

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

**Moderator: Irene Aihie
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12:15 pm ET**

Coordinator: Good afternoon and thank you all for standing by. For the duration of today's conference, all participants' lines are on listen-only mode until the question-and-answer session. At that time, if you have a question you may press star 1. Today's call is being recorded. If you have any objections you may disconnect at this time. It is my pleasure to introduce Irene Aihie. Thank you, ma'am. You may begin.

Irene Aihie: Hello, I am Irene Aihie, of CDRH's Office of Communication and Education. Welcome to the FDA's 17th 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 the Public Health Emergency.

Today, Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, both 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 might be under review.

Now, I give you Timothy...

Dr. Timothy Stenzel: Welcome everyone to this week's call and thanks for all that you're doing, during this emergency. I'm going to turn it over now to Toby, for some opening updates and then we'll open it for questions. Thank you.

Toby Lowe: Thanks, Tim. Thanks, everyone for joining us today. Just a quick update today, this morning we made some updates on our FAQ page to the question about obtaining viral transport media and swab alternatives. The edits were primarily for clarification and additional language around the warning regarding media that includes guanidine thiocyanate or similar chemicals. And then the other update that we made this morning was to add a new question under the "What test should no longer be used or distributed?" section, and that is for laboratories that had previously provided notification under the policy in section 4A of the guidance but has now been removed from the notification list and the tests should no longer be used.

So those are the only updates that we've made to the FAQs since last week's call I believe. And now we can open things up for questions.

Coordinator: Thank you. And if you would like to ask a question please unmute your phone, press star 1 and record your first and last name clearly when prompted, so I may introduce you. Again, that is star 1 if you have a question. Our first question is from (C. Wolfe). Your line is open.

(C. Wolfe): Yes, hi. I've recently seen some neutralizing antibody tests and I was wondering what criteria does FDA use or plan to use to assess assays for neutralizing antibodies, especially assays that involve binding of spike proteins to its receptors the surrogate to the use of live virus?

Dr. Timothy Stenzel: How are you going to determine titers part of the assay?

(C. Wolfe): We might want to take a...

Dr. Timothy Stenzel: ...for quantitative?

(C. Wolfe): Yes. I think more semi-quantitative.

Dr. Timothy Stenzel: Okay. Yes, so we're very welcome of EUA applications for neutralizing antibody tests. Obviously, there's health determined among other things, folks who might be good donors for convalescent plasma. And there are two types of assays that include say neutralizing claims. One is a routine serology test that then - or not routine. One that is say quantitative or tittered and makes a correlation to a neutralizing reference method. And notes that at a certain titer or a certain cut off that there's a certain overlap between the detection of antibodies in a patient and a high level of neutralizing antibodies.

And so that's not a direct sort of neutralizing antibody assay. And then there are various ways to do this testing more directly and that is often also semi-quant or quantitative in order to make that assessment. It may be that a minimum titer is required for the significant neutralizing antibodies present. In both cases you want to compare ultimately to a validated reference method. How do we know that an assay is truly neutralizing or correlates to a truly neutralizing antibody? And then there's the added addition of making this semi-quant or quantitative. And so, for semi-quants or quantitative assays, I don't believe our current templates go into a lot of detail about how to validate that. So, we do ask you that you approach us and describe that.

But in many cases, in order to be - to have a good precision and accuracy

around quantitation, that there is a calibrator or calibration that goes into effect. And then of course an appropriate validation of that quantification portion of the assay. So that's about all I can say right now, are the things that we're thinking about. For more details, you know, ask questions. The more details you can provide, sending an email to our template email address, the better, so we can provide more information. This is a relatively new area of review for us and before we provide a more definitive feedback and recommendations that would be put into a template, we want to understand the assays that we first see in submissions, understand their performance, understand that we can establish truth to a reference assay, and develop the recommendation based on those early applications.

And then we'll, presuming that there'll be more and more, we'll make a template available, a template addition available for the them, OK.

(C. Wolfe): Okay. Thank you.

Coordinator: And your next question is from (Lewis Perlmeyer). You may go ahead.

