

CDRH Virtual Town Hall #93
Monkeypox and COVID Test Development and Validation
September 28, 2022

Moderator: CDR Kimberly Piermatteo

CDR Kimberly Piermatteo: Hello, and welcome everyone to today's virtual town hall number 93, which is our first combined virtual town hall for monkeypox test developers as well as SARS-CoV-2 test developers. Today, we will discuss and answer your questions about diagnostic tests in response to the monkeypox and COVID-19 public health emergencies.

Thanks 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 virtual town hall.

Our panelists for today are Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics, which is also referred to as the Office of Health Technology number seven or OHT7 in CDRH's Office of Product Evaluation and Quality, or OPEQ. Joining Tim 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 virtual town hall, we'll begin with opening remarks from Tim, followed by a presentation from Toby on the COVID-19 test policy guidance updates. Then we will answer your previously emailed questions about both monkeypox and COVID-19. And then lastly, we will address your live questions.

A recording and transcript of last week's virtual town hall for monkeypox test developers should be posted by the end of this week on CDRH Learn under the section titled, Specialty Technical Topics and then the subsection titled "Public Health Emergencies."

We will continue to hold these virtual town halls weekly every Wednesday. Therefore, the next two scheduled virtual town halls will be on Wednesday, October 5 and Wednesday, October 12 from 12:05 to 1:00 PM Eastern Time. These virtual town halls will be for monkeypox test developers specifically.

Future dates for virtual town halls will be announced once they have been confirmed. Please refer to our "Medical Device Webinars and Stakeholder Calls" webpage, specifically, our "Virtual Town Hall Series - Test Development and Validation During Public Health Emergencies (COVID-19 and Monkeypox)" webpage for details on upcoming virtual town halls. Links to both of these webpages have been provided on the bottom of this slide.

And lastly, as a friendly reminder, for those of you participating live in today's town hall, please be sure you have joined the town hall via the Zoom app and not through a web browser to avoid any technical issues.

I'd now like to welcome Tim, who will be providing today's opening remarks. Tim, the floor is yours.

Timothy Stenzel: Thank you, Kim. And welcome, everyone, to the town hall today. I will begin with three different updates for monkeypox. And then we'll move into COVID where I'll give some introductory remarks before turning it over to Toby.

So first up is a reminder of the October 13 '22 deadline for the monkeypox. It is 30 days. That date is 30 days after the publication of the monkeypox test policy guidance.

This is the deadline for both LDT notifications to be sent to the FDA and also for experienced developers, kit test developers, who informed FDA by email of their intent to submit an EUA request for a monkeypox diagnostic test. So that's the first key important update is to be aware of date.

The second update is that primarily for monkeypox LDT developers. I'd like to remind callers today that the FDA does not expect an EUA request for certain validated monkeypox diagnostic LDT tests that are developed and performed in a single app that use PCR and the only sample size is lesion swab samples. Lesion swab samples are broadly defined as any swab from a lesion that could be monkeypox.

FDA just expects a notification by email with no data, no review, no decision by the FDA on an application, and then no EUA authorization. Outside of a declared emergency and prior to the EUA test declaration for monkeypox, the FDA generally has to exercise enforcement discretion for LDT. And for this subset of monkeypox diagnostic tests, single-site PCR lesion swab, the FDA has also implemented a narrow policy of enforcement discretion after the EUA test declaration.

And the final update for monkeypox is the clarification on the use of the CDC assay, the CDC cleared NVO assay, for test validation. So there may have been a misunderstanding based on comments about validation last week. So we want to clarify that we are not aware of any shortage for monkeypox tests, test kits, or reagents, especially, the CDC NVO orthopox assay.

The FDA's current validation recommendations for monkeypox diagnostic tests include the use of contrived samples when it may be difficult to obtain positive clinical samples for validation. If you have access to clinical samples, you may validate using your clinical agreement study with an appropriate comparator as described in the template. As discussed in the town hall last week, the CDC performed by the LRN labs and the five commercial labs that are currently the only-- and that test is currently the only appropriate comparator until we have additional EUA authorizations that make additional appropriate comparators available.

