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 a listen-only mode until the question-and-answer portion of today's call. During that time, if you would like 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 am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's 42nd 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, Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, and Timothy Stenzel, 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 the development and validation of tests for SARS CoV-2. Please remember that during this Town Hall, we are not able to respond to questions about specific submissions that are under review.

Now, I give you Toby.

Toby Lowe: Thanks, Irene. Thanks everyone for joining us again today.

First, we have a new funding opportunity to tell you about. There should be a slide showing now that has some additional information about this. This is a funding opportunity for COVID-19-related diagnostics that opened on February 5.

FDA is not leading this effort, but we wanted to flag it for you. It's being coordinated by HHS OASH, Office of Assistant Secretary for Health, and the DoD, and it's open until March 7. The slide that's showing now has more details, including a link for information and the process for submitting proposals. And we will get the slide deck posted on our Website on the Town Hall page either later this week or when we post the transcript.

So, this is an Area of Interest, or an AOI, that's soliciting for proposals where you may request investment funding for capacity expansion and provide price quotes for raw materials, test components, supplies, et cetera for COVID-19 point-of-care tests and other IVDs. This is an expedited process that's coordinated by HHS and OASH and DoD to support the government's

COVID-19 response to rapidly increase manufacturing capabilities within the diagnostic supply chain.

So, with that, we can go on to the next slide, Irene.

And we've added a couple of additional links to this slide as well that we think will be helpful resources for you. One of them is the January 2021 HHS FAQ on COVID-19 diagnostic data standards and core data elements for test reporting.

And then the next one is the HHS COVID-19 testing and diagnostics working group additional testing information. So, those links will be up on the slides that will get posted as well and may have some helpful information for you.

And then my last update is that we had a question last week about UDI, Unique Device Identifiers, and whether UDI is required for EUA devices. And generally, for - at least for the diagnostics, UDI has not been included as a condition of authorization. So, we would not typically expect a UDI unless it is included as a condition of authorization in the letter - the EUA letters.

However, there's no restriction from providing UDIs, which many manufacturers do, and this is really helpful because the device identifier is a required data element to fulfill the laboratory reporting requirements listed in the HHS COVID-19 laboratory data reporting guidance. So that was just a follow-up from last week's call.

And with that, I think we can turn it over to questions.

Irene Aihie: Operator, we'll now take questions.

Coordinator: Thank you. 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. Also, we ask that you limit yourself to one 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 Christy Bergerson. Your line is open.

Christy Bergerson: Great. It's Christy Bergerson from Exponent again. I wanted to ask you about transferring ownership. So, is there a process for transferring ownership of the EUA, such that a new developer would take on the responsibility for deployment and liability? And also, when should that happen? Should we wait until after authorization, or could it occur at any time?

Timothy Stenzel: If it's preauthorization, let's take care of that prior to authorization. If it's post-authorization, just go ahead and contact the Reviewer to review what they may have to update.

Toby, you have anything to add?

Toby Lowe: Yes, I think that's absolutely correct.

Coordinator: Our next question is from Shannon Clark. Your line is open.

Shannon Clark: Hi, this is Shannon Clark with UserWise Consulting. We specialize in home-use human factors testing.

So, if an antigen test kit developer fulfills all requirements for over-the-counter home use noted in the molecular and antigen diagnostic COVID-19

tests for non-laboratory use template, including clinical evaluation, and basically fill all the requirements there, then will they automatically receive authorization for selling to moderate, high, and point-of-care contexts without having to do further testing with five-to-six non-laboratorians, like health care providers and at least 30 positive samples?

Timothy Stenzel: Yes, it already - automatically gets a deemed waived status, and waived tests can be performed in CLIA waived settings as well as moderate- and high-complexity labs.

Coordinator: Our next question…

Timothy Stenzel: And…

((Crosstalk))

Timothy Stenzel: Okay, go ahead.

Coordinator: Oh, I'm sorry. Our next question is from…

Timothy Stenzel: I think I answered the question. Thanks (over there).