(Lewis Perlmeyer): Sure. I've got just a follow up on the first question person. Are there any EAUs being requested for neutralizing antibodies? And if so, are there any that have been accepted yet?

Dr. Timothy Stenzel: So, we have not authorized any assays for correlation or actual neutralizing antibodies. There is very strong interest and we welcome them now of course. And I can't really say any more details other than that.

(Lewis Perlmeyer): Okay. Okay, thanks, Tim.

Coordinator: And your next question is from (David Hug). You may go ahead.

(David Hug): Hi, yes. Can you talk about...

Irene Aihie: Operator, did we lose our caller?

Coordinator: He is still connected.

((Crosstalk))

(David Hug): Can you hear me now? Can you guys hear me?

Dr. Timothy Stenzel: I was worried that I got dropped.

(David Hug): No. Can you hear me now?

Dr. Timothy Stenzel: Go ahead, (David). Yes.

(David Hug): Can you comment on where you see saliva-based serology tests either absolutely or in terms of the prioritization of EUA review and separately, whether you see IgA as a viable pathway for antibody evaluation versus IgG or IgM?

Dr. Timothy Stenzel: So, this would also be a new area for us. So, we haven't authorized any yet. And trying to understand what the performance should be and how you establish the validation is still something that we're noodling on. You know, there is the capability of looking in saliva for - specifically perhaps for IgA. And it could be that IgA detection and maybe in saliva, could correlate well with some types of immunity. And I'm not saying that's easy to establish or that that's taken as truth right now and just talking about the potential for such tasks. But we certainly don't have any recommendations yet for how you would

validate that.

So, anybody who is interested in developing a saliva-based antibody test, it's not so much a serology test that we usually think about it, as a blood-based or a blood-derived analyte. But it's, you know, it could have importance. We're not going to discount that. So, we would welcome ideas on how to validate and proposals. And we'll take a look at them.

(David Hug): Thank you.

Coordinator: And your next question is from (Dana Hubbell). You may go ahead.

(Dana Hubbell): Hi. Thank you for taking my call. My question is regarding the importation and sale of RUO or Research Use Only rapid serology kits that we manufacture outside of the US. If we would like to import finished kits for research use only in the US, do you foresee any challenge with testing clearance from the FDA point of view? Of course, these kits will be labeled clearly for RUO and will only be marketed for research use only until we receive an EUA. And also, would we need to provide any sort of official notification to the FDA prior to our pre-EUA submission in order to import and sell the RUO kit?

Dr. Timothy Stenzel: Yes. So that's a potentially challenging area and Toby, do you - are you prepared to address this, because you've thought a lot about this.

Toby Lowe: Yes. So RUO is a little challenging especially for complete test kits. Complete test kits should really not be distributed to clinical laboratories as an RUO. I would encourage you to take a look at the guidance document that we have on distribution of IVD products labeled for RUO. And as noted in that guidance document, it's not appropriate to label a product as RUO and then promote it to clinical laboratories with the intent that the laboratory validate the test and offer

it for clinical diagnostic use as a laboratory-developed test.

((Crosstalk))

(Dana Hubbell): What about selling to researchers?

Toby Lowe: I'm sorry. Can you repeat that?

(Dana Hubbell): Oh. I said, what about the intent to sell to researchers? That's what I was thinking.

Toby Lowe: Sure. So, depending on your plan selling it to researchers may be appropriate. I would again, encourage you to take a look at that guidance document because it does talk about what you uses are appropriate and not appropriate for products labeled RUO.

Dr. Timothy Stenzel: And I would add that we're really encouraging developers and people like yourselves who may be considering distributing serology kits, that they consider early on to just go ahead and submit an EUA if ultimately they, you know, they should, you know, if you want to market this to clinical labs. So...

((Crosstalk))

(Dana Hubbell): I was just wondering if we could sell the RUO kits in the meantime. But we can...

Dr. Timothy Stenzel: Have you been...

(Dana Hubbell): ...definitely considering...

((Crosstalk))

Dr. Timothy Stenzel: Have they been validated for clinical use of your performance data that could be used to submit to the FDA?

