

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

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in listen-only mode. At the end of today's presentation we will conduct a question and answer session. To ask a question please press Star 1. Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the meeting over to Irene Aihie, you may begin.

Irene Aihie: Thank you. Hello, I'm Irene Aihie of CDRH Office of Communication and Education. Welcome to the FDAs 34th in a series of virtual town hall meetings to help answer technical questions about the development and validation of test 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, Toby.

Toby Lowe: Thanks Irene. Thanks everyone for joining us again. We're always glad to have a good audience, good discussion. So my update today is, you may have seen an email announcement that went out on Monday, regarding the FAQ website. I know a lot of you use that site regularly. And we did update it to restructure the entire page. So it looks quite different than it did before. The page had become fairly cumbersome to use with so much content that it became difficult to find what you're looking for. And it also became difficult for our web staff to maintain. So we've updated it to break it out into separate pages for the different sections of questions. And to break the question down into sections that hopefully makes them a little easier to find what you're looking for.

And if you do find that it is difficult to use, or you have thoughts on ways to make it easier to use, please send those and we're always looking for feedback on that. And hopefully you'll find the information to be easier to navigate and to be useful.

And we did also update a few questions while we did the restructuring and added some new information and mostly made some clarifying edits to questions that we had heard were a little bit confusing. Hopefully, that's helpful.

And I will turn it over to Tim for his update.

Tim Stenzel: Thank you, Toby. Yes, welcome again to the session. Obviously, we have a little bit of big news. And that was released yesterday. The FDA has authorized the first COVID-19 test for self-testing at home. This is an entirely self-contained test. And it doesn't require a separate instance. Single use device. And it's a swab based test, molecular based test. And it's pretty good. About 94% PPA or sensitivity in that population.

So it is by prescription. And so we had heard from a number of developers that they might seek the first home test through the prescription pathway as Jeff Shuren and I wrote in September and as I've mentioned multiple times, we are open to over the counter availability of testing, OTC for short. Both on the home collection side and on the home testing side.

As far as I know, the last time I checked, that we have not received any EUAs with complete data for a home test that is over the counter. We look forward to authorizing the first over the counter home test. I think that's going to happen. I can't say exactly when that's going to happen. But again, this is big news of something that I'd hoped for and worked with our team and encouraged the community to develop - a long time. So I'm very happy to see this first example and should see many more coming in.

The second topic I wanted to cover briefly. We continue to get a number of questions frequently about conversion from an EUA authorized test to a test that's fully authorized. For all the SARs related test, that pathway will likely, if not in all cases, be through the de novo pathway for the first submission. And then subsequent submissions after that first grant of de novo will be through the 510(k) pathway.

And we'll work with -- if we get multiple submissions for de novos, we'll work with developers to authorize as soon as we can.

But just so you know, not all - only the first submission is the one that is required to pay the de novo fee and we'll work with all others after that. And it's something that we've handled before prior to the pandemic. So once we grant that first de novo, there will be special controls written. These are special -- these are instructions for developers to follow in order to fall within the grant - that pathway, that newly created pathway regulation.

To tell developers that this is what we expect to see. And obviously that's going to be in line with our thinking and interactive review that we share with developers, so that anyone who has submitted a de novo, will get that feedback from this. And then, you know, thereafter special controls and at first glance becomes publicly known and we post the summary statements, then that's for all to see about what our current thinking is, short of approaching this.

We are inundated with both COVID related application and our normal volume of non COVID applications in our office. They are - the non COVID related applications are just as numerous as they have ever been, if not more. So we, you know, one of those things that we have decided that for Q subs and pre submissions is a bit challenging for us to answer all of those. So we do hope to provide more information as time goes along for, you know, what are what is our thinking about conversion.

But a good guide would be, you know, what we've done for similar tests in the past. That will cover the vast bulk of questions, you know, is to look through previous authorization for respiratory viruses in recent ones, especially for and this is for 510(k) most of the time, for panel tests, for individual molecular

tests, and the panel test could be antigen or molecular. And also for serology tests.

So we do want to be as informative as we can area. However, our focus still remains on getting through the many, many EUA applications we have coming to a decision point. The current thought is that guidance is being drafted by OPEQ and the center that will cover diagnostics. And as soon as we can make that draft available we will. I can't promise when that will be available. But obviously we're thinking about this and thinking about how to provide developers with more directions. We're also - that will have important timeline. And we want to establish timelines for each of the technologies and the types of devices that makes sense.

