Virtual Town Hall #84
May 4, 2022

Moderator: CDR Kimberly Piermatteo

CDR Kimberly Piermatteo: Hello and welcome to Virtual IVD Town Hall Number 84 for SARS-CoV-2 test developers, in which we'll discuss and answer your questions about diagnostic tests in response to COVID-19. Thank you for joining us today. This is Commander Kim Piermatteo of the United States Public Health Service, and I am the Education Program Administrator within the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be your moderator for today's Town Hall.

A recording of today's Town Hall and transcript will be made available on CDRH Learn under the section titled, Specialty Technical Topics, and then the subsection titled, Coronavirus COVID-19 Test Development and Validation Virtual Town Hall Series.

The April 20th IVD Town Hall recording and transcript have been posted. The next scheduled IVD Town Hall will be on Wednesday, May 18, 2022, from 12:05 to 1:00 PM Eastern Time.

Our panelists for today's Town Hall are Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics, which is also referred to as the Office of Health Technology Seven, or OHT7, in CDRH's Office of Product Evaluation and Quality. Also joining Tim today is Toby Lowe, Associate Director for Regulatory Programs in OHT7, and Dr. Kristian Roth, Deputy Director of the Division of Microbiology Devices, also in OHT7.

For today's Town Hall, we'll begin with opening remarks, followed by answering your previously emailed questions, and then we'll proceed to address your live questions. I'd now like to welcome Toby, who will provide today's opening remarks. Toby, the floor is yours. Oh, sorry.

Toby Lowe: Thank you, Kim. Thanks, everyone, for joining us again this week. We do have some updates of actions that have happened since the last Town Hall.

Last week we updated the at-home over-the-counter COVID-19 test web page to add information about expiration dates. Some of the over-the-counter tests have had their expiration dates extended, so we added information on that page to explain more about how that works and how to find the updated or extended expiration date if the test that you have has been updated.

And at the same time, we also updated the at-home COVID-19 diagnostic test Frequently Asked Questions page, to add additional questions about expiration dating, and also to update the question about shipping and extreme temperatures, to add information about summer shipping.

Then we also recently posted a web page about counterfeit at-home over-the-counter COVID-19 diagnostic tests. We are aware of some counterfeit tests that are being distributed or used in the U.S. These obviously should not be used.

The website walks through some of the information about counterfeit tests and the risks, and how to tell if a test might be counterfeit or authorized. And on that page, we included specific information about two tests-- the Flowflex COVID-19 test kits, and iHealth COVID-19 antigen rapid test kits, both of

which we are aware of counterfeit versions that are being offered. So the information on that page includes details of how to tell the difference between the counterfeit and the authorized test kit.

We also just posted a recall notice for a Class I recall for certain Celltrion point-of-care DiaTrust COVID-19 antigen rapid test kits. There were some of these tests that may have been distributed to unauthorized non-CLIA certified users. And since these are point-of-care tests, not over the counter, that is problematic since those users may not have the appropriate equipment or training to use those tests. So that recall posted last week as well.

And then just earlier this week, FDA put out an announcement about organizational changes within CDRH's Office of Product Evaluation and Quality. You've likely heard us refer to our office as the Office of In Vitro Diagnostics and Radiological Health over the past few years. And now we are splitting into two offices-- the Office of Health Technology Seven, which will remain Office of In Vitro Diagnostics, and the Office of Health Technology Eight, which will be the new Office of Radiological Health.

This structure will not change anything from your perspective. As IVD developers, you'll continue to interface with the same people and same processes. But we wanted to flag that, since some of you have likely seen that announcement.

And that is the end of my updates, and I can hand it back over to Kim.

CDR Kimberly Piermatteo: Thanks, Toby. We'll now go to answer your previously emailed questions about COVID test development and validation. Please note, we have received some questions that are too detailed or test-case specific, that we will not address during today's Town Hall. For those questions, we will try to send you a response in writing within a few days. If you have submitted a question and do not hear it addressed today, please look for a written response. If you do not receive a response within a few days, you may reach back out to the CDRH-EUA-Templates@fda.hhs.gov mailbox for an update.