(Dana Hubbell): Yes. We have some data and we have submitted our test to the NCI.

Dr. Timothy Stenzel: Yes. So, I mean I think that's a gray area. We're not encouraging labs to buy RUO kits for this purpose. There are now some authorized kits that they can use. And there are notified kits that they can use and to go ahead and purchase RUO when there are so many notified tests and already quite a few authorized tests, doesn't really make a lot of...

(Dana Hubbell): I agree.

Dr. Timothy Stenzel: ...sense to us. So, if you've got, you know, data for a EUA submission I would just encourage you to, you know, notify us if you want and or just submit the data.

(Dana Hubbell): Okay. Perfect.

Dr. Timothy Stenzel: And then that's the way to market such a test. Because it sounds like it's already been developed for and at least some validation for clinical purposes.

(Dana Hubbell): Yes. Okay. Perfect. Thank you so much.

Coordinator: And our next question is from (Jeff Kerriberry). Your line is open.

(Jeff Kerriberry): Hello. Can you hear me?

Dr. Timothy Stenzel: Yes.

(Jeff Kerriberry): Oh. You can hear me? Good. Thank you for taking my call. I have a kind of a two-part question. The first part being a little general regarding the status of quantitation or standardization of the EUA submitted tests and what are the current status or thoughts of providing quantitative results based off of the standard curve in terms of nanograms per mil or (U) per mil, mass or massless units or preferred or anything regarding that. And then how the FDA is dealing with multiplex tests that can report individual antigen responses, epitope responses and separately the isotypes and if there is a better - should this be done by the pre-EUA to get better traction on what's required for multiplexing?

Dr. Timothy Stenzel: Yes. Are all your questions having to do with serology tests?

(Jeff Kerriberry): That's correct.

Dr. Timothy Stenzel: Okay. Yes. I did respond to an earlier caller and talked a little bit about semi-quants and quants. I think in our template we say that if you want to come in with that that there may be some, I don't know Toby if you have that template up. I don't know how much information we provide on validation of quant or semi-quant assays. But we're open to it in whatever appropriate units that you use to report out your results, we're welcome to consider. And, you know, standard curves, you know, calibration, are important for reporting out those results. And we want to look at sufficient validation to support a semi-quant and quant claim so to speak.

In regard to the multiplex, we have authorized some that report out individually IGG and IGM. There's also assays that sort of claim pan or total antibody that don't report out individual results. We don't have a preference. We just authorized recently our first IGM only for those developers who want to do

IGM only. There are challenges with IGM. It may not stick around as long as IGG.

(Jeff Kerribery): Yes. And what about reporting the antigen separately?

Dr. Timothy Stenzel: So, if you have a multiplex assay that can say, you know, I forget the antigen that you mentioned, but...

(Jeff Kerribery): Spike and nucleic acid for instance.

Dr. Timothy Stenzel: Yes. So, an NNS protein, an assay that can report out those separately would be fine. It's potentially a way to get two assays in one that could potentially improve the positive predictive value without having a reflex test.

(Jeff Kerribery): Yes. Exactly.

Dr. Timothy Stenzel: So very open to that.

(Jeff Kerribery): So, all of these kind of subtleties are best addressed via dialog with the FDA during the pre-EUA submission process? So, if we get that template going with you guys then we can fine tune some of these standardization issues and stuff like that?

Dr. Timothy Stenzel: Yes. The more you can propose what your validation would be the easier. But really, I mean our templates are pretty good already for individual antigens. And the fact that you would report out individually it just matters how you would like. And then the validation could be done individually and separately, you know, by isotype and by antigen. But then it also depends on how you might want to aggregate that data and report it overall. That's probably the biggest question and that's not a super important question at the beginning, as

long as each isotype and antigen are properly validated and performed well.

And, you know, to any extent that you report something individually we will look at that individual performance and make sure it meets our minimum specs, and those are pretty well laid out in the template. So, I don't know that a lot of interaction with the Agency is required. I think the novelty of this is reporting it all out on one test instead of doing it on multiple different tests or doing it one test after another.

(Jeff Kerriberry): Yes. So, there is some area to populate the templates regarding standardization and then if you have further questions you would get back in response to the template?

