenzel: So if you're talking about generating data for a specific app (unintelligible) reader; is that what you're saying?

Man: Yes - no, what I'm asking is do we contact the FDA together in advance and let them know what we're planning on doing so that the FDA is ready to receive all the data corroborating the accuracy and precision along with our reader and their script? Should we let them know we're planning on doing that first so that the gears are moving and then we send in the (unintelligible) with all the data or do we have to start...

Timothy Stenzel: I would ask that you follow the sequence of events that you identify at least one test developer who will work with you and at that point...

Man: Yes.

Timothy Stenzel: ...once you identify somebody and then come in together with any questions you have with any data you're gathering.

Man: All right. Thank you very much. I really appreciate the extra time. Thanks.

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

(Brant): Hello? Hello?

Timothy Stenzel: Hi. Can you hear me?

(Brant): Yes, this is (Brant), B-R-A-N-T.

Timothy: Oh, (Brant).

(Brant): My question has to do with the revocation of the Chembio EUA and it was apparent that some of the tests on the EUA list, the serology test, I do not believe have the NCI data posted. Now, the NCI data I realize from the letter you sent them along with - I should say the FDA sent them, not you - along with the - with some other data were the basis for the revocation. But it - isn't it going to be difficult to use those tests that don't have the NCI validation data posted because they could be subject to revocation.

For example, I sent a query to one manufacturer just this morning and asked for their NCI data, they're on your list, and they said we're in the process of submitting it. So if we were to use that in a clinical trial, we could get down the line and then suddenly find out that that test kit was revoked; isn't that true?

Timothy: That is a possibility and which is why we're seeking to authorize as many arm (unintelligible) and serology list and then is notified as soon as possible. So when we get NCI data, whether it supports authorization or not, we've asked our reviewers to make that a priority once NCI data has been received.

And again, if a developer has the NCI data, we've asked them to share that with (unintelligible) customers or potential customers. We can't do that until

we make a decision on the application because - but once again when we make a decision, we'll share that.

(Brant): Well...

Timothy: So there is obviously a lag between getting some NCI data, making a regulatory decision, making that regulatory decision public and then posting that information.

(Brant): ...let me just clarify. I don't think I asked the question correctly right at the end. In other words, the manufacturer I contacted is on your EUA list now. They're not on the notification list. They are on their - your EUA authorized list and yet, they apparently have not sent in the NCI data yet.

So couldn't there be an asterisk somewhere on that list that says this manufacturer's on our list like ChemBio was, but we have not fully evaluated the NCI validation data and it could be subject to revocation depending on how that testing comes out?

Timothy: I understand now. Apologies for not answering your question yet. So there were some authorizations made for tests that are prior to testing at NCI and we're working to as appropriate to have NCI's testing performed.

Pretty much all going forward, authorizations are going to include that. So that should reduce that list going forward. I understand your question and we'll take that back and see how we might address that, okay? (Toby), you can add anything to that if you want.

(Toby): Nothing to add. Thanks.

Coordinator: Next question comes from (Alyssa). Your line is open.

(Alyssa): Thank you. I know that earlier you did address this, but I just would like confirmation, please. That remnant specimens can be used for antigen clinical validation. In other words, it's not the expectation that we must do the clinical trials to that clinical validation; is that correct?

Timothy: The clinical validation is section...

(Alyssa): Validation, correct.

Timothy: ... four - yes, clinical validation section test and I'm going to pull that up now. So - and we will be open to use any remnant specimens, but it should be intact and not engineered and not contrived. For example, we authorized the (unintelligible) engine test using BTM and they, you know - so that was totally appropriate in that situation.

It's good for our reviewers to - if you want to make sure that a particular type of remnant is feasible there could be limits on the authorization, you know, if there is anything (unintelligible) particular about, you know, if you selected those remnants in some way.

We are looking for an unbiased selection of those remnants. So if you have a source of remnants, we would (unintelligible) based on a comparative molecular test identify those, but we would ask that you reduce the chance for bias through various mechanisms using (unintelligible) recommended and that you between (unintelligible) dates that you're selecting samples that consecutive positive and consecutive negative (unintelligible) collecting those would be used rather than non-random or some sort of biased approach for selecting those samples.

So that - we understand, you know, the performance (unintelligible) as the lab (unintelligible) and understand (unintelligible) in the way that they receive samples. Not sure if that was clear or not, but I can pause for any follow-up question.

(Alyssa): Yes, no, thanks, and thanks for earlier you mentioned LTD's. We hadn't considered that. We had just had administered that. So thank you very much.

Timothy: Oh, you're welcome.