Toby, I'll be directing the first few questions to you. So the first question is, can moderate to high complexity labs that are not CLIA-certified, and who do not generate or report patient results, be used to perform candidate testing?

Toby Lowe: Thanks, Kim. Yes, from FDA's perspective, we do not have an issue with clinical study testing being performed in a non-CLIA lab, provided the results are not returned to the patient or provider, and the laboratory is able to perform the testing according to an appropriate study protocol.

CDR Kimberly Piermatteo: Great, thanks Toby. Alright, our next question is, in a previous Town Hall, you stated that it is acceptable to use the candidate test to screen negative clinical matrix used for analytical validation. Is this approach applicable to both EUA and 510(k) submissions?

Toby Lowe: Yes, it is acceptable to use the candidate test to confirm negative clinical matrix that will be used for 510(k) analytical validation studies, as well as for EUA.

CDR Kimberly Piermatteo: OK, thanks. Toby, the next question is, can FDA clarify the future availability of the SARS-CoV-2 reference panel to help developers meet their authorization requirements to test their limit of detection, or LoD, from FDA recommended reference materials?

Toby Lowe: Yeah. So when additional information becomes available regarding the reference panel, or alternate FDA recommended reference materials, FDA will contact EUA holders regarding the condition of authorization requirement to evaluate the analytical limit of detection, and assess the traceability of their device with FDA recommended reference material. The condition of authorization regarding evaluating your test with FDA recommended reference material is not specific to the FDA produced reference panel.

While that was used as an FDA recommended reference material earlier in the public health emergency, for the purposes of fulfilling this condition, it is not currently available. So unless and until the FDA indicates that there is current FDA recommended reference materials to use, the FDA does not expect EUA holders to provide data for this condition of authorization.

CDR Kimberly Piermatteo: Thanks, Toby. Alright, so our next question has four parts. So I'll read them and then I'll let you answer all of them at the same time. So we have a rapid antigen test offered under EUA for POC and OTC use, and are looking at the transition to a 510(k).

The first part is, does FDA have guidance on what is needed for OTC antigen tests for 510(k)? Two, can clinical performance data for a lay user study be used to support both the OTC and POC indications? Three, do we need labeling comprehension data for a 510(k)? And four, do we also need separate CLIA waiver studies and a separate CLIA waiver application?

Toby Lowe: Thanks, Kim. There are a lot of parts to this, but they are all good questions. So since the FDA has not yet granted full marketing authorization for a SARS-CoV-2 rapid antigen test, the first of that type would likely be a De Novo. And FDA generally recommends that if you intend to pursue the De Novo or 510(k) pathway for a rapid antigen test, that you submit a pre-submission to discuss your approach for your proposed point-of-care and over-the-counter test configurations.

So regarding the clinical performance data, generally for an OTC device, clinical performance data from the intended use population-- which is generally lay users-- would be expected. And generally, all over-the-counter tests can then also be used at the point of care. So the clinical performance data from the lay users would suffice for those users.

Additionally, both usability and labeling comprehension would be expected to ensure that the lay user can both use and understand the test appropriately. Since these tests are already being offered under EUA, we recommend that you include in your pre-submission, your proposed approach and justification for leveraging existing EUA data.

And then lastly regarding the CLIA waiver, all IVDs that are cleared or approved for home use are automatically categorized as CLIA-waived, following clearance or approval. So with that, they can be used at the point-of-care setting, operate-- at the point of care in settings that are operating under a CLIA certificate of waiver. So no separate CLIA waiver application is needed for an over-the-counter test. As I said that if a test is cleared or approved for home use, it is automatically CLIA-waived.

CDR Kimberly Piermatteo: Thanks, Toby. Our next question is, is the COVID EUA pathway ending soon?

Toby Lowe: Well, we do encourage developers to start moving towards full marketing submissions. The EUA pathway is still available. Any speculation about it closing on specific dates is just speculation and

rumors. So we do recommend that you refer to the recently published FAQ regarding the difference between the public health emergency declaration and the EUA declaration.