Coordinator: You're welcome.

The next question is from (Gary Block). Your line is open.

(Gary Block): Hi, Tim. We are a sample collection device manufacturer, and we want to know if we can apply for an EUA making the following claims: We're not an assay developer, so the current templates probably don't apply to us. But

specifically, we wanted to claim for SARS that our sample collection can detect SARS.

The second claim is that we want to make a home collection claim that it's safe to be collected at home.

The third thing is that our sample collection collects from the area of the nasal cavity, the nasal pharynx, and all the pharynx, and the device also concentrates it. So, we get a very high level of viral load.

We also wanted to make a claim that our sampling device can be used across all platforms - all molecular platforms, molecular point-of-care platforms, and over-the-counter molecular or immunoassay platforms. Obviously, we would provide data that our sample met the required threshold line.

We don't necessarily want to be - we don't necessarily want to partner with other assay developers as that would significantly limit out market exposure to any specific assay. Thank you.

Timothy Stenzel: Uh-huh. Stay on because there may be some clarifying questions. We definitely want Toby's help on this as well.

So, yes, if you make any claims about SARS, it's important to get an EUA authorization about a device - a collection device.

And then, of course, the validation that we would ask for could depend on whether you're going for a prescription-use device or an over-the-counter device. And so, I'd refer to the templates for home collection for the different recommendations for validation of those.

You know, if you've got a device that might increase sensitivity through concentration, that's great. We'll just, you know, want to make sure that it works.

And then, as far as how broadly you can claim for use with molecular assays, you know, I would ask that you come in with a protocol and a pre-EUA with a study plan to demonstrate that.

So, we typically have been authorizing these collection devices in a kit based on single-test data. We are making it relatively easy for other tests to be added.

But to date, we have been asking for data for the test that it's going to be used with to make sure that it performs well in the marketplace.

Toby, do you have anything to add?

(Gary Block): I'm sorry?

Toby Lowe: I think that covers everything that I would have - all the points that I was planning to make it on. Yes.

Timothy Stenzel: Okay. I wrote it to Toby's standard. I did well.

(Gary Block): Okay, if I can just add, if we would, for example, demonstrate, you know, our platform - so for, let's say, just as an example, three or four amino assay platforms, and three or four point-of-care items assembled, you know, platforms, and several molecular platforms, would there be a chance that would be enough to show that this works, I guess, just as well with all when

you compare the swab across, and therefore, that can be extrapolated for use across all platforms?

Timothy Stenzel: We're open to creativity here. And so, I can't make any promises, but you know, something along those lines is something that we can certainly consider.

Coordinator: Thank you. Our next question is from (Thomas Knott). Your line is open.

(Thomas Knott): Hi. Thanks for taking my call. Representing a firm that has a device that - detecting COVID, but it's not ELISA serology or antigen tests or PCR tests. And it uses kind of a non-typical specimen. It's not invasive at all - very safe. It's portable. It could be set up in an industrial or academic setting, and the analysis takes minutes.

It's envisioned that it would use as a screening for a large number of participants - say, you know, in an academic setting or something like that - identifying negative subjects who would go on - with, of course, using precautions with their normal activities. And those that are positive would be directed to take another confirmatory test.

So, what - we need to know what you would like to see in an EUA application, or beyond that, a 510(k) or De Novo. So, interested in the process, or maybe if we could set up a meeting, and how would I do that?

Timothy Stenzel: Okay. I didn't catch the actual technology that you were mentioning. We have, for example, developed some recommendations that we can share for breath tests that work with…

((Crosstalk))

Thomas Knott: That's what this one - it's a breath test, yes.

Timothy Stenzel: Okay. So, if you email our templates email box and ask for the breath test recommendation, they can provide you with their current thinking. And we are obviously working towards a template eventually, but it's not all ready, and it's not obviously not been cleared, otherwise we would post it.

Thomas Knott: Okay.