The CDC has asked that their tests primarily be reserved for diagnostic testing, not validation of testing. The laboratories performing the CDC assay may provide leftover samples, including the test results and Ct or cycle threshold values that are outputted by the cleared test that other test developers can use for validation. So we are encouraging that if you want to validate using real samples that you obtain samples that have been tested with the CDC NVO cleared assay.

However, we are not recommending asking those laboratories to use the CDC to test clinical samples you may have acquired elsewhere since the testing will be potentially solely for assay validation and not to diagnose the patient. Hopefully, that clears up that. Moving on to COVID.

So just brief remarks by me. So as many probably have noted, if not all in the call, the FDA has updated its policy for COVID test validations and submissions to the FDA. And I will turn this over to Toby now as she will go through this update to the policy. Thank you, and over to you, Toby.

Toby Lowe: Great. Thanks, Tim. And welcome, everyone, again this week. So as Tim mentioned, I will go through some updates that are in the new version of the COVID test policy guidance that was issued yesterday. So we can go to the next slide.

So yesterday, September 27th, we did update the COVID test policy. There's a link on this slide to the press release and to the reissued guidance as well as updated frequently asked questions that may be helpful for developers who are looking to see how things will be handled moving forward. So the main point of this guidance update was to indicate new reduced priorities for reviewing EUA requests for COVID and to encourage developers to seek traditional premarket review for most COVID-19 test types. Next slide.

All right. So the guidance was updated to ensure continued access to tests, but also, to encourage that transition to traditional premarket review pathways. And so effective yesterday, September 27th, we generally now expect COVID-19 tests to have been issued an EUA or a marketing authorization prior to the tests being distributed or offered. This is a continuation of the November 15, 2021 policy where we ended the acceptance of new notifications.

But we will be continuing the prior enforcement policies for tests that have already been offered or are currently already being offered during an ongoing FDA review. So those are those tests that had previously notified or the lab developed tests that were being offered without authorization under previous policies. And then going forward, we generally intend to only review a small subset of new EUA requests for COVID-19 diagnostic tests.

Tests that have EUA requests pending prior to yesterday's announcement will remain in the queue. And we're recommending the traditional premarket review pathways for other types of COVID-19 tests. So that's the De Novo classification route if there's no predicate or the 510(k) premarket review pathway. Next slide.

So these are the types of COVID-19 tests that we do intend to focus our review. And generally, that's going to be EUA requests and supplemental EUA requests, so supplements to previously authorized tests, that are for diagnostic tests likely to have a significant benefit to public health, diagnostic tests that are likely to fulfill an unmet need. And then for supplemental requests, so modifications, those will be when the request is intended to fulfill a condition of authorization or if the modification would significantly benefit public health or fulfill an unmet need. And then as before, we will continue to review EUA requests that are from or supported by a US government stakeholder. Next slide.

And then beyond that, we are encouraging the use of the traditional premarket review pathways. So as I mentioned before, that's De Novo and 510(k). And then it's important to note that the statutory requirements for the level of evidence for authorization under a traditional premarket review pathway is higher than the statutory requirements for emergency use authorization.

So we would encourage you to submit a pre-submission to discuss your validation approaches. And we can also provide recommendations that are specific to a test developer situation. And we can do that both by email if they're simple questions or through pre-Subs for the more complex questions.

And if you're unsure whether your test may be prioritized for review or if you should consider a traditional premarket review pathway, we encourage you to reach out through the mailbox to have that discussion. Next slide, please.

So the State Authorization Policy-- just noting here that this policy has been maintained from the 2021 version of the policy without further revision. So the States and territories that are listed and were listed on the notification list prior to November 15, 2021 will continue to fall under that policy. We are not accepting new notifications there and haven't since November of 2021. And as previously, this applies only to tests designed, developed, and used in a single high-complexity CLIA lab and does not apply to home tests or home specimen collection. Next slide.