The title of that FAQ is “what will happen with tests offered under EUA if the public health emergency expires and is not renewed?” And that FAQ page is also linked on the slides today. And so generally, that FAQ makes clear that FDA does not plan to take any action that would leave the American public without the tests that they need, and it also explains the difference between the public health emergency determination, which does require renewal, and expires if it's not extended, and the EUA declaration, which is what gives FDA the authority to issue EUAs.

And the EUA declaration is in effect until the HHS Secretary terminates it. It is not dependent upon extension of the public health emergency declaration. So check out that FAQ and be assured that we will give notice if the EUA pathway is going to end.

CDR Kimberly Piermatteo: Great, thanks Toby. Alright, our last previously submitted question I'll be directing to you, Tim. So the question is, some recently authorized at-home antigen tests include tables showing performance calculations at varying percentages of low positives. How and when is this type of data analysis appropriate?

Timothy Stenzel: Thank you, Kim. So data from recent prospective clinical studies with the omicron variant have shown unusually high rates of low viral load samples. Typically we've seen 10 to 20% low positive for all previous variants. This one, which may in fact-- this time, which may in fact be linked to omicron, we're seeing the low positives range from about 30 to 40%-- with obviously poorer performance with those low positive samples versus higher positive samples.

Our current performance targets are based on a target of 10 to 20% low positives in the clinical study. For data sets that have more than 20% low positives, we have additional recommendations that can be used to calculate performance within the 10 to 20% target range. There are caveats to this approach, and so far it has only been used for tests evaluated by the NIH's Independent Test Assessment Program, which utilizes study designs developed in collaboration with the FDA, as well as a calibrated RT-PCR reference method.

If you have completed a current clinical validation study with confirmed omicron positive samples, and have collected more than 20% low positives in your prospective study, then please submit all of your data, including all the low positives, and we can work with you on this new analysis approach. If you have not yet completed your clinical validation and are planning your approach, we recommend that you submit a pre-EUA if you would like to discuss your study design, including the percent low positives and the comparator method.

CDR Kimberly Piermatteo: Great, thank you both, Tim and Toby. That wraps up our previously submitted questions. We'll now take your live questions. So to ask a live question, please select the Raise Hand icon at the bottom of your Zoom screen. When you are called on, please follow the prompt in Zoom to unmute yourself, then identify yourself and ask your question. Please remember to limit yourself to asking one question only. If you have an additional question, you may raise your hand again to get back into the queue, and I will call on you if time permits. And please remember, we are not able to discuss specific submissions under review.

OK, our first live question is coming from Homer. Homer, I'm going to unmute you. Please unmute yourself and ask your question.

Homer Wu: Hi, this is Homer Wu from Hopkins Medtech Compliance. Thanks for taking my call. I have a question about the multiplex OTC COVID-19 plus flu A and the flu B. I believe in the previous call, we mentioned that we can do within two weeks of our clinical study to find prospective flu A and flu B. And if we cannot find within that two weeks, we can use banks of samples to do the clinical study. Is this still the case?

Timothy Stenzel: So this is an OTC antigen test?

Homer Wu: Yes.

Timothy Stenzel: OK. Well, we do want you to get prospective samples for-- you know, to see a product that's an antigen test. And the tests are designed for freshly collected direct swabs in general, and not some other sample type. If there are banks of frozen direct swabs you can access, that would be not in VTM, which is going to be-- or saline, which is going to be rare, if ever. Because that's not how they usually are held.

But if you are having trouble enrolling flu patients like in the U.S. right now. I mean, we're seeing flu A. It's not tremendously high, but it is present. But we're seeing almost no flu B. And so I got a question earlier today from somebody and they asked if they could go to the southern hemisphere. And I think we're going to be open to that as well to get those prospectively collected samples that are the sample type that's going to be used in the test.

I'd also like to make the point that we're not in a flu pandemic. We're in a SARS-CoV-2 pandemic. And we're trying to be as flexible as possible under the EUA statute for a multi-analyte tests, but we're still laser-focused on making sure that we can authorize accurate SARS-CoV-2 tests.

The other thing is, if you have a SARS-CoV-2 test that is multi-analyte, you can if you're waiting on positives for the analytes, you can still submit your data for SARS-CoV-2 as long as there's a method to hide or shield the results of the other analytes, at least in the first iteration of the product, when it goes to market.