Timothy Stenzel: But we do have - a significant amount of thinking, already, and you can check the transcripts from last week because I went into some detail about our current thinking on breath tests, which may provide a little bit more information than our templates email box will respond with on our current recommendations for current thinking about recommendations for breath test validations.

Coordinator: Our next question is from Jessica DeLalio. Your line is open.

Jessica DeLalio: Hi there. Thanks for taking my call. Can you please provide an update on FDA's review of laboratory-developed COVID-19 tests because it's my understanding that HHS has contracted with NDA partners to help with their review of LDT EUAs. And also, that NCI may have some role to play.

So, at this time, should LDT developers continue to submit their EUAs to FDA? And does FDA have any additional details on either of the two alternative reviewers?

Timothy Stenzel: Thanks for that question. We at this time are still in dialog with HHS on this matter. Toby, do you have anything else on it?

Toby Lowe: No, that's correct. We're engaging with HHS on that matter.

Coordinator: Our next question is from Michelle Rubin-Onur. Your line is open.

Michelle Rubin-Onur: Hello. Can you hear me?

Timothy Stenzel: Yes.

Michelle Rubin-Onur: Perfect. Thank you. Thank you for taking my question.

My question is, would FDA find value in home-use serology testing and how it can support the vaccination efforts in determination of potential immunity for people who have either had COVID or have had the vaccine?

And does FDA expect to release a template for this type of product?

Timothy Stenzel: We've drafted a template for home serology testing. It's not been cleared. As soon as it's cleared, we will post it. You can send an email to our template email box, and we'll give you our current thinking about recommendations for home serology tests.

And if you are interested in any authorizations relative to vaccines, then we would ask you to draft a study design to demonstrate what you want to claim for your device and submit that study design as a pre-EUA for our consideration.

Coordinator: Thank you. Our next question is from (Yousef Peterson). Your line is open.

(Yousef Peterson): First of all, thank you so much for hosting these calls. I'm the CEO and Co-Founder of a clinical CLIA lab in Boston, and we're doing COVID testing.

I have a question about the process to validate tests that detects these new variants that we are seeing. Right now, we are only testing the standard test, but I see that becoming increasingly important.

Timothy Stenzel: Okay. I just want to clarify. You want to know what we recommend for variant testing?

(Yousef Peterson): Yes.

Timothy Stenzel: Okay.

(Yousef Peterson): How would we go about getting an EUA for a variant test, compared to the current template for the standard PCR test?

Timothy Stenzel: Right. So, our current thinking on this - because there are so many mutations, and the number of variants that is - that are present and of concern is growing and there's many different mentions of that.

Whole-genome sequencing may be a good modality to do genotyping because mutations can occur, you know, anywhere in the virus, and then we want to know about that. However, we are accepting applications for any subset of variants that a developer wants to review.

I would hope that any work you do around variant testing wouldn't be of value for just a short amount of time. So, it's something to consider as you develop an assay because, you know, as soon as you might have a, you know,

a test that can identify the Brazilian, the UK and the South African variants and their various branches, you know, there may be some - a new variant that's, you know, of importance that's not on your test.

So, that's just, you know, the challenge in the current state of the pandemic, and with the biology that the virus has presented - the biological challenges that the virus is giving us right now.

Coordinator: Our next question is from Ron Domingo. Your line is open.

Ron Domingo: Hi. Thank you for the Town Hall. We're a company that's initiating studies for home collection and tests of a rapid antigen test, and it's using a cartridge, a reader, and a phone app.

So, we're using Abbott Binax as a model, and we understand from the authorization provided that it's the obligation of the EUA holder to ensure that the telehealth provider has systems in place to properly manage prescriber obligation and patient support.

So, based on this, can FDA confirm that the EUA can be authorized without a specific telehealth provider identified in the EUA?

Timothy Stenzel: Let me ask a clarifying question. Do you - so we don't require that you use a telehealth provider. That's up to the test developer for home testing. So, if you choose to do so, you know, we would evaluate what they would do. Like if they're online instructing a user how to use the test and get an accurate result, then we would look at that protocol that the telehealth provider would be going through.