So as I mentioned earlier, we are continuing the policies for tests that have already been distributed and offered during FDA review. We are generally continuing to not intend to object, which means that we don't have any concern with the continued distribution or offering of the test while under FDA review. And that's for tests that are on one of the notification lists on our website at the time of issuance of the guidance, so as of yesterday as well as the LDTs that were offered prior to November 15, 2021 where an EUA request was submitted to FDA under that policy described in that 2021 version of the guidance. So those are the EUA requests that should have been received by January of 2022.

And then generally, we expect that developers have or will cease distributing, marketing, and offering their tests within 15 calendar days if they receive a notice from FDA that we declined to review, declined to issue, or otherwise declined or decide not to authorize the test for any reason. Next slide.

And then modifications. So in general, we now expect modified tests to be authorized under an EUA or a traditional marketing authorization before being distributed or offered.

We generally don't intend to object to continued implementation during FDA review for modifications that were made prior to yesterday's guidance update under the policies that were in the previous version of the guidance. And we also continue to not object to implementation without a new EUA of certain validated modifications made by a high complexity CLIA certified laboratory to an authorized COVID-19 diagnostic test. So that is similar to the policy that has been in place in previous versions of the guidance.

We do, as I mentioned, intend to review supplements for previously authorized tests when the request is intended to fulfill a condition of authorization or when the modification is within the priorities that are outlined in the guidance. And then some modifications that are beyond the scope of the priorities, we encourage submitting that modification through the traditional premarket review pathway. And that is pretty much the end of my presentation.

We have two slides coming up next that has resources for test developers. So the next slide is resources for COVID-19 test developers. And that one includes most of the links that we just talked about. Kim, if you want to go to the next slide there.

CDR Kim Piermatteo: Toby, yeah. We're going to display those when we do the previous email questions.

Toby Lowe: OK. And then I think we are ready to go do that.

CDR Kim Piermatteo: All right. Thank you, Toby, for that presentation on those updates. We will now answer your previously emailed questions. We will address today's previously emailed questions in two

parts. The first part will address monkeypox previously emailed questions. And then we will address the COVID-19 previously emailed questions.

As always, please note we do receive some emailed 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 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, please feel free to reach back out to the appropriate mailbox, either the MPXDx@fda.hhs.gov mailbox or the COVID19DX@fda.hhs.gov mailbox for an update. So Toby, I'll be directing these previous emailed questions about monkeypox to you. The first question is: for monkeypox diagnostic test developers informing FDA of their intent to submit an EUA request, can the intent to submit be provided without a timeline for completion of validation studies and submission of an EUA request?

So as discussed in the monkeypox test policy guidance, FDA generally recommends including certain preliminary information in the test developer's email to FDA to indicate their intent to submit an EUA request for a monkeypox diagnostic test. So that information includes the description of the test technology, manufacturing capacity, test throughput, any available validation data, and the expected timeline for development validation and submission of an EUA request. While these are recommendations, not requirements as laid out in the guidance, this information will be beneficial to facilitate FDA's prioritization efforts.

CDR Kim Piermatteo: Thanks, Toby. That was actually our only previous emailed question on monkeypox, so we'll go ahead and move to our previous emailed questions related to COVID. So our first COVID-related question is: is FDA considering multiplex antigen tests that can detect a combination of viruses, for example, SARS, COVID-19, and influenza intended for use in an over-the-counter setting for symptomatic users only?

Toby Lowe: Thanks, Kim. And sorry for that typo in the question. That tripped you up there. Definitely meant to be SARS-CoV-2 and influenza. And so we have authorized a few antigen multianalyte diagnostic tests intended for use at laboratory and point of care sites as well as several molecular multianalyte diagnostic tests intended for use at laboratory and point of care sites for use with home collected specimens.

We have not yet authorized any multianalyte over-the-counter tests. However, we do have recommendations in the EUA templates and have discussed on previous town halls that we are considering over-the-counter multianalyte tests. Following issuance of the updated guidance yesterday, we recommend that you consider a pre-submission and traditional marketing pathway for this type of test.