CDR Kimberly Piermatteo: Thank you, Tim. Oh yeah.

Homer Wu: Thank you.

CDR Kimberly Piermatteo: OK, thank you Homer. Alright, our next question is coming from Coco. Coco, I have a muted your line. Please unmute yourself and ask your question.

Coco Yu: OK, hi, can you hear me?

CDR Kimberly Piermatteo: Yes, we can.

Coco Yu: Nice. I would like to ask if we want to-- in the assembly process, do we need a clean room, including the interior package or exterior package, where we can just only use the manufacturer with the standard.

Timothy Stenzel: So I mean, manufacturing should be suited for the purpose. So we have typically to this point, limited the QSR requirement to a handful. We are beginning to expand from that though, especially when appropriate. And so you should manufacture in facilities that can produce tests that give accurate results. That's the most important thing.

Coco Yu: So do we need a clean room?

Timothy Stenzel: So yeah, if you want to follow up and ask that specific question-- that's pretty specific-- then I would come in either with a pre-EUA, or ask that question to the templates email box.

Coco Yu: Thank you.

CDR Kimberly Piermatteo: OK, our next question is coming from Tianyang. Tianyang, I've unmuted your line. Please unmute yourself and ask your question.

Tianyang: OK, thank you. My question is that, is there any plan for FDA to open the pathway for antigen OTC test for 510(k)?

Timothy Stenzel: Yes, we are accepting full marketing authorization submissions for antigen. However, the first one is likely to have to be a De Novo since we will write special controls and down classify it to class II so that subsequent submissions would be 510(k). So the first authorized product for antigen in all likelihood will be a De Novo grant. Then after that, 510(k).

Tianyang: Oh, OK. So if we would like to do the EUA-- I mean 510(k) submission, when could I get this information that it is open?

Timothy Stenzel: The best way to handle it is to submit a pre-sub or a Q-Sub-- a pre-submission, Q-submission to the FDA for your product-- for your antigen test product-- and ask any questions in that pre-sub that you want to ask.

Toby Lowe: And I would also add that it's not a matter of opening the pathway for 510(k)s. It's a matter of having that first De Novo be granted. So if you're not interested in submitting a De novo, and you want to wait until that first antigen test is already granted, then once the first antigen test is authorized under a De Novo, that will be announced publicly. That will be posted, and then that will be the available legal predicate for a 510(k) for an antigen COVID test.

Tianyang: OK, thank you.

CDR Kimberly Piermatteo: Thank you, Tim and Toby. Our next question is coming from ArionBio. Arion, I've unmuted your line. Please unmute yourself and ask your question.

ArionBio: Oh, hello, can you hear me?

CDR Kimberly Piermatteo: Yes, we can.

ArionBio: Thank you, yeah. This is [INAUDIBLE] from ArionBio. So my question is also about the EUA and the 510(k). So let's say we are in the middle of EUA clinical study. But you know, let's say FDA all of a

sudden stopped accept the EUA program. Can we still use the existing clinical data to continue for 510(k) submission?

Hello?

CDR Kimberly Piermatteo: Yes, I can still hear you. Yes, I can hear you.

ArionBio: Yes. [INTERPOSING VOICES]

Timothy Stenzel: I'm sorry, I'm sorry, I was speaking on mute. In general, yes, but it depends. So we are looking to leverage as much of the EUA collected study data, both clinical and analytical, for use in the full authorization of any of the conversion of any EUAs to full authorization.

So the best way to get feedback on how to do this and whether the data is able to be pooled for your full submission, is through the Q-sub and pre-sub process. So you'll want to explain how you're doing your EUA clinical studies and analytical studies, and then what you propose to do for your full authorization. And letting us know everything that you know is important, including the comparator test that you're using for your EUA and any alterations, you might use in the comparator test for the full submission. So the process is, go through the Q-sub/pre-sub pathway to ask those questions of our review team.

ArionBio: Thank you.

CDR Kimberly Piermatteo: Thank you for that question. Our next question is coming from Richard. Richard, I have unmuted your line. Please unmute yourself and ask your question.