(Toby): (Unintelligible) I just wanted to add to that. You mentioned in your question a comment about IRBs and about, you know, doing clinical assessment and I just wanted to make it clear that using left over specimens and remnant specimens is considered to be clinical studies.

So you should consult with your IRB to see what requirements you would have for that study.

(Alyssa): All right. Thanks so much for that clarification.

Timothy: Yes, excellent point. Thank you.

(Toby): Thank you (unintelligible).

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

(Coda Modee): Hello. Thank you for taking my question. I am (Code Modee) (unintelligible). I really appreciate mentioning today that within two weeks that leads to the - a

review - a lead reviewer will be assigned when the application is (unintelligible).

Can you in the same way (unintelligible) our test to the NCI (unintelligible) more than three weeks ago? Is there any timeline like that when at least NCI will respond to us what they are doing with our test kits? I'd appreciate it if you can give the guidance.

Timothy: Yes. So we have a triage procedure for - at NCI. We have more tests than (unintelligible) can be performed in one week at NCI or so. They're working very hard. They're looking at adding staff. We're looking ahead to accumulating ahead of time of the testing capacity at NCI, that we only have samples to test with the test.

The NCI looks to the agency, the FDA, to triage. So what we're doing is we're reviewing applications and making assessments and the same sort of priorities that I mentioned before do affect the NCI testing. So point of care is a priority.

So if all of point of care studies have been submitted and they look good, we would move that out (unintelligible) ahead in the NCI (unintelligible) and likewise should there be any sort of high throughput that would also be - I can't think - and then a home test would also be a home collection or a home test would also be on the high priority list.

So otherwise, I directed that - the NCI list to be on a first-come, first-serve basis.

(Coda Modee): Well, the way in which, you know, you mentioned when the application is (unintelligible) at least within two weeks you are (unintelligible) in from the performer (unintelligible) and then take (unintelligible) date the same way can

NCI give us data sub-date on a two-week basis or some periodical basis?

Timothy: So as I said, every developer within two weeks of submission going forward - and I hope that most of them is backwards for some period of time - have a contact. That contact will have access to the priority list. The challenge is - and I should be able to give you some feedback and especially based on the priority.

If you are a priority candidate, you're already going to have a reviewer and if your assay is at NCI and you and I as part of the candidate, then NCI will really (unintelligible) any reason to remove that. So the NCI has the rank order of based on (unintelligible) and put some preserve in that high priority list that they will get to and it's just a matter of where you are in the high priority list.

The high priority list is longer than NCI's (unintelligible) performing testing, you know? The perform testing on multiple devices each day that they test and - but there's a limit on how many different devices of the test on a given day.

So - and that - the list - high priority list is longer than the batch (unintelligible) NCI currently can test on a daily basis.

(Coda Modee): Thank you. I think the - your suggestion (unintelligible) lead contact at FDA, we can communicate with them about the NCI thing also. Thank you.

Timothy: Yes. Yes (unintelligible).

(Coda Modee): I appreciate all your work.

Timothy: You're welcome.

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

(Kay John): Hi. This is (Kay John) with Synergy and I'm being told by different labs for serology that they're using dried blood as their specimen and that this is acceptable. I can't find anything in any of the letters of authorization that refers to approval for dried blood as a specimen. Does that require a separate approval if they change the specimen to dried blood?

Timothy: So it's an LTD serology test. The laboratory developed a serology test. It's probably good on this call to make it - reiterate that even though they're not required to submit any new EUA application they are required to notify us of their - if they've completed their validation and their offering and they'll be (unintelligible) serology test.

Kit manufacturers are allowed to, you know, validate any sample blood they can validate as long as it's not a home collection or a home testing situation. They can complete their validation, notify us, and also their test, you know?

If a lab wishes to validate an alternate sample type for an EUA-authorized test, that's a good question. I would do that under the LDT pathway for serology tests and that we would not - we would love to see validation data. We would ask that they validate that properly and that we hear about any problems.

From molecular, if we have not validated the sample type before, we do require even for LDT situations to see that application so that we can review and authorize it so we can add to the list of EUA-authorized sample types.

I'll pause and let (Toby) add to (unintelligible) on that.

(Toby): Yes, no, I think that's accurate. I think you're correct. I would have to double-check, but I don't believe we have any tests that are specifically authorized using dried blood at this point although they're, you know - there is quite a bit of interest in it.

But that - what (Tim) said regarding the policy and the test notifying under the policy is correct.

(Kay John): Thank you.

Timothy: You're welcome.

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

(Dana): Hi. Thank you for taking my call. My question is regarding a serology antibody rapid test for point of care and I was wondering if, one, if you foresee a possibility for the NCI program to also perform the (unintelligible) blood sample testing and then can you clarify if the requirements in the template is 30 positive samples and 30 negative or 30 positive and 75 negative for the finger pricked (unintelligible)?