We hope that you feel that as well. We are really looking to support all COVID, really, developers through this process so that everybody has good chance to get through that conversion. And the timelines aren't too short. So stay tuned on that. I can't promise again when that draft guidance will be issued, but as soon as we can, we will.

With that I think we can go to the open line and to Q&A. Thank you.

Coordinator: Thank you. At this time, we will now begin the question and answer session. If you would like to ask a question, please press Star 1. Please unmute your phone and record your first and last name clearly when prompted. Your name is required to introduce your question.

To withdraw your question, you may press Star 2. Once again, at this time, if you would like to ask a question, please press Star 1.

And our first question is from (Shannon Clark). Your line is open.

(Shannon Clark): Hi, this is (Shannon Clark) of User Wise Consulting. Thanks for taking my call. And I'm very excited that we have this first home use kit approved, very excited about that authorized, I mean. And thank you, Dr. Lowe, if you're on the line, for replying to my question.

This week, we have templates email. This is a follow up question about conducting point of care testing with non-laboratory personnel. So imagine that we're observing a healthcare provider using an antibody test kit as part of this point of care testing. And in step seven, or a step in the instruction, it notes to wait 15 minutes before reading the results. So if the healthcare provider does not wait 15 minutes, can we ask them after the session to please review step seven before proceeding with their next 25 patients? Or should we allow the health care provider to repeat this error with the next 25 patients as part of this point of care testing?

Tim Stenzel: So that's really part of this guidance and I understand the challenge. The participants are required to follow the material that you will have only in the kit to perform the testing. But we're asking that the observer don't interfere in that kind of in that testing.

So obviously, you want to - I think it's important that you choose sites correctly. They can be experienced from performing other point of care tests, but we don't want specific training other than what is present that they can read in the kit. And you know, that is one of those risks.

You know, hopefully that's specific enough, you know, for specific applications or situations that you reach out to us; we can provide more feedback on that. But that is one of the challenges you as the developer, or

sponsor are not going to be there when after authorization and can correct somebody.

(Shannon Clark): Yes, and your sponsor certainly aligns with the 2016 CDRH Human Factors guidance, they are interested in adhering to the instructions. So we'll take care of the not bias users as part of this testing towards following the instructions once they get started. I think your response makes a lot of sense.

Tim Stenzel: Thank you.

Coordinator: Our next question is from (Mark Hackman). Your line is open.

(Mark Hackman): Yes. Good morning, Tim. Good morning, Toby. Good afternoon. I'm on the left coast. So it's still morning time for me. I echo what the previous caller said about the approval of the new first home device. Just, you know, I'm having a real hard time hearing Tim when he talks. It sounds like he's going through a typewriter. But I think I caught what he said. But I just wanted to reiterate - just make sure I did. Did he say that the agency is still looking for people to submit fully at home tests, which other sample types, like a finger stick test - a finger stick sample is going to be used? Are they still welcoming these types of tests, please?

Tim Stenzel: I just switched my - to do earphones. Is this any better for you?

(Mark Hackman): Yes, it's a little better. Thank you very much.

Tim Stenzel: Okay, sorry about that. So, yes, we are welcoming all COVID tests for home use - antigen, molecular and serology. So, you know, they all can play a role in this pandemic, and so we're not steering anyone away. We don't have a published template for serology tests for home collection, or for home testing,

but they have been drafted and they've cleared my desk. And so we're awaiting for final clearance and that's so we can post. And, of course, I can't tell you - I can't predict exactly when that will be.

And - but in the interim, if you send emails to the templates, email address specific emails about anything specific related to home serology collection or serology testing, I've given our reviewers and our staff permission to relay our current thinking. It won't be complete draft of the template, but it will provide the specific information that we've drafted, that you request and our current thinking. But, you know, they will probably say wait for our final clearance, cleared templates.

(Mark Hackman): Okay, thanks very much. Have a great day, guys.

Coordinator: Our next question is from (Lewis Perlmutter). Your line is open.

(Lewis Perlmutter): Yes, again, I iterate the same thing that you talked about the home testing. Can you elaborate? Can you say which company is producing that? And I think you said it was a molecular test, correct?