Richard Montagna: Yes, this is Richard Montagna from Rheonix. We are in the final stages of preparing to run external trials for an expanded respiratory panel, and we are now contemplating using two separate collection kits. One would be a standard VTM, and one would be our proprietary based buffer system.

So the question is, if we were to run with both of these collection devices, would it be acceptable if we ran both the internal and the external studies in one collection device, and then perform bridging studies to show how the second one performed? Or would FDA prefer that perhaps we randomize which collection device is used for each individual?

Timothy Stenzel: No, you can use one for EUAs, and then do studies to validate the other. Kris, do you want to give any more specific details on the call?

Richard Montagna: And this would not be for EUA. This would be a 510(k).

Timothy Stenzel: Oh, for 510(k)? Kris, are you able to give any feedback for a 510(k) on the call? Or would you like to see a pre-sub/Q-sub about this?

Kristian Roth: Yeah, we prefer to see a pre-sub, Q-sub, of course.

Richard Montagna: Yeah. OK. We've actually had a pretty ongoing conversation with the committee right now. So I guess we could add that in when we go back with another set of questions.

Kristian Roth: Sounds good, thanks.

Timothy Stenzel: Thank you.

Richard Montagna: Thank you very much.

CDR Kimberly Piermatteo: Thank you, Richard. Alright, our next question is coming from Wenli. Wenli, I have unmuted your line. Please unmute yourself and ask your question.

Wenli: Thank you very much. This is Wenli Zhou from XYZ Laboratory. And I have just a question regarding the SARS-CoV-2 lots we used for the evaluation of OTC antigen performance. I think the question is, can we use the multiple lot, or more than one lot throughout the study? For example, one lot used for antigen analytical performance, and another lot used for stability tests. As long as each lot, the LOD is determined for each lot. And also this question is--

Timothy Stenzel: Um--

Wenli: After-- I'm sorry. Someone--

Timothy Stenzel: Go ahead, go ahead.

Wenli: Yeah. And also to prepare for future. If the-- some EUA, probably want to go to the 510(k) or De Novo. Then there are more testing will be done then the current lot may not be available. And then we're still able to use the previous study and just add use the new lot and do the-- yeah, so that's the question.

Timothy Stenzel: Well for traditional full authorization-- 510(k) or the initial De Novo-- we typically want to see multiple lots, at least in the analytical studies. And so there is no problem with using more than one lot for your EUA studies. And then in your test question of how many lots the FDA would like to see for the full validation, for full authorization, then that's best handled through the pre-sub/Q-sub. Just be sure for the EUA, that you always note the lot number for each validation work that you do, so that we know that you are switching lots when we're looking at the data.

Kris, anything else to add?

Kristian Roth: No, I think you covered it. Thanks.

Wenli: OK, thank you very much.

CDR Kimberly Piermatteo: Thank you, everyone. Our next question is coming from Min Yao. Min Yao, I have unmuted your line. Please unmute yourself and ask your question.

Min Yao: Yes, thank you for taking my call. This is Min from PureVision AI. And the question is for the multiplex test kit such as COVID and the flu A and flu B. In the previous Town Hall meeting, FDA responded that there is established requirements for them. However, there is no template for this multiplex test kit. So does this mean the sponsor needs to follow the related 510(k) requirements for flu A and flu B performance evaluation? Or can you use existing ---. Thank you.

Timothy Stenzel: Yeah, yeah. Give me a little bit more background. Is this a molecular or antigen test and--

Min Yao: Oh, it's antigen. Antigen test.

Timothy Stenzel: It's antigen test? And you're asking about EUA recommendations or full authorization recommendations?

Min Yao: It's just the EUA.

Timothy Stenzel: OK. So I believe there is some information in both -- the templates for our multi-analyte validation. So I'm not sure that I understand your question enough to be able to answer it.

Min Yao: We had trouble in finding the detailed information requirements for the flu A and flu B part.

Timothy Stenzel: OK. Kris, do you think you can cover at a high level on the call, what we're asking for with an EUA for including flu A, flu B? I assume you're asking the number of positives for each?

Min Yao: Yes, yes.