Dr. Timothy Stenzel: Yes.

(Jeff Kerriberry): Is that correct?

Dr. Timothy Stenzel: Yes. I mean the only - yes, the only area that we haven't necessarily addressed specifically to this, is how you report out overall results. Right?

(Jeff Kerriberry): Right.

Dr. Timothy Stenzel: You combine it all together for a positive.

(Jeff Kerriberry): Yes. You can do combined likelihood ratios like the PPV or you can yes, that's these are some of the issues we wanted to discuss. And if you see like the CDC guidance has a criteria for IgM that's 90% sensitive, is that typical? Or a lot of cases the IgM disappears, and you get 80%. Is that acceptable? Or no?

Dr. Timothy Stenzel: So, if it's IGM alone and no other markers we know that it needs to be at

90%. If it's in conjunction with IGG, IGG needs to hit 90% but IGM can hit 70%.

(Jeff Kerriberry): Oh, okay. That's good. Thank you.

Dr. Timothy Stenzel: All right. All right, anything else?

Coordinator: And the next question is from (Carol Cooper). You may go ahead.

(Carol Cooper): Hi. Thank you for taking my call and first I want to thank Dr. Stenzel and your staff, for the huge amount of work that you are currently doing in trying to keep all of us safe. I must say I'm a former bench immunologist who strayed into the regulatory affairs area and now I'm a (rep) board member and I guess I have a very not so technical request. I do believe that EUA for the specimen collection kits is sorely needed. I'm assuming for every molecular assay EUA there are several specimen collection kits without a 510(k) clearance. And from what I can gather there are - there's so much variability.

We could also assume that specimen collection kit can follow portions of the home test, simply, potentially, and some of the 510(k) requirements from the existing products that are out there. But an EUA template is not only beneficial, it also provides a minimum threshold for all kit developers in this space. So, the hodgepodge variability of supplies requires some FDA attention when it comes to specimen collection.

((Crosstalk))

Dr. Timothy Stenzel: Yes. I just want to know a little bit more details about what kind of specimen collections in what environments that would be collected?

(Carol Cooper): Not necessarily. Currently, the State of Illinois is collecting from whatever, whomever they can get the supplies from. And from what I can tell none of these have any type of 510(k) authorization. The - or clearance rather. And the EUA authorization would at least make sense that the viral test media as well as the swab are somewhat qualified for use. And the EUA would provide that...

((Crosstalk))

Dr. Timothy Stenzel: You're talking about swabs and the VTM.

((Crosstalk))

(Carol Cooper): Yes.

Dr. Timothy Stenzel: Yes. Take it over Toby.

Toby Lowe: Sure. So, I think we discussed this briefly last week on the town hall also because we agree the issue of unauthorized collection devices is challenging. And there's also a desire by developers to expand sample collection to new specimen types like saliva and I know that's not one that you mentioned. But a lot of collection devices are 510(k) exempt so they should be registered and listed and have a quality system and be following FDA regulations. But swabs and certain types of media are 510(k) exempt. Some others are not. As you mentioned, VTM does generally require 510(k) and we have worked with some newer manufacturers of VTM on different issues that have come up there.

And we're working on ways to address that. And so, we are accepting EUA requests for specimen collection devices. But it is important to note that we are trying to, you know, figure out the best way to handle the issue of unauthorized collection devices. And right now, what we're advising companies, especially

saliva collection devices have been the area that we've had the most discussion around with developers and with manufacturers. And we're advising them at this point to refer to the home collection template. While not everything in there would be applicable, there is a lot of information there about what we would be looking for in terms of validation from the collection device side of things.

(Carol Cooper): Perfect. That's what I assumed. And then fill in the blanks with some of the other requirements that you would probably find in the 510(k) which would be the eventual clearance?

Toby Lowe: Exactly. Yes.

(Carol Cooper): Okay. So, will there be an EUA template posted?

Toby Lowe: We don't have an EUA template in the works right now for collection devices, but we are working on different ways to get the necessary processes in place for collection devices. And we'll continue to update as soon as we have more information on that.