Tim Stenzel: Yes, it was a molecular test. It was a real time loop mediated amplification reaction. So it runs in about 30 minutes.

(Lewis Perlmutter): Okay and can you mention the company or I guess I missed that.

Tim Stenzel: It was Lucira. L-U-C-I-R-A.

(Lewis Perlmutter) Yes and then I have some comments about the rapid antigen test.

It's been a while since we've had, or something that's come on the market for rapid antigen test. It just seems that it takes so long to get these tests approval. It is because of the negative or the false negatives and false positives that's inhibiting these tests to get marketed or what is the problem?

Tim Stenzel: So rapid antigen tests are a priority in the office. And we've authorized, I believe, seven to date. I'll say that we have denied authorizations to some. I'm not going to mention names. Confidential information. The scale of authorization and the rate of authorization really depends on, you know, the applications we receive. Are they complete? Is the test accurate? And can they authorize it without asking the sponsors for additional work?

The antigen team, I think, has done a pretty good job when something is able to be authorized to move it through quickly and get it authorize.

(Lewis Perlmutter): Tim, where can I find the seven that have been approved?

Tim Stenzel: So we have an EUA, IVD, FDA page that lists for all of the test types, not just the antigen tests, but the molecular and serology tests as well. And shortly after authorization, we post a new test. So that - I don't know if the Lucira test of yet public there, but we, in this case with the FDA, did issue a press release to announce that.

(Lewis Perlmutter): Just a thought. I'm just wondering, hopefully with the new task force coming through in a month or so, that they develop a national testing policy, because that's really badly needed. Because there doesn't seem to be standardized very much. And I just wondering what your thoughts are on that?

Tim Stenzel: Yes, no, I'm a good soldier. So I've been asked to speed access to accurate testing through the authorization process. And end of the day, we've authorized almost 300 tests of all now different shapes and types. And, you know, I think it's upwards of 600 through additional notification pathways. So almost 1000 tests to date, which is my role and the federal government, so it's the others in the task force, perhaps, who could better address that question.

(Lewis Perlmutter): I appreciate that Tim. Anyway, thanks very much.

Coordinator: Our next question is from (Savannah Estes). Your line is open.

(Savannah Estes): Hello, this is (Savannah Estes) with User Wise Consulting. Thank you, again, for hosting there's these calls. They're very helpful. My question is about human factors. In observational Human Factors study, we record all instances of difficulties, close calls and use errors. For the purposes of point of care testing, can we report exclusively on the comparative quantitative results in use errors that influence the quantitative results, as well as user feedback relevant to use safety? Mostly because compiling analyzing or reporting on all difficulties, close calls and these errors is a very significant resource investment. And we're wondering if we could keep the data on file, instead of submitting it with EUA.

And just to give you some background, this scheme, to us, seems reasonable because observation of user interaction is optional in the template. So we could admit to collect this data altogether and just ask for subjective feedback from the healthcare professionals.

Tim Stenzel: Yes. I mean, we typically go by our recommendations in the template, and I'd have to check this specific recommendation in order to make an authorization determination.

The subjective questions may prompt additional questions from the FDA review staff, but may be informed by the additional data that you have. I would let the team know that you have the additional data, you can provide it if needed. But that you'd like to, go ahead with subjective responses.

(Savannah Estes): Okay. So for point of care testing, you believe that that would be a reasonable approach?

Tim Stenzel: Well, I'm sure and I have to refresh my memory on what user studies recommendations are for point of care. And I just don't have that at my fingertips. So the - at the template's email address, I think you can get a clarification on that, or when you get assigned a review. So but if you have all that data, that's great. I just don't know if the reviewers are going to want to see that upfront or not. You know, having that is great. And if needed, they can ask for it. But I really can't. And I'd have to review that template.

Unless Toby, you have a response for that.

Toby Lowe: Yes. I was going to say generally we would request that you submit all the data to us. It does make it easier for the review teams to complete their review without having to do quite as much back and forth. Typically, if you provide some subjective data, they will - the reviewers will often look at that and want to see the underlying data behind it.

So you definitely could submit, you know, the partial data and include, you know, include a notation that the additional data is available upon request. I

would just make sure that you're prepared to provide it since it is generally likely that the reviewers will ask to see that depending on their review of what you do provide.