Kristian Roth: So thanks, Tim. The number of positives is listed in either the antigen or the molecular template. So I would look there first. And then if you are developing something for home use, there would be the home use template that you could apply to issues that are specific for home use. But the sample numbers and the types and-- in general, it's very similar to what we'd ask for a 510(k) for flu A and B. And those numbers are listed in that antigen template, so I would just open up that and then search for flu or search for multiplex. You should be able to find it fairly quickly.

Min Yao: OK, thank you so much. Thanks.

CDR Kimberly Piermatteo: Alright, thank you. Our next question is coming from Tianyang. I believe you have another question. Tianyang, I've unmuted your line. Please unmute yourself and ask your question. Or-- I apologize. I think you just lowered your hand. So I will move on to the next question, which is coming from Miraj. Miraj, I've unmuted your line. Please unmute yourself and ask your question.

Miraj Patel: Yes, how are you describing what type of take it to work lunch program you're using? They've waited for the program to begin once around these jobs to eat.

CDR Kimberly Piermatteo: Sir, I believe-- I don't know if you're on the right call. This is for the in vitro diagnostics call. We are not discussing lunch programs or anything like that, so I apologize.

Alright, our next question-- looks like, Tianyang, you have come back online. I'm going to unmute you. Please unmute your line and ask your question.

Tianyang: OK, thank you. So my question is that, is FDA already open for submissions for OTC flu A and flu B, COVID, multi-complex products?

Timothy Stenzel: Yes. We're recommending that you submit a pre-EUA if you wish to pursue an OTC multi-analyte test to make sure that you're performing the studies in an acceptable manner, and you're sourcing your multi-analytes for the clinical study in an appropriate manner.

Tianyang: Oh, OK.

Timothy Stenzel: And there are going to be differences between an antigen submission and a molecular submission.

Tianyang: Oh OK, thank you. And didn't-- so for this multi-analyte flu A, B, COVID product, is there guide documents for product research and development? Or it is separate-- we need to search COVID and flu A, flu B, separately?

Timothy Stenzel: So our templates for recommended validations for multi-analyte tests, for antigen and molecular, are in our templates. And I would refer to you there. But beyond the recommended validation experiments, the FDA doesn't get into how to R&D a product.

Tianyang: Oh, I see, thank you.

CDR Kimberly Piermatteo: Thank you, Tianyang. Our next question is coming from Joshua. Joshua, I have unmuted your line. Please unmute yourself and ask your question.

[AUDIO OUT]

Josh, we're having a hard time hearing you. It's cutting in and out.

Joshua Levin: Is this better?

CDR Kimberly Piermatteo: It's still cutting a little bit in and out.

Joshua Levin: [INAUDIBLE] OK, I'll try again in a bit.

CDR Kimberly Piermatteo: OK, thank you. Alright, our next question then is coming from Ezra. Ezra, I have unmuted your line. Please unmute yourself and ask your question.

Ezra: Hey, guys, can you hear me?

CDR Kimberly Piermatteo: We can hear you, but it's very faint.

Ezra: Very faint. OK, how about now?

CDR Kimberly Piermatteo: Yes, that's much better. Thank you.

Ezra: OK, thank you. Thank you for taking my call. I have a question regarding the analytical study. So during the analytical study, do we need to elaborate the preparation of the negative sample matrix as well as the comparator test? Prepare like the demographic or something like that? Thank you.

Timothy Stenzel: Yes, so we give options for what we're looking for in our templates. And yes, we do want to know how you create the material that you use for your analytical study. So please specify that in your protocols when you submit your application.

Ezra: OK, terrific. Thank you.

CDR Kimberly Piermatteo: Thank you, Ezra. Our next question is coming from Caroline. Caroline, I have unmuted your line. Please unmute yourself and ask your question.

Caroline H.: Good afternoon, thank you for taking my question. For a point-of-care antigen test, what is the difference between a test that is authorized for use under moderate or high complexity CLIA-waived laboratories versus one that is approved under moderate, high, or waived complexities?