CDR Kim Piermatteo: Great. Thanks, Toby. Our next COVID-related question is: to support 510(k) for COVID-19 rapid tests, is FDA requiring serial testing as part of the clinical performance study for symptomatic individuals?

Toby Lowe: So we do continue to recommend submitting a pre-submission to discuss your proposed clinical validation strategies if you intend to pursue a 510(k). We have not yet granted a De Novo for a COVID-19 rapid antigen test, so we cannot say with certainty exactly what will be required for a 510(k).

As is discussed in our safety communication issued in August, we are now recommending serial testing for all rapid antigen tests, including for symptomatic individuals. And we will be updating our recommendations in the template to reflect this.

CDR Kim Piermatteo: Thanks, Toby. Alright. Our next COVID question is: in August, FDA released a safety communication titled, “At-Home COVID-19 Antigen Tests. Take Steps to Reduce Your Risk of False Negative.” This communication recommended that at-home COVID-19 antigen test users that are asymptomatic should test a total of three times based on a recent NIH-funded study, provided that test manufacturers adapt their labeling accordingly. Will the FDA require additional clinical study results under an EUA or 510(k)? And the second part is or is the right to reference to the NIH study sufficient?

Toby Lowe: Thanks, Kim. So we have discussed a bit on previous town halls that FDA continues to work to reflect the need for serial testing in antigen test authorizations. The results of the NIH-supported UMass study have been published. And FDA plans to use this data in support of serial testing claims.

One of the goals of the study was to provide broadly applicable data to avoid the need for individual developers to perform large and expensive tests-- or expensive studies, rather. And so at this time, the FDA is not likely to request additional studies to support serial testing under EUA. And as I noted previously, we do continue to recommend submitting a pre-submission to discuss your proposed clinical validation strategies if you intend to pursue a 510(k).

CDR Kim Piermatteo: Thanks, Toby. Alright. So our last COVID-related previously submitted question is: to support an at-home testing claim, in a clinical study where the comparator is not being used as the standard of care, does FDA recommend that clinical study subjects swab themselves and perform the test before the comparator swab is taken, in order to not train or mislead the lay tester?

Toby Lowe: Yes. FDA continues to recommend that study participants swab themselves and perform self-testing before the comparator swab is collected in order to minimize potential bias.

CDR Kim Piermatteo: Great. Thanks so much for your responses, Toby. That wraps up the previously emailed questions for both monkeypox and COVID. So we will now take your live questions.

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 and select the blue button to unmute your line. Then identify yourself, and then indicate if your question is related to monkeypox or COVID-19. And then 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 as time permits.

So our first live question is coming from Kal Mansoor. Kal, I have unmuted your line. Please unmute yourself and ask your question.

Kal Mansoor: Hi. This is Kal. My question is for COVID-19. I'm looking for clarification on the test policy update from September 27 where it states that tests for which EUA authorization requests are pending prior to this announcement will remain in the queue. Can you clarify if the pre-EUAs that have already been submitted and are under review prior to this announcement will still remain in the queue? Thanks.

Timothy Stenzel: So Toby can back me up on this. But EUAs that are in the queue have all the data relevant to the submission. And they will remain in the queue through the completion of the review and the decision made on that. Pre-EUAs are designed to provide feedback on test development and are not designed for a submission for authorization. So those with pending pre-EUAs, if they wish to make a submission to the FDA, it would be through the traditional route unless it meets some of the unusual conditions for continued EUA review. That can be assessed through a pre-EUA to determine whether we would at this point accept an EUA submission.

So if a test developer wants to market a test that isn't one of the unusual categories that we would still review, I would recommend that you convert that pre-EUA, those questions, into a Q-sub or pre-sub submission to the FDA to find out what the expectations are for a full authorization submission. Toby, anything to add on that?