(Carol Cooper): Okay. Thank you very much.

Toby Lowe: Sure.

Coordinator: And the next question is from (Josima). You may go ahead.

(Josima): Hello? Can you hear me?

Toby Lowe: Yes, we can.

Dr. Timothy Stenzel: Yes, we can.

(Josima): Yes. This is (Josima) from (OG). Thank you for taking my questions. I have a question - I have actually two questions - very quick questions. Do you have an EUA on screening samples based on the saliva PCR kit? And also, if we do need to do that, I understand we have to do a paired screening. But do we need to do even for screening, do we need to pair NP and saliva, or we can just use 20 saliva samples for screening and contrive them and use it?

Dr. Timothy Stenzel: So, you're really talking about doing saliva for asymptomatic patients? Is that correct?

(Josima): Yes. Yes.

Dr. Timothy Stenzel: Are you going to make - are you going to advertise, claim, make the statement that you have validated asymptomatic testing? Or, you know, because the FDA currently if you get an EUA for - a typical EUA says that testing on patients suspected of having COVID, we had stated that it's for prescription that if you get an order from a clinician on a patient it doesn't matter whether they're asymptomatic or symptomatic.

And you can do that testing. So, it's only if you want to specifically validate and make that claim in your information that you can detect asymptomatic patients. That would be required to be validated for the FDA. Is that something that's important to you? If it is, the answer can change based on that. And would saliva be the only sample type?

(Josima): We have done a validation. The last set we paired 30 samples for nasopharyngeal and saliva. So, we are using contrived samples, and we took negative samples and, you know, (unintelligible). My question is that we want to advertise as a screening of asymptomatic patients. So, we will do that not

later on, because right now, my question is can we use - right now, contrive 30 samples for screening submission?

Dr. Timothy Stenzel: Not for asymptomatic. And I - there's screening that really, I think, refers to patients who aren't necessarily suspected of having SARS-CoV-2. You may be looking at a work population or school population and wanting to test individuals and report results back to individuals. So, I'm just struggling a little bit to - and I'm not understanding, and I apologize, exactly what you're going after here.

Woman 1: We're going after businesses. As you said, you're going after businesses and schools, like we get samples from them and screening them if we - you know, if they have COVID-19 or not. So, we are developing a diagnostics kit, as you said, by prescription only. And for that, we are doing a paired set with both nasopharyngeal and saliva. So, my question is, for screening also, do we need to have a paired set? If yes, can we use contrived samples for the screening?

Dr. Timothy Stenzel: So, for the screening, really, in your question, has to do with testing and claims for screening asymptomatic people. And like I said earlier, you don't need that as long as you're not claiming that. But if you're reaching out to businesses and saying, we want to have an FDA-authorized test that the FDA says is okay to screen asymptomatic patients, then it would require asymptomatic studies.

And if you already have an EUA authorized assay or if you've already done the EUA-authorized work of 30 positives and 30 negatives and NP and cross-validated, too, and you've done a paired study with saliva, and all those need to be on natural patients, not contrived. Actual patients, you know, an actual patient sample, a swab sample.

Then, if you want to add to that, the asymptomatic screening claim to an already authorized assay, it does require 20 - the first 20 in a, samples that are consecutive, asymptomatic samples, compared to another - not yours, to another EUA-authorized high sensitivity assay, molecular assay. And I believe 100 consecutive negative samples for that authorization, and adequate performance in order for that authorization to happen.

If you want to - and you've already done the initial validation, so this isn't - pathway isn't open to you, but for anybody else who wants to start out with an asymptomatic claim, then they do their normal study at 30 positive, 30 negative. But they also include at least ten prospectively, ten asymptomatic patients.

Woman 1: Asymptomatic positive or asymptomatic negative?

Dr. Timothy Stenzel: Positive.

Woman 1: Oh, positive. And it looks like that both for whether it's diagnostic prescribed or for screening, you are not - it's not okay to use contrived samples anymore? Because initially, in your policy, that was listed, that you could use contrived samples.