Timothy Stenzel: Yeah. So I mean-- our office performs the CLIA categorization for non-EUA, full authorization submissions. And there are suitable workflows for each of those environments. The most complicated workflows can obviously be performed in the high complexity with highly skilled and trained technologists.

A moderate complexity, typically those who do not have training in, say, molecular biology but are perhaps more akin to a traditional med tech. And then CLIA-waived deemed status for use in most of the point-of-care settings. But there can be point-of-care that use moderate complexity tests as well. It all depends on the staffing of the certificate lab.

But in the CLIA certificate lab, those are non-laboratory trained individuals-- health care workers typically. So the test needs to be extremely simple. If you look on the FDA website, if you look at the tests that have a W by them for Waived, or any of the OTC tests, you'll see the level of simplicity that we're looking for in a test to be used in those settings.

Caroline H.: OK, thank you.

CDR Kimberly Piermatteo: Thank you, Tim. Alright, Josh we're going to come back to you. Hopefully this time we have some better comms. So I've unmuted your line. Please unmute yourself and ask your question.

Joshua Levin: Hi, is this better?

CDR Kimberly Piermatteo: Much better, thank you.

Joshua Levin: Oh, great. Hi, this is Josh Levin from Asell-- A-S-E-L-L. We have heard that FDA is de-prioritizing pre-EUA reviews in favor of EUAs. And given that FDA has recommended the pre-EUA process as a way for developers to get information on complex topics, enrichment for example, what would be the mechanism for developers to get this kind of information if pre-EUAs are de-prioritized or not reviewed? OK, thank you.

Timothy Stenzel: Yeah. So we are continuing to be challenged by so many applications still, both pre-EUAs and EUAs. So when somebody submits an EUA with full data, we do feel compelled to make sure that that gets an adequate priority review. For those that are seeking pre-EUA feedback, it's typically for

something that's not very clearly spelled out in the template. So we do recommend that you follow our recommendations in the templates.

And so if you're seeking some sort of alternate approach, we still do recommend that you check in with us. But we are struggling with the volume, but we are dedicated to working through them as soon as possible. And if it's been weeks since you submitted your pre-EUA and haven't heard anything, you can submit an email to the templates email box and ask for Toby and Tim to be copied. And we will look into the status of that for you. But you should be receiving regular email with status updates, and the team is doing their best.

Joshua Levin: OK, thank you.

CDR Kimberly Piermatteo: Thank you, Josh. Thank you, Tim. Our next question looks like it's coming again from Wenli. Wenli, I am unmuting your line. Please unmute yourself and ask your question.

Wenli: Thank you very much for taking my question again. So I actually follow up with a previous question. I have a question about the Q-sub and the pre-submission. And a multiplex molecular and test on COVID and the plus flu and all those things.

So I think the question is like, if I read the guidelines-- it says like, in the pre-pandemic submission guidelines, usually within 70 days, you will get a meeting-- scheduled meeting. And waiting about two weeks or something, you get the lead reviewer assigned. So I wonder if this is still-- I'm sure now everything must be different.

So I just wonder what's approximate time-- at least you get a lead reviewer, you know? If we do that Q-sub with this pre-submission, and the approximate time you can get a lead reviewer at least so we can have some interaction with the lead reviewer in terms, or if we can still schedule meetings.

Timothy Stenzel: So our current status is that we are not accepting all pre-subs and Q-subs across the board, except for categories that we've previously announced. But that includes pre-subs/Q-subs for COVID. So we are reviewing them. Our first goal overall is to get back to reviewing all pre-subs and Q-subs.

But because we're not doing them all yet, and because of the volume of submissions that are continuing for COVID, our review times for pre-subs and Q-subs are extended. And I can't give you a firm time period. But if you've submitted it, you should be assigned a reviewer. That reviewer will do an assessment and should let you know when they think they can get back to you, and then keep you updated. And that should be happening.

And then as far as meetings go, if-- meetings take a lot of time. And since we're so busy, we are trying to handle as much work through email as possible, and reserving meetings for those times when email is not suitable to get the work done, so that we're getting to as many applications as possible, as soon as possible, given our time and resource limitations.

Wenli: OK. So do you-- what's the expectation to get a lead reviewer? How long will that take to assign the reviewer once we submit [INAUDIBLE]?