(Savannah Estes): Okay, thank you. I appreciate it.

Coordinator: Our next question is from (Griffin Soriano). Your line is open.

(Griffin Soriano): Hi, good afternoon. Thank you for taking my question. I just wanted to know, you know, if the pace of EUAs has nslowed down a bit. I think last week was the first week since March that there wasn't an EUA granted for an individual COVID test.

Is that a result of resource constraints as you kind of alluded to in your prepared remarks? Or is the FDA rethinking that process or priorities just how we should think about that would be great.

Tim Stenzel: I missed the first part of that question. I apologize. Could you repeat the question?

(Griffin Soriano): It's just the pace of EUAs. I think, as I said last week, was - I think the first week since March, so there wasn't an individual EUA granted for a COVID test. Just how we should think about that pace and whether or not it's a result of resource constraints or rethinking of the EUA process on your part.

Tim Stenzel: Yes, well, it's kind of - it's somewhat of the reverse. And then we don't make denials public. So - and there has been an increasing number of denials. So it's actually been, as far as resource goes - we've added resources. But when you add folks who need to be trained, it can slow some things down. And, obviously, I've been fairly transparent on this town hall I continue to be.

And so we've more than doubled our staff. That and we took them off of non COVID work.

And they - unfortunately, some folks who have submitted some developers who have submitted non COVID applications, have heard there could be some delays on their non COVID work. We have been communicating that clearly.

But our staff - our leaders tell me that additional staff, the doubling of staff, in the surge, it's about a 90 day surge, will result in more speedy reviews going forward. And that was our focus. But there's been a slight pause for training of these people, which has devoted some attention temporarily.

(Griffin Soriano): Thank you.

Coordinator: Our next question is from (Lonnie Edelman). Your line is open. Once again, (Lonnie Edelman), your line is open.

(Lonnie Edelman): Yes, I'm sorry, I was on mute. This is (Lonnie), where - I'm from MyAssay we have this universal radio. We spoke before and asked a few questions. My question today is we've been expecting a new template for serology. The last one we saw was, I believe, end of June. One came up for antigen and we were thinking that there would be a new one coming out. Actually, I think a couple weeks ago. I was wondering, is there one there and we didn't see it? Or is there a scheduled date for the updated template?

Tim Stenzel: It's, you know, it's under the clearance process right now, along with a number of other new templates, new template updates. So I cannot predict when it will finish - that clearance process and then be able to be posted.

Toby, you may have some additional information you can provide.

Toby Lowe: No, we can't predict - just like you said, we can't predict the date, but it is something that we are working on getting out as soon as possible.

(Lonnie Edelman): Okay, thanks a lot.

Coordinator: Our next question is from (Chris Shede). Your line is open.

(Chris Shede): Hi, my name is (Chris) and I'm the founder of RapidTest.org. I have a question about the requirement for public health antigen tests to show data on asymptomatics. So in the past couple of weeks, there are two new preprints on antigen tests that have shown something that I think is very important and interesting.

So while coot sensitivity differs between symptomatic and asymptomatic, both studies showed very clearly that if you restrict the analysis to cases with high viral load, meaning those that are likely to be contagious, the sensitivity of the antigen test is 90% in both symptomatics and asymptomatics.

So my question is, if someone submits an EUA for a public health antigen test designed to detect contagious individuals and if they can show 90% sensitivity and high viral load that is contagious symptomatics, shouldn't we reasonably conclude that the test will also have 90% sensitivity in the high viral load asymptomatics? And if so, could this mean we may consider dropping the requirement for asymptomatic data?

Tim Stenzel: Some of the preprints I've seen maybe the same ones that you're referring to show about an 80% sensitivity of a particular brand - a decent brand, I think, that has about an 80% sensitivity relative to PCR. And in symptomatic

population and the different studies varied a little bit on the asymptomatic sensitivity, but it was in that 30 to 40% range.

So I don't know the preprints that you're referring to. The challenge for us is that we want to ensure that there's good accurate testing available.

What matters in our current reviews is the performance and the first five days minimally of symptoms or the equivalent period. And so this does present a regulatory challenge when it comes to how do we study the asymptomatic population.