Toby Lowe: Yeah. I think that that's all exactly right. If the pre-EUA is for a test that would meet the new priorities for EUA review, then we are likely to continue to review the pre-EUA. If it is not of a type that we would intend to prioritize, then your best bet at that point is to proceed with a pre-submission and look towards that marketing submission.

We will be making our way through the submissions that are in the queue. And we will be sending responses to the sponsors. The response may be that this is closed and we're not providing feedback at this time. Or it may be that we are continuing to review, depending on the type of test and where it falls in our priorities.

Timothy Stenzel: Thanks Toby – great clarification.

Kal Mansoor: Just to clarify, should we be reaching out to our pre-EUA reviewer and to see if the review is still going on, or we should just wait?

Timothy Stenzel: No, you can reach out. And you can ask if your test would qualify. But if there's a large queue, I don't know how quickly they can do that review. But they'll get back to you.

Kal Mansoor: OK.

Timothy Stenzel: We have a lot of questions. We should move to the next. Thanks, Kim.

CDR Kim Piermatteo: OK. Thank you, Kal. Thank you, Tim and Toby. Alright. Our next question is coming from Ashanti. Ashanti, I've unmuted your line. Please unmute yourself and ask your question.

Ashanti Brown: Hi. Good afternoon. Ashanti Brown with MCRA-- M-C-R-A. My question is a COVID-related question related to the updated policy. Just very quick, I want to quote it.

The FDA states to prioritize the review of EUA request for tests from experienced developers. The FDA defines experienced developers as those who have interacted with FDA through a successful EUA request during the current public health emergency or have similar experience. Can you please let me know what is meant by a successful EUA request? Does it include the actual EUA and approval and/or pre-EUA interactions?

Timothy Stenzel: So I think you're referring to the monkeypox guidance, not the COVID guidance. Is that correct?

Ashanti Brown: No. I'm referring to a policy for COVID-19 tests.

Timothy Stenzel: Toby, can you respond to that? Because I was thinking that was monkeypox.

Toby Lowe: It's a similar language in both guidances I believe at this point. So a successful EUA request would be having been issued an EUA following submission of an EUA request.

Ashanti Brown: So actually, EUA approval?

Toby Lowe: Correct. EUA authorization. Yes.

Ashanti Brown: And that's not inclusive of any pre-EUA interactions?

Toby Lowe: That's correct.

Ashanti Brown: OK. And last question is similar experience for an experienced developer. It says that successful EUA requests during the current public health emergency or have similar experience. So can you elaborate on what a similar experience would be for an experienced developer?

Toby Lowe: Excuse me. So we would be happy to answer a specific question if you want to reach out about a specific developer. But generally, that's going to be a developer that's had a positive decision on a submission to FDA, whether that's an EUA or a premarket submission under a traditional 510(k).

Timothy Stenzel: Yeah. So for a test, for an IVD test, not for other products, but for IVD tests for a 510(k) clearance, or a De Novo granted, or a PMA approval.

Ashanti Brown: Thank you.

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

Niya Su: Hello. This is Niya Su from Coyote Bioscience. And thank you for taking my question. My question is for monkeypox. Does FDA accept clinical study data from outside of the US for point of care device and high throughput device for high complexity lab?

Timothy Stenzel: That's possible. The comparator tests that the FDA recognizes at the moment is the CDC NVO orthopox test that is FDA cleared. So I don't believe that that's available for this kind of study. So that would be the challenge with that. But I think this is a very specific question. And you can come in with a pre-EUA for that question.

Niya Su: Thank you.

CDR Kim Piermatteo: Thank you, Tim, for that response. Alright. Our next question is coming from Mary. Mary, I have unmuted your line. Please, unmute yourself, and ask your question.

Mary: Yeah. So hello. My name is Mary. And my question is regards to COVID-19, specifically, the antigen COVID-19 at-home test kits. For the EUA, the recommended samples were 30 positive and 30 negatives with 10 asymptomatics. I was inquiring about going the regular 510(k) submission pathway. How many samples are recommended, positive and negative, and out of those asymptomatic?