Timothy Stenzel: Yeah, if it's more than two or three weeks, then send an email to Tim and Toby through the template--

Wenli: OK, I see.

Timothy Stenzel: --- email and we'll look into it. OK?

Wenli: Alright, thank you very much.

CDR Kimberly Piermatteo: Thank you, Wenli. Alright, our next question is coming again from ArionBio I've unmuted your line. Please unmute yourself and ask your question.

ArionBio: Yes, thank you. Can you hear me?

CDR Kimberly Piermatteo: Yes we can.

ArionBio: Yes, so I have a follow-up question about the EUA transition to 510(k) and I heard that FDA plans to start the transition progress in July. Does that mean in July, FDA will stop accepting the EUA submission? And also another question is, will FDA handle this EUA transition to a 510(k) the same way to all the technologies such has molecular, antigen, combo tests, or like breath test? Or there's some kind of a different schedule for this transition for different technology? Thank you.

Timothy Stenzel: Well, yeah. So I'll let Toby handle this as well, cause she did mention it I believe earlier in the call. But we're going to be transitioning all the assay technologies at the same time when that time comes. We've only put out draft on transition guidance, and that draft guidance needs to go through finalization and published as a final before we even consider moving towards the transition process.

And then there isn't a set time to make that—first of all we can't predict when that final guidance will come out. And therefore we can't even contemplate when a transition might occur. We do know it is going to occur, and there will be a transition timeline that should allow developers to come in with an application. And if they're in by the deadline, then they can stay on the market while the FDA reviews those applications. Toby, you want to add anything else?

Toby Lowe: Yeah, thanks. So I did mention earlier on the call during one of the prepared questions that we received ahead of time-- the question was about whether the COVID EUA pathway would be ending soon. I think you mentioned something about July. And the original question we received also was noting that they had heard a rumor that the COVID EUAs would be closing on July 1st. As I mentioned earlier, that is just a rumor.

As Tim said, we've issued a draft guidance about the transition. After the comments are considered for that, then a final guidance will be issued that will lay out a timeline for transition. And that all, as I mentioned earlier, is also related to the EUA emergency declaration, which is still active. We are still accepting EUAs. And we will -- [CLEARS THROAT] -- excuse me. We will provide advance notice if and when any of that is changing. But that said, as Tim has also mentioned, we do encourage developers to work on their transition to a full authorization.

ArionBio: Great, thank you very much.

CDR Kimberly Piermatteo: Thank you very much, Toby. We have time for one more quick question. Tianyang, we are coming back to you. If you can ask your quick question and then we'll provide a response. So I've unmuted your line. Please ask your question.

Tianyang: Thank you very much. So my last question is that, if we follow the combo antigen OTC test, does it need to be only one loading vial and one reaction strip? If we develop a product with two sample loading vials and two strips, is that fine? For the OTC combo-- OTC--

Timothy Stenzel: Yeah, I recommend you come in with a pre-EUA for something that's non-standard like that. So typically, all multi-analyte tests will have one sample collected and one sample loading. But we want to look at your design and your thoughts on it.

Tianyang: OK, OK. Because we already got the EUA for COVID OTC test, so we want to see if this—OK we will submit the pre-submission. Thank you.

CDR Kimberly Piermatteo: Great, thank you, Tianyang. Thank you to Tim and Toby and Kris for all of your feedback and responses to the questions today.

As I mentioned earlier, a recording of today's Town Hall and transcript will be made available on CDRH Learn, so please visit CDRH Learn at the link provided on this slide. You will find the recording and transcript under the section titled, Specialty Technical Topics, and then the subsection titled, Coronavirus COVID-19 Test Development and Validation Virtual Town Hall Series.

If you have additional questions about today's Town Hall and COVID-19 IVD topics in general, you may send an email to the CDRH-EUA-Templates@fda.hhs.gov email that is also provided on the slide.

And lastly, please remember to join us for the next IVD Town Hall, which is scheduled for Wednesday, May 18th, 2022, at this same new time, from 12:05 to 1:00 PM Eastern Time. This concludes our Town Hall for today. Have a nice day.

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