But I will say that we're aware of numerous data that have shown that in the symptomatic population, that CTs can be extremely high. You know, well above 30 and above 35, in the first five days of symptoms.

And so to simply use a cycle thresholds to restrict the data would, you know, in the symptomatic population, withhold data that is important for us to look at. So why that is? This has been repeated through numerous data sets that I have been able to access. And why that is? I'm still trying to understand. Could it be the biology? Could it be the sampling? How good the sampling is? How good the swab is? How good the saliva collection is? Whatever it might be.

That is a challenge for us, because we're assuming, I think with good reason, that the first five days of symptoms, somebody is contagious. That consistent in the data too and the fact that you have the variability by CT adds quite a challenge for our reviews.

So we're, you know, we can authorize a test, that in the asymptomatic population, has a lower sensitivity, you know, if there's mitigation. So one of

those mitigations is that a health care worker is involved, so it's by prescription. When you refer to public health, if it's totally a surveillance program where individual results are not returned to patients in a sort of CLIA testing manner.

But rather, groups of people are referred to CLIA testing within that purely surveillance testing. Surveillance pure testing is as defined by the CDC, CMS and FDA website is not something that the FDA is regulating. When it comes into asymptomatic screening, we want to return the result to an individual patient through a CLIA lab result that we do regulate.

But no, I understand the challenge here. But we can find mitigations. One of those mitigations is that it be by prescription and then healthcare workers are involved.

(Chris Shede): I just wanted to add one quick comment. From our perspective, where the goal is to detect contagiousness, the key thing that matters is viral load. Perhaps it's measured by CT value. And you know, there are differences in CT value between a symptomatic and asymptomatics. But from our perspective, that's sort of a bit beside the point. When you have two samples with the same CT value, it doesn't really matter whether it comes from asymptomatic, or symptomatic. All that matters is the viral load. And the test depends on that. And it doesn't directly depend on whether the person is symptomatic or asymptomatic if that makes sense.

Tim Stenzel: Yes, I know what you're saying. I think the CDC has a great paper on cautions against the CT values. And I've read that paper obviously. And I agree with many of the scientific concepts in it. Just because the CT value is high doesn't mean the patient's viral load isn't high. That's our challenge.

(Chris Shede): Okay. Thank you.

Coordinator: Our next question is from (Carolyn Schmidt). Your line is open.

(Carolyn Schmidt): Hello, thank you for taking my question. My question is regarding the antigen template for test developers.

Page 15 of the template speaks to swabs being taken from the same anatomical area for the comparator and subject device. And my question is, does the FDA view swabs that are collected from the mid turbinate area and from the nasal pharyngeal area as being collected from the same anatomical site from both of those things being from the nasal sites?

Tim Stenzel: So, we would be transparent in however the sponsor, the developer did the study whether it's the nasal pharyngeal or mid- turbinate. But you may be asking can you replace, where we might recommend, or ideally in a nasal pharyngeal swab may be used, would we allow a mid-terbinate swab? Yes. So, you know, we - that would be an acceptable alternative for where we want - typically would want a nasal pharyngeal swab. There may be a direct sort of study you're thinking about.

But the one area that I remember currently where we want to see a good swab and not a nasal swab, not an anterior nasal swab, is when we evaluate saliva or fluid base test. We still want to see preferably a nasal pharyngeal swab, but if it's difficult, we have been allowing mid-turbinate swabs to be used. But in many other applications, we don't require either a mid-turbinate or a nasal pharyngeal swab. That's up to the sponsor.

There may be some tests that, in order to increase the sensitivity, you want mid-turbinate or nasal pharyngeal swab. And that's up to your developer.

Does that address your question?

(Carolyn Schmidt): It did. Thank you very much.

Tim Stenzel: You're welcome. And I wanted to follow up on the last caller. I think I misstated something. And what I was saying is in symptomatic patients, even though the CT results may be very high, that doesn't mean - we're not sure if that translates to infectivity and necessarily to a low viral load. There are other variables that we don't know how to control for yet, such as sample collection, or the biology. Are they expressing high viral load in their nasal or oral fluid sample?

So we just, you know, we're concerned, anytime we see a miss by a test for symptomatic patients in the first five days of symptoms. We expect performance to be relatively high in that period by whatever method is used.

Thanks we're ready for the next question.