Timothy Stenzel: So a lot of this depends on all the aspects of your test and what you're seeking for the test. It's best handled through a Q-Sub or Pre-Sub submission or normal Q-Sub Pre-Submission process that will then be directed to our COVID team to help you. We have prepared recommendations for antigen tests. And that team can provide those to you under that process.

Mary: Thank you so much.

CDR Kim Piermatteo: Thank you, Mary, for that question. Our next question is coming from KB. KB, I've unmuted your line. Please, unmute yourself, and ask your question.

KB: Hi. This is KB from Morrison and Foerster. I was wondering if you can elaborate on and potentially provide more examples on the meaning of new technologies and fulfilling an unmet need. Sorry. This is for COVID-19 new policy. In the re-prioritization, can you please elaborate on the meaning of new technologies and fulfilling an unmet need? Thank you.

Timothy Stenzel: Yeah. Yeah. I mean, it's anything that would be valuable to the pandemic or to the ongoing COVID emergency now and isn't a "me too" product. For several categories of tests, we have multiple examples of them.

One is new technology where we only have one authorization that is open for EUA submissions is the breath test. We authorized one breath test. And we're willing to accept additional breath tests.

At some point, we may have more than enough breath tests. And the policy may be updated again. But that's a concrete example of a new technology where we only have one authorization.

So where we have plenty of tests already authorized, and an additional test would be a "me too" test, that's what we're steering away from now. You can come in for a pre-EUA submission to ask if your technology would be likely to qualify under that novel technology exception.

KB: Thank you.

CDR Kim Piermatteo: Thanks, Tim. Alright. Our next question is coming from Amanda. Amanda, I have unmuted your line. Please unmute yourself and ask your question.

Amanda: Hi. This is Amanda. Thanks for taking my question. It's regarding COVID-19, specifically, the safety communication for at-home COVID-19 antigen tests - take steps to reduce your risk of false negative results.

So at the August town hall, it was stated that FDA will be reaching out to all test manufacturers with additional information for how the studies referenced in the communication can be leveraged for authorization of tests and to recommend labeling changes. When can test developers expect to receive this guidance?

Timothy Stenzel: So we are continuing to work on that process because we will probably reach out to all relevant EUA holders at once with one process. And we're just refining that, so that it goes as smoothly as possible. Kris, anything to add as you're in charge of rolling that out?

Kristian Roth: Yeah. Thanks, Tim. Like Tim said, we do want to be able to cover all developers at the same time. So that's something we are addressing. And when we do reach out, we want to make sure that everyone has the information simultaneously. So that's where we are in the process right now.

Amanda: OK. Thank you.

CDR Kim Piermatteo: Thanks for that question, Amanda. All right. Our next question is coming from Ling. Ling, I've unmuted your line. Please unmute yourself and ask your question.

Ling: Hi. This is Ling calling from BD. I also have a COVID-19 question. And it's actually a clarification on a question that was emailed in.

We're happy to hear that the agency continues to be open to over-the-counter multianalyte antigen tests. But I wanted to clarify whether the Agency meant over-the-counter non-prescription, for example, for a test that's visually read, does not have a companion app, but is labeled for symptomatic users only. And if so, does the Agency have any additional recommendations to strengthen risk controls associated with such a test? Thanks.

Toby Lowe: Just to clarify some from a definition perspective, over-the-counter is, by definition, non-prescription. There is prescription home use, which is another sort of category of home use tests that do require a prescription. But over-the-counter is essentially synonymous with non-prescription. So can you clarify if you're asking about over-the-counter or a prescription?

Ling: No. That answers it. Over-the-counter, meaning a prescription is not required is exactly what I wanted to hear. So that answers it very succinctly. Thank you.

Toby Lowe: Great.

CDR Kim Piermatteo: Thanks, Ling. Alright. Our next question is coming from Tamasha. Tamasha, I have unmuted your line. Please unmute yourself and ask your question.