Dr. Timothy Stenzel: Yes. No, there's - it's better to use actual samples to measure actual performance, and so we switched a while back. We're expecting on actual patient, and unfortunately, there's more than enough positive patients out there right now, so it's not really - in the beginning, there were no samples, at the beginning of this pandemic.

And so, we offered this alternate pathway, even though it's not ideal. But now that there's plenty of positive patients, that's not a pathway that we're

recommending right now.

Woman 1: Okay. That's good to know. Thank you so much.

Coordinator: And our next question is from (Luke Nguyen). You may go ahead.

(Luke Nguyen): Oh, hi. Can you hear me?

Dr. Timothy Stenzel: Yes.

(Luke Nguyen): Yes, we are a glass exam specimen blood capillary device manufacturer. And we have a lot of our customers applying for EUAs with our at-home collection kit or device. So, I'm just - I have a question. Do we need to submit our own EUA? Because our device is actually classified as Class 1 exempt.

Dr. Timothy Stenzel: So, it depends. And if you want to get an EUA authorization for home collection, yes, you would need an EUA. If you want to stay a Class 1 exempt provider and your customers are going to come in to obtain a home collection authorization, which has to happen before home collection can begin, then you can rely on their validations.

And we're encouraging collection kit manufacturers to come in for getting home collection EUAs. And that's going to be much more efficient, if multiple developers are going to use that collection kit for that situation, so that they don't all have to do the same study, right? And so, it may be attractive to your customers and other developers like you, for their kits, if they get an EUA authorization.

And I would even go so far as to say that, you know, seeing the home collection situation, that it's ideal if - and the first one would have to come in with a

partner, where you work with a partner who has a test where they want a home collection. It can be already an authorized test that you're adding this to, or somebody who is seeking an EUA authorization.

Because your authorization would be dependent on showing adequate performance for specific tests, right? And then - but you could do a lot of things upfront, such as usability testing, inadequacy of sample collection in the home environment. And then, it would be shipped, right?

And so, during the appropriate shipping study, even to the point of usability studies describing having a common set of instructions so that each other developer you might work with, test developer, wouldn't have to come up with their own instructions for use of your collection device.

And to the extent that you can get all of that reviewed in one package and authorized along with at least one other test, then - and you can simply give a right of reference to any other developer you want to work with, that can utilize the data that you've developed for that collection device, making it much easier for any other subsequent test developer to work with you, because they don't have to repeat all that.

And if you look at - I think there's an example on the molecular side. There's probably others, but the one that's coming to mind is the Everlywell swab collection kit that was authorized, and then authorized for use in a number of other platforms. Toby, do you have anything to add?

Toby Lowe: Yes, sorry if I missed it, but did you say what type of collection device or which collection device you were referring to?

(Luke Nguyen): Yes, we - it's - our device kind of looks like a swab, but it's collecting capillary

blood through finger prick methods. So, it just - it collects a fixed amount of volumetric blood on that tip, and then it will be shipped at ambient temperature in a biohazard foil bag to the, you know, the partner lab, so they can do the testing.

Toby Lowe: Okay, thank you. So yes, it would - just to piggyback on what Tim said, you know, it is important that any lab doing testing and any, you know, test being offered is for use with a legally marketed collection device. So, we would, you know, ask that you come in with a submission for that device, prior to offering it for use with any test.

(Luke Nguyen): Yes, but for the application, because I - we currently have one of our customers applying for an EUA with our collection device. So, in our application, would we just reference their validated test for our device application?

Dr. Timothy Stenzel: So, you would cross-reference each other, and their test would need to be validated with your device.

Toby Lowe: Right, so you could give each other right of reference, and then either - the submissions could be done concurrently.

(Luke Nguyen): So, should I submit a pre-EUA or just submit an EUA notification, and then use the validated data for our submission? And then also for usability data, we have a lot of peer-reviewed literature talking about the usability of our product. Can we use those data?

Dr. Timothy Stenzel: It can be supportive. We're still working on templates for home collection for serology, and so that's not out yet. So, I would urge you to submit your validation plan along with your partner, and we can evaluate that for appropriateness since we don't have a template out yet, as a pre- EUA.

And then, realize that the home collection and home testing is not a notification pathway. It requires an EUA authorization before you can begin home collection or home testing.