Coordinator: Our next question is from (Christian Bangar). Your line is open.

(Christian Bangar): Hello. Thank you for taking my call. I just had a quick question. I understand that the FDA is prioritizing review of tests, where authorizations would increase the testing accessibility or increase testing capacity. But with the flu season upon us and across critical need to differentiate between SARS and flu infection, are multi analyte tests also being prioritized for EUA review?

Tim Stenzel: Yes, in general - yes. We will prioritize based on the access to that test once authorized if we have multiple, you know, submissions. So - and, of course,

there's still the notification pathway. Well, not for - I'm sorry, not for panel tests. For every other test, essentially the notification, not the panel test.

So - because the panel tests do require an authorization, we are making that a priority. But within that category, we would prioritize those submissions that provide the greatest impact from a public health perspective.

You know, anything that can be authorized, we want to move it through that pathway as quickly as possible. That's for sure. But we are being challenged by the number applications, even the ones that do require authorization. Which is why we added additional staff - doubled our staff.

(Christian Bangar): Okay, thank you so much.

Coordinator: Our next question is from (Franco Calderon). Your line is open.

(Franco Calderon): Thank you for taking my call. So my question is going to have a couple of parts. So the first part has to do with the institution that I am teaming up to do my clinical validation. It's an academic institution here in Texas. And they are performing the clinical part quite well. It's going kind of slow because of the low incidence. But they have a question regarding the cross reactivity information that we need to report.

Does FDA provide any resources, perhaps panel, for the cross reactivity information part of the test? So that's one. The other question is if we're going to be making a claim for OTC use, I noticed that on the last test, or the first home test that FDA approved, the youngest age is, I think, 14 years old. So does that mean that we need to show that if we're going to be making that age claim, does that mean that younger children cannot perform a, let's say, a nasal swab by themselves if they're being coached? How does that work?

Further to the specimen question, if we want to show that the test works with nasal swabs, let's say buccal swabs, do we have to submit the information for those too? I'm guessing that we do so.

Tim Stenzel: So, a couple of questions. You're developing a kit and it sounds like it's for a molecular? Is that correct?

(Franco Calderon): No, I'm sorry. This is an antigen. It's a pure, naked paper strip.

Tim Stenzel: Okay, until you asked about the buccal swab, I was thinking molecular and then I was thinking antigen to molecular and so the buccal swab would obviously be a new sample type and would need to be validated by you and performance acceptable for us to authorize for an antigen test. And the same thing goes for a molecular. But I was curious.

As far as - I will need to dig into some of the details about the first home test authorization. But I may not be able to share, due the proprietary confidentiality reasons. But I'll say in general - and I don't know of anything that's not acceptable about this first home test, but in general, we make decisions based on data, of course, if not in all cases.

So we definitely have allowed children to be tested. And we allow an adult present to swab in clinical studies and to support an authorization. I will say, though, you know, if a developer has not shown that an adult in the home can adequately swab a child in the home, then we wouldn't have data to make an assessment about whether or not that can be authorized because there is an age and this is, you know, we have pediatrician on our staff.

There's an age at which we're just not sure if somebody can accurately self-collect and run a test uniquely so. But as far as the collection part of the home

test, if a developer comes in with data that shows an adult can swab a child, then we'll - and the data looked good, obviously, then we will authorize that as well, whether it's OTC or prescription, it doesn't really matter.

And as far as cross reactivity goes for antigen test, I think I would - if you could, and Toby may know, but my recommendation is to send something to our template's email box about that. I don't know if we have a list of providers, we can share that, make samples available or not. We are sometimes hesitant if we can't vouch for the quality of those panels from the FDA perspective and - but there may be resources out there that we can point you to as a possibility.

But of course, with molecular tests, you know, we have allowed in silico analysis. It's much harder to do that sort of thing, obviously, with antigen tests.

Toby, do you have anything to add about any of those questions and my answers?

Toby Lowe: No, I think just what you said, there's information in the template about performing those studies and if you need assistance, finding where to get, you know, where to buy organisms to test for cluster activity, you can send it to the mailbox and we'll see if we have anyone that we can point you to.

(Franco Calderon): Okay. Thank you. Just to that to that last comment. I do have an assigned reviewer. So would it make sense for me to just communicate with that person?

Tim Stenzel: Yes.