Timothy: Yes, (Toby), can you pull up that template and maybe address that? I think it happened to differ based on whether you're adding (unintelligible) EUA-authorized (unintelligible) has been a (unintelligible) versus finger sticking, the only (unintelligible) that you're going to do.

So we have investigated during something at NCI with regards to this and it's a huge challenge because the NCI does not have direct access to patients in

clinic settings and (unintelligible) the Frederick Lab doesn't have that access.

Finger stick samples are obviously in most cases (unintelligible) all need to be tested fresh and that's not what we're currently able to be geared up to do right now. (Unintelligible) for old blood. So right now, the umbrella for NCI testing is limited to (unintelligible) plasma and then the testing of the device of (unintelligible) also limited to (unintelligible) at the NCI.

However, we're very open to suggestions that (unintelligible) may incorporate this and certainly then a topic for conversation. We're just not able to figure out how we can do it in an appropriate manner for all considerations. And I would add that even add...

(Dana): (Unintelligible)...

Timothy: ... that even if you had old blood samples, a old blood can behave and we know it can behave differently than a finger stick. They are two different sample types and their composition (unintelligible) different. And so they need to be tested and validated differently.

So even if we were to find a way to (unintelligible) old blood samples, that would be a challenge (unintelligible) itself to try to configure (unintelligible) the assessment. And, you know, we do extensive examinations of these samples prior to being used at NCI to get them and make sure they're appropriate for the panel.

And as we run out of one sample to replace with a like sample with the best of our ability so that over time our performance assessment in devices is equivalent as possible.

(Dana): Okay. Thanks.

(Toby): And to follow up on that with looking for the template, I can clarify that the clinical agreement study is looking for 30 positive and 75 negatives if you're - so if you're doing finger stick only, that's what we would be looking for. If you're adding finger stick on and already have the 30 positive and 75 negative from a clinical agreement study, you can do 30 and 30 for the finger stick add-on.

(Dana): Okay. So even if the 30 and 75 is through the NCI program (unintelligible) plasma we could just add on 30 positive and 30 negative for finger prick (unintelligible)?

Timothy: Yes.

(Toby): Right.

(Dana): Okay. Thank you so much.

Coordinator: Thank you. And our last question...

Timothy: Operator, are there additional questions?

Coordinator: ... is from (Nadia). Your line is open.

(Nadia): Hi. Thank you for taking my call. I just wanted to confirm that if you have a COVID case just for an automated system on the market as an R&D, do you still need to notify?

Timothy: If you're using an EUA-authorized test, labs do not need to notify.

(Nadia): No, if a manufacturer wants to manufacture a kit for research use only.

Timothy: Oh, for research use only with COVID?

(Nadia): Yes.

Timothy: So that is possible. They cannot promote it for use in the pandemic in this emergency and that would be examined closely and appropriate action would be taken if that's the case, but there are some labs who will take an RUO test and validate it for their purposes.

If it's a serology test and they validate it, it would require notification, but not an EUA submission. If it's a molecular test, a nucleic acid test, it would require validation and notification and an EUA submission. So it does put a burden on customers if they're going to use it for that.

And so therefore, we recommend that all developers with COVID-19 prepare, validate and submit their kits.

(Toby): I would also encourage you to take a look at the RUO guidance that we have, the labeling for RUO guidance because it's important to note that if you know that your test is being used in a research (unintelligible) if you're - if you know that it's being used in clinical and you're selling it purposely to a clinical lab for use on clinical testing and clinical - for clinical testing, that would not be labeled appropriately if you're labeling it as RUO.

RUO labeling is really intended for components and tests that are intended to be used for research.

(Nadia): Okay. Thank you.

Timothy: Thank you (unintelligible).

(Nadia): Thank you.

Coordinator: I would now like to turn the call back over to your host, Ms. (Kemba Ford).

(Kemba Ford): Thank you. This is (Kemba Ford). We appreciate your participation and thoughts and questions during today's virtual town hall. Today's presentation and transcript will be available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by next Tuesday, June 23.

If you have additional questions about today's presentation, please email cdhr-eua-templates@fda.hhs.gov. Also, we would appreciate your feedback. Following the conclusion of this virtual town hall, please complete the short virtual question survey about your FDA/CDRH virtual town hall experience.

This (unintelligible) available now at www.fda.gov/cdrhwebinars. Again, thank you for participating and this concludes today's virtual town hall. We'll talk with you again next Wednesday.

Coordinator: That concludes today's conference. You may disconnect at this time and thank you for joining.

END