So, you know, if it was the same protocol, reviewers may be open to not limiting it to one telehealth provider if they have a standard protocol they're going through. And it doesn't necessarily matter who it is as long as those people are trained appropriately to be able to manage that call.

And of course, there's a prescription pathway and an over-the-counter pathway for home testing. We are encouraging people to try to get over-the-counter testing, which does not require a prescription, and therefore, you know, there's perhaps a greater ease of access to that kind of testing.

The thing with the telehealth provider is it could add cost, and I know there's lots of folks who'd like to keep the cost down for this home testing as low as possible. So, those are just factors to consider.

But it's up to the developer, like yourself, to decide the method that you're going to do home testing, and the pathway and what claims you are going to go for.

Coordinator: Our next question is from Cheryl Skinner. Your line is open.

Cheryl Skinner: Hi, yes, can you hear me?

Timothy Stenzel: Yes, indeed.

Cheryl Skinner: Great. Hello. Thank you so much for this Town Hall, and thank you for taking my question.

I work for an immunodiagnostics company and the question I had is around - we're looking to propose claims to detect antibodies after vaccination - not

specifically immunity, but just level of detection - detecting antibodies after - post-vaccination.

I understand for the home test there was a question that came up around serology testing and that a pre-sub would be likely your position to review this. Are you open to reviewing this type of claim?

And if a pre-sub is the right method to submit this claim with the study design?

And then the third question is, what would be some of the requirements around to support this claim?

Timothy Stenzel: Yes. So, it's always good to start with, you know, your intended use statement, as you would like to propose to the FDA. And how you write that and how you propose that will determine the validation study designs that would be appropriate to support those claims.

So, if you're saying you can detect antibodies after a vaccination, you would want probably - you know, different antibodies may be accumulated by different vaccines. So, there may be, you know, data that we need to look at regarding each specific vaccine that you're going to make a claim for.

Think of this as kind of a companion diagnostic test, right? And companion tests are specific for - we evaluate them specifically for each drug, even it's a drug for the same - a different drug for the same target.

You know, and what data - and in your study design and proposal, you know - what data would be, you know, important in your minds to show - to support the claim that you seek.

You know, if you're going to say, you know, after a vaccine - just a thought; I'm not saying these are recommendations - but if you're looking at the impact of the vaccine, you'd probably want to have a test prior to vaccination to show that your test was negative. And then, after the vaccination, you know, how many days before it becomes positive.

So, we'll want to definitely see, you know, how long it takes for how many people to be positive after a vaccine. So, those are just some high-level thoughts that you should consider in putting together your study design and submitting it as a pre-EUA.

Coordinator: Our next question is from Joanne Gonzalez. Your line is open.

Joanne Gonzalez: Hi. Thank you for taking my question. I'm involved in a clinical trial to support a prescription home-use EUA, with plans to submit shortly afterwards. But we will continue the trials to obtain enough asymptomatic subjects to support an OTC EUA.

If I've already submitted my prescription home-use EUA and want to now pursue the OTC EUA, how do we effectively transfer that review over to an OTC review?

Timothy Stenzel: Typically, the same review team that reviewed the prescription test - home test - can evaluate the asymptomatic data needed for us to authorize, you know, for asymptomatic use and update the test for an over-the-counter situation.

So, you know, that's a very legitimate and efficient way to go about validating your test and getting your first authorization and then making a supplement later to update your authorization from RX to OTC.

Coordinator: Our next question is from Christy Bergerson. Your line is open.

Christy Bergerson: Hi. It's me again. I just had a follow-up to my earlier question.

So, when we are transferring ownership of an EUA, is there any vetting of the new company that we should consider or think about to propose as we prepare for the transfer? Like, what information would our reviewer be interested in?

Timothy Stenzel: I think it's just a matter of the, you know, listing a new - changing out the legal manufacturer and, you know, the company that's transferring it to the new entity would need to give their permission, and we would review that.