Toby Lowe: Yes.

(Franco Calderon): Okay. Great. Thank you.

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

(Daniela Lloyd): Hi, first of all, thank you guys so much for the update to the website. That is awesome. It really was getting unwieldy. Second, perhaps I missed this, in the phase where Tim sounded like he was speaking through a typewriter, as someone said, one concern that you all had raised that we share is the notion of results, you know, in the home, how they are going to be shared back into surveillance efforts and back to the providers in the care planning.

So not sure if you can discuss and share a little bit about how that closing of the loop will occur with this new test where the result is provided, you know, furnished to the patient there in the home.

Tim Stenzel: So as far as requirements for reporting from home testing, that is not within a CLIA lab and it is my understanding that there is not the legal requirement to report. There might be, you know, a public health service sort of bent to wanting to make sure that those results get reported. But I would refer you to CMS, who are the ones that get the final word on those reports required for reporting or the CDC.

And so as a result, we asked for home tests. We ask developers to please give us, you know, your thoughts about how you might make it possible to report those results. But we don't make it a review requirement that there be something in place. We just think that it's something that's a responsible thing to do is to find a way.

Now, of course on Monday, this week, there was an app design-athon for reporting COVID results publicly announced by the department and other entities within the US government.

And we're hoping that those applications, that are developed, will allow any developer sort of connect up with an even home test use situations where a consumer could use an app to report their results.

So I hope that interest all of your questions.

(Daniela Lloyd): That's great. It's just - you say that you ask for them to share thoughts on how that might happen. Is the response in that respect public somewhere as part of the review materials or?

Tim Stenzel: You know, that's a great question. Toby may know this. Obviously, if there is some sort of app that's associated with a test, that's usually mentioned in the authorization if it was submitted with the application and it was part of the application. But, you know, it would depend on the situation on exactly what the apps doing, whether or not we would require an FDA review because it is - the software is a medical device. And that's an entirely different regulation which can be very complicated.

But where, you know, where there's an instrument that has connectivity, that would genuinely be in the instructions for use in what we authorize.

Toby Lowe: And I believe for the one that was authorized yesterday, there is a condition of authorization that they will develop a mobile app or website to further facilitate reporting results.

(Daniela Lloyd): Great, thanks so much.

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

(Oliver Lizenhawl): Thank you for taking my question. FDA has authorized many diagnostic tests for SARS Corona, and only very few prognostic tests. I'm thinking about interleukin-6, which I think the two manufacturers have been given authorization. What is FDA's idea about manufacturers developing tests that would provide both a diagnostic and a prognostic result? And as your template is obviously helpful for the diagnostic test, how should a manufacturer go about the PEUA?

Tim Stenzel: So anything that's not involved with direct detection of virus antigen molecular or direct detected detection of antibodies in serology tests, we would evaluate those requests for feedback on a case by case basis and turn that over to the division within our office that most closely aligns with the technology.

So for example, our microbiology division did not review IL-6 application. That was reviewed by our immunology and hematology group who was used to reviewing that kind of application.

(Oliver Lizenhawl): Okay.

Tim Stenzel: And because we can't anticipate what developers are going to come up with, it's hard to put together any sort of template like we've done for most everything else. But templates are relatively new for us to do. And we, you know, it's not something that we've traditionally done. And we just knew that it would be helpful. And after we developed the first template and continued to work on that, we decided we would template everything, you know, that we could.

Those things that we were going to see enough repetition of where it makes sense to dedicate resources to develop the template.

Otherwise, the more unique tests will, you know, provide more, you know, specific information on a case by case basis. Once you submit your idea to us, to the templates email box, we will push that to the appropriate division who can provide feedback on it and make a determination whether it's EUA eligible.

(Oliver Lizabeth): Okay. Thank you very much.

Coordinator: I'm showing - we have no further time for questions. I would now turn the conference back over to Irene.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the CDRH Learn webpage at www.fda.gov/training/cdrhlearn by Monday, November 30.

If you have additional questions about today's presentation, please email cdrh-eua-templates@fda.hhs.gov.

As always, we appreciate your feedback. Following the conclusion of the presentation, please complete a short 13 questions 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. And this concludes today's discussion.

Coordinator: Thank you for your participation. Participants, you may disconnect at this time.

END