(Luke Nguyen): So, pre-EUA package would be ideal to get, like, have some sort of guidance on how we move forward with our usability study or the design of our study?

Dr. Timothy Stenzel: Yes. Yes, we don't have any home collection or home test template out yet. We're working hard on them. And we do have a home collection, I'm sorry, for molecular. So, you can look at that template and try to derive some information from that, as to inform you on a home collection for serology. But obviously, there's different issues with serology than with molecular.

So, adapt it to your purposes. Put it in writing and send to us by email. We recommend using our template, our serology template for this, but you don't have to use that. But we do recommend it. Okay? We're going to move on to the next caller.

Coordinator: Our next question is from (Phillip Cowell). You may go ahead.

(Phillip Cowell): Hello?

Dr. Timothy Stenzel: Hi, (Phillip).

(Phillip Cowell): Yes, hi. How are you? Mine's a little different question. I'm with Thermogenesis Corporation. I'm the CTO, and we have a kit in, one of the lateral flow kits under evaluation for EUA. But there has been a corollary project that we've been working on at a high rate, which is a reader that can empower, we hope, semi-quantitative information.

It basically reads better than the human eye, by a considerable margin, and provides semi-quantitative information. It also has - it's designed into it, the ability to, over time, monitor both seroconversion and seroreversion, we believe, and are prepared to provide information. And so, we think it may have some public health consequences that are useful.

We have filed a document to CDRH, requesting a meeting, and I know (Dr. Whitacre) has been wonderful, is requesting time for us to present, because we need guidance. We're focusing on having this available by the end of summer, and we're at a period of time where some advice would be useful.

We haven't been able, so far, to obtain that, and I'm wondering if you people are so busy, that we're unlikely to have a meeting that works for our trajectory on the development itself?

Dr. Timothy Stenzel: Yes, if you're having trouble getting a meeting, just send an email -

(Phillip Cowell): I don't want to be unfair to anyone. I think people are trying - they've given us advice, and I know (Dr. Whitacre) is trying to pull the team together. But it may be that you're just so busy that it's not going to happen, and we're trying to - we're a limited resource.

Dr. Timothy Stenzel: Well, we are way too busy. You know, I also - well, I also know we don't have, you know, good template information up about a serology meter, for a lateral flow device whether it's visual or, you know, nonvisual.

(Phillip Cowell): Yes, we are aware of that. And so, to that extent, we're anxious to show it to you, because we feel it does have public health consequences, and it might help make all that happen.

Dr. Timothy Stenzel: Right. So, if - you know, I'm glad that you're getting some feedback. But it sounds like you could use some more in a shorter amount of time. And you know -

(Phillip Cowell): I think if we can get just in 30 minutes, we could show enough that your interest level would be - help us get the rest of the way.

Dr. Timothy Stenzel: Yes. So, I mean, I want to - I get involved early on when we don't have templates, so that we can help drive towards providing template information. And then, I can step out of it, because if there's a template, there's little need, usually, for me to be involved.

(Phillip Cowell): It's a battery-operated, handheld, very rigorous, very inexpensive, and provides, you know -

Dr. Timothy Stenzel: Let me just go ahead - we try to stay away from all the specific questions, you know, and specific advice. But yes, if you just send an email to the template email address and ask to connect -

(Phillip Cowell): We have done that. Attention to who, please?

Dr. Timothy Stenzel: (Dr. Stenzel), S-T-E-N-Z-E-L.

(Phillip Cowell): Okay. We will - I'll redo that, with that attention to. Okay?

Dr. Timothy Stenzel: Yes, okay. I hope to help. So, alright. We have time for another caller?

Coordinator: And our next question is from (Coda Moody). You may go ahead.

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

Dr. Timothy Stenzel: Yes, hi.

(Coda Moody): I have a question related to the serology assays. The serology assays, one is for diagnostic, the second one is for screening, and the third one is for surveillance. Can you just, do all three applications need an EUA authorization or the surveillance can be done with the research use only test?

Dr. Timothy Stenzel: So, you have a serology test that measures antibodies?