And you know, we'd want assurance that the test was going to be manufactured in the same way, and all the conditions of the original authorization would be transferred to the new owner.

Coordinator: Our next question is from Ron Domingo. Your line is open.

Ron Domingo: Hello, can you hear me?

Timothy Stenzel: Yes.

Ron Domingo: Okay. Thanks again, Tim.

So, FDA has indicated that they're likely to authorize three De Novos. Are these likely to be molecular, antigen, antibody, or moderately complex point-of-care or OTC?

Timothy Stenzel: So, we're - you're talking about the conversion from an EUA to a full authorization for anything SARS-related. We are currently reviewing, you know, the most efficient way we're going to do that. And if you want to do that any time soon, and one hasn't been authorized, of course, we would expect a De Novo submission.

And then, as we're looking at it, there may be a way to make it more efficient around a single technology like molecular, or around antigen, or around serology. And we're currently looking at that in order to minimize as much as possible the number of De Novos for the pandemic as possible.

Toby, do you have anything to add? I know that we're still discussing that topic internally.

Toby Lowe: Yes, I think that's right. We haven't necessarily finalized that process, and that may not be finalized until we get the first De Novo authorized.

Coordinator: Our next question is from Joanne Gonzalez. Your line is open.

Joanne Gonzalez: Hi again. Are fact sheets for patients required for at-home tests if the content in the patient labeling and FAQs include the content typically found in fact sheets for patients? I've looked recent EUA authorizations for at-home tests and saw that FDA indicated that content typically found in fact sheets for patients were provided in other labeling.

Timothy Stenzel: Hold on, Joanne. You're talking about a home test or home collection?

Joanne Gonzalez: Home test.

Timothy Stenzel: Home test. Prescription or OTC?

Joanne Gonzalez: Prescription.

Timothy Stenzel: Prescription home test. Okay. So, I don't remember what we're asking to see on a prescription home test.

Toby, do, you know, what we're currently asking in that content?

Toby Lowe: Yes. I think, you know, in terms of fact sheets, it's the content that is most important and, you know, that it is provided to the user in an accessible format. So, that's something that we would work with you on during the review to determine whether, you know, whether that information can be included in other ways than a separate fact sheet such as you mentioned - the FAQs or other labeling to just streamline that process.

Coordinator: Our next question is from (Richard Montagne(. Your line is open.

(Richard Montagne): Thank you. We already have an authorized COVID-19 test, and we also have submitted an EUA for an expanded respiratory panel that includes Flu-A, B, RCA, B and SARS CoV-2.

My question is that during the interactive discussions for the pre-EUA for the expanded respiratory panel, we were advised by FDA that for the current flu season, that EUA authorized test would be permissible. But beyond that, we would require either 510(k) or a De Novo.

And inasmuch as the incidence of flu is so low this year, for obvious reasons, it's going to be difficult, I think, to obtain the number of samples that FDA had recommended that we use in the clinical studies.

So, my question is, has FDA had any additional thoughts on that, or should we still assume we're going to have to have a cleared assay for the subsequent flu seasons, which may mean going into the Southern Hemisphere this year.

Timothy Stenzel: So, there, thankfully, for patients, you know, there isn't much flu out there. Probably due to the precautions we're all taking to prevent transmission by SARS, which appears to be obviously much more transmissible, even with precautions.

So, I would ask that you send an email to our templates email box and ask this question that I can look into specifically with regard to your own application. Ask for Toby and Tim to get involved after you send that email onto the - when you send that email to the templates box, and either Toby or I will look into this further.

Coordinator: Your next question is from Ron Domingo. Your line is open.

Ron Domingo: Hi again. Tim, I just wanted to loop back on the De Novo discussion earlier. So, what happens if I submit my De Novo, and you're already reviewing someone else's De Novo for the same indication. Will my De Novo be rejected? And will I have to retest my devise against the predicate? Thank you.

Timothy Stenzel: No, it would get converted, and I believe we would refund the difference between a De Novo and a 510(k). You would not have to make a new submission.

Ron Domingo: Great. Thank you.

Coordinator: And at this time, I'm showing no further questions.

Timothy Stenzel: And actually…

((Crosstalk))

Irene Aihie: (Over to Tim)? Operator, do we have any other questions?

Coordinator: Yes, I'm sorry. One just came into the queue. One moment, please.

Irene Aihie: Okay.

Timothy Stenzel: Well, then, as they're coming into the queue, I am going to turn the call over at this time over to Toby because I have another meeting that I'm going to need to attend. I'm leaving you in the great hands of Toby. Thanks, everyone. Over to you, Toby.

Coordinator: And our next question is from Brian. Your line is open.

Brian: Hello, thank you, this is (Brian Sell). Just wondering; is FDA accepting Q subs or reclassification requests at this time for COVID for a De Novo submission?

Toby Lowe: By reclassification request, you mean the De Novo submission itself?

Brian: Yes, so, you guys are accepting the Q subs for the De Novo submission - for a De Novo submission?

Toby Lowe: Oh, a Q sub for a De Novo?

Brian: Yes.

Toby Lowe: Yes. We are at least entertaining them, depending on what the content is and, you know, what the questions are, and if they go beyond what is available elsewhere. We may or may not be able to dedicate resources to it, but you can certainly submit a Q sub and we will consider it.

Coordinator: Our next question is from (Luis Silvestre). Your line is open.

(Luis Silvestre): Thank you. This is a question from one of the previous sessions. Can you confirm that there is no universally recognized, certified, commercially-available formulation for viral transport media to be used with nasal swabs, is Question 1.

And Question 2, has the FDA became aware of any differences in reactivity for antigen testing, depending upon the commercially available transfer media that is used?

Toby Lowe: Can you repeat the first part of your question about the VTM?

Luis Silvestre: Whether or not - or can you confirm, that there is no universally recognized formulation there is - from commercial manufacturer to commercial manufacturer - there isn't a standard or certification that is required to have the exact same formulation? Can you please confirm that that is indeed the case?

Toby Lowe: Correct. Yes. Different manufacturers make different formulations for their proprietary transport media. Yes, we have issued a guidance document on transport media that references the CDC formula, and, you know, we have provided some regulatory discretion for manufacturers that are conforming specifically to that CDC formula.

And then, you know, you had asked about the differences with different transport media being used in the antigen testing. And yes, there are differences, and we do review specifically the transport media - the specific transport media being used with a specific antigen test when we look at the EUA requests for antigen tests.

Coordinator: Our next question is from Shannon Clark. Your line is open.

Shannon Clark: Hello, again. Shannon Clark with UserWise Consulting.

Question about - I'm really looking forward to this template coming out for this home-use test kits for antibody testing. Do you expect that it's going to require a sample size of 30 participants for prescription-only; then 150 participants, or 100 sessions with some pairs for over-the-counter? Because I've received conflicting emails from the FDA implying that perhaps OTC could be achieved with a sample size as low as 30.

Toby Lowe: I don't - I can't speak to what exactly will be in that template. Hopefully, we will be able to get it out soon so that we will be able to speak to it more definitively.

But if you do have specific questions as you're planning your approach now, you can send them to the mailbox. And if you're having difficulty getting a

uniform answer, you can flag the question for Tim and me, and we'll take a look into it.

Coordinator: Your next question is from Jackie Chin. Your line is open.

Jackie Chin: Hi. This is Jackie calling in Palo Alto. I have a question about - as we go through an EUA - that and process through the EUA.

Toby Lowe: I'm sorry. We're having trouble hearing you. Can you maybe move closer to your speaker?

Jackie Chin: Hi. Can I try this again? Let me try my question again.

Toby Lowe: Much better.

Jackie Chin: Thank you. My question is about the software validation requirement for EUA submission. And on the template, there are two tables. One is the system specification and validation example. And the other one is the passive analysis example.