(Coda Moody): Yes.

Dr. Timothy Stenzel: Okay. Well, they should not be used for diagnosis, and should not be used for screening. They can be used as an aid, and specifically to detect antibodies, and whatever isotypes that you want. And we evaluate and authorize based on that, but there's very specific language that should not be used for sole diagnosis of SARS-CoV-2, which at the moment, and probably for a long time, if not forever, you know, should be a direct detection of the virus assay, whether it's antigen assay or molecular.

As far as surveillance goes, surveillance would be looking at sero-positivity with a serology test. That, we have publicly stated and it's on our FAQ, that surveillance, if it's not reported back to individual patients, it's certainly something that is not something that the FDA, at least for this pandemic, is - has purview over. So, it can be RUO for that purpose, for surveillance, not reporting results back to individual patients.

(Coda Moody): How about screening for the group of people - I mean, it's not - I mean, individual tests are done, but it is done in a group, people returning to work or

some other things? So, they are not for - I mean, again, the antibodies can say only the exposure to the virus or not. So, does that come under EUA authorization, or it does not come under that, just like surveillance?

Dr. Timothy Stenzel: Diagnostic testing and screening are - and reporting results back to individual patients, at a high level, are under the FDA's purview. Surveillance can be done with a non-EUA assay. We ask that it be validated to the same level that an EUA assay would be validated, so that the data that's coming out of that surveillance testing can be relied upon for surveillance information.

But if you're screening individual patients who are not showing symptoms for workplace, return to work, school or return to school, that is something that's very clearly under FDA jurisdiction, and will require an EUA for that. It would be challenging for a serology test to be used in that manner, because you would have to presume that not only do you detect antibodies, but that antibody equals immunity.

And while we're open to developers that want to come in and make claims about immunity, the study design to demonstrate immunity is - could be rather challenging, and we're open to study designs that would show that. I'd also refer you to all the CDC guidance on the use of serology, and for this purpose. Toby, do you have anything else to add?

Toby Lowe: No, I think you said it.

(Coda Moody): Thank you.

Dr. Timothy Stenzel: Yes, okay. Alright, do we have time for another caller? It looks like we do, barely. If there's another caller?

Coordinator: And our next question is from (Julie Larson). You may go ahead.

(Julie Larson): Hi, thanks for taking my question and thanks for holding these meetings. They're very helpful. My question is a follow-on to the earlier question, about template use for sample collection kits consisting of, you know, a swab and viral media. And I just want to confirm an understanding that they would - that those approvals should be thought through the home collection template. Is that correct?

Dr. Timothy Stenzel: Well, if you're going for a home collection claim, yes. And then, I would refer to what Toby relayed, you know, related to developers. Toby, do you want to reiterate anything?

Toby Lowe: I apologize, I didn't quite follow what your question was. Could you just repeat it?

(Julie Larson): Yes, it's a follow-on from the earlier question about viral media and the need for a template for that. And I just wanted to confirm that, you know, for those who don't have an approval and are seeking emergency use approval, it sounded like we were saying use a home collection template information for the viral transport media approval.

Toby Lowe: So, the home collection template includes a lot of information about what we'd be looking for to demonstrate the validation for a collection device. But it is - you know, it has a lot about usability, and its sample stability. And so, that's where I would consider reviewing that with the information that we'd be looking for.

But that, like I said, we're most interested in EUAs for collection devices for things like saliva, where there are not already legally marketed collection

devices. For VTM we could also consider that route, but I would also encourage you to reach out to us through the EUA template mailbox, so that we can discuss your particular situation and see, you know, what the best pathway would be for you.

(Julie Larson): Thank you very much.

Toby Lowe: Sure.

Coordinator: And this concludes the question and answer session. I would now like to turn the call back to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn's webpage, at www.FDA.gov/training/CDRHLearn by Tuesday, July 21. If you have additional questions about today's presentation, please email CDRH-EUA-Template@FDA.HHS.gov.

As always, we appreciate your feedback. As always, at the conclusion of today's presentation, please complete 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. This concludes today's discussion.

Coordinator: And this concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please stand by.

END