On the first table, it asks for evidence that the design of the system can fulfill the specifications. For the EUA submission, do we just have to reference the validation test plan and test report that we have? Or should we submit the full documentation because that is a lot as well.

Toby Lowe: You can start with a summary report, and if we have additional questions, we can follow up. Does that answer that question?

Jackie Chin: It's okay to just fill out this table and include this table in the EUA submission?

Toby Lowe: Right. So, we would want to see a summary report indicating what has passed and what has failed.

Jackie Chin: Okay. Thank you. Thank you, Toby.

Toby Lowe: Sure.

Coordinator: Our next question is from (Kodumodi Venkat). Your line is open.

(Kodumodi Venkat): Good afternoon. Thanks for taking my question.

My question is about the submissions for the serology assays that I submitted many months ago, and still, we are getting it's a low priority. So, is there - because last week Tim was mentioning that you are reviewing at least nine applications a day or something. So, is there any possibility some of those applications that are waiting for many months, that they will get assigned a reviewer and then reviewed any time soon?

Toby Lowe: So, we have indicated, you know, in our FAQs and in other talking points, what types of tests we're currently prioritizing. Those are generally tests where the authorization would increase test accessibility or significantly increase testing capacity.

So those remain our focus right now. Other tests, we would move into the review queue once we have gotten through the priority submissions.

Coordinator: Thank you. Our next question is from Jennifer Lee. Your line is open.

Jennifer Lee: Yes, hi, Toby. Just a quick question. And I was able to join only by audio today, so I missed a slide. Is there a Website or somewhere to learn more information about that new funding opportunity between HHS and DoD?

Toby Lowe: Yes. The slide that was projected will be posted on our - on the Town Hall Website. And that does include a link.

Jennifer Lee: So, there's nothing to access today to learn about it?

Toby Lowe: You can always send me an email, and I can send you the link.

Jennifer Lee: Okay, wonderful. Thanks so much.

Toby Lowe: But it will be posted fairly quickly.

Jennifer Lee: Great. Thank you.

Coordinator: Our next question is from Brian Jones. Your line is open.

Brian Jones: Yes, I was looking at the EUA template, and it has instructions for doing a comparison study between paired NPS and saliva specimens. And so, in our case, we would be - we have a device that's already has EUA for NPS. So, we would be testing that - those specimens - on our device, both as the candidate for the saliva and then the NPS that's already authorized.

My question is, there's no information in the template about doing discrepancy investigation, and I just wondered if there was any input from FDA on that.

Toby Lowe: So, first we would recommend that you use a different test as a comparator and, you know, we would recommend that you select one that has high sensitivity. If you take a look at our reference panel information, that's a good starting place to select a comparator test with established high sensitivity.

And then, so, can you repeat the second part of your question?

Brian Jones: Oh, so, sorry. Just to clarify on that, would that be a comparator on both specimen types or on only one of those specimen types?

Toby Lowe: So, if you're already authorized for NP, then - and you're seeking a claim with saliva, we would expect you to run - use an NP comparator on a separate authorized - on a separate comparator test that is authorized for NP swabs.

Coordinator: And at this time, I'm showing no further questions. I'll go ahead and turn it back over to you, Irene.

Irene Aihie: Thank you so much. Again, this is Irene Aihie. We appreciate your participation and thoughtful questions during today's Town Hall. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.FDA.gov/training/CDRHlearn by Friday, February 19th.

If you have additional questions about today's presentation, please email CDRH-EUA-templates@FDA.HHS.gov.

As we continue to hold these virtual Town Halls, we would appreciate your feedback. Following the conclusion of today's virtual Town Hall, please complete a short 13-question survey about your FDA CDRH Virtual Town Hall experience. The survey can be found now on

www.FDA.gov/CDRHwebinar. Again, thank you for participating, and this concludes today's Virtual Town Hall.

Coordinator: Thank you for participating in today's conference. All lines may disconnect at this time.

END