Tamasha Parsons: Hi. Good afternoon, everyone. My name is Tamasha, and I'm calling on behalf of Orasure Technologies. In the recently released recommendation document by the FDA, FDA indicates that usability comprehension study is required, including reading and interpreting results. Is interpretation of a low positive result required for the study?

Timothy Stenzel: I think you have a COVID question. And I'm wondering--

Tamasha Parsons: It's a COVID question. I'm so sorry.

Kristian Roth: Yeah. Thanks. So you're talking about a COVID antigen test read by a lay user and the difference between usability and user comprehension? Or can you clarify that?

Tamasha Parsons: So comprehension studies required, including reading and interpreting. And this is, yes, COVID tests over-the-counter.

Kristian Roth: Right. So user comprehension, of course, is reading the test. I think there's an element of both usability and comprehension. And I believe we do have some recommendations for what should be included in those studies. Of course, a bright line or a very dark easy to read line, perhaps, may have different usability or user comprehension than a faint line. So in general, we would want to have a comprehension of usability evaluated on the edges of the performance of the test. So certainly, faint lines would be helpful to evaluate those types of studies.

Tamasha Parsons: OK. Thank you.

CDR Kim Piermatteo: Thanks for that question. Thank you, Kris, for the response. Alright. Our next question is coming from Jennifer. Jennifer, I've unmuted your line. Please unmute yourself and ask your question.

Jennifer Stanford: Hi. Thank you. This is Jennifer Stanford from Hopkins MedTech Compliance. And my question is COVID-related. Just to clarify on this new guidance from yesterday, so if we have EUA submissions already submitted, and they're in the queue, it sounds like you'll continue to review those.

The new guidance, such as having prior EUA approval being backed by a government agency, whatever, will those apply to the ones that are already in the queue or only for new ones?

Timothy Stenzel: Toby, do you think you can respond to both of those?

Toby Lowe: Yeah. So submissions that are currently pending will remain in the queue until we respond to the developer. So we will be making our way through those to determine whether or not they will proceed towards authorization or whether we will decline to issue. Those decisions will be made based on a combination of the priorities and where they are in the review.

Something that's not going to meet the new priorities but was a couple of days away from being authorized, we're probably going to move forward with that. Something that was sort of sitting in the queue and does not meet the priorities, we would have to consider whether there are other factors that would apply there. So you sit tight, if you will. And you will hear an individual decision for each submission that's in-house. The information about those tests that are in queue was really intended to assure that there's not a blanket decision being made on all of the submissions that are in the queue.

Jennifer Stanford: That sounds good. So in that new guidance, one of the slides you just went over, I thought I saw that it said it does not apply to home tests, that this new guidance applies to lab developed tests. But would it also apply to over-the-counter COVID home testing, which would probably be considered a "me too" as Tim was just saying, I think?

Toby Lowe: I'm sorry. I didn't quite follow that.

Jennifer Stanford: So I'm sorry. I thought one of the slides you just showed talked about that this new guidance does not apply to home tests. Did I misread that? I thought maybe you'd said it only...

Toby Lowe: I think you may have misread that. I think the language that you're referring to, that it does not apply to home tests, was specifically on the slide about the State Authorization Policy. So that is only for that policy where a specific state that's listed on the FDA's notification list is authorizing laboratories within that state to develop and perform COVID-19 tests. And that's done without any submission to FDA. And that specific State Authorization Policy does not apply to the home tests or tests with home specimen collection.

Timothy Stenzel: Yeah. Just to clarify that exception, it is for LDTs only. It is for LDTs run in high complexity CLIA labs and only for labs that are in the state that the FDA has allowed to do that. And it does not include any testing in the home either, self-collection in the home or a home test of any sort.

Jennifer Stanford: OK. Thank you.

CDR Kim Piermatteo: Thanks, Jennifer, for that question. It looks like we have maybe time for two more questions. The next question is coming from Allen. Allen, I've unmuted your line. Please unmute yourself and ask your question.

Allen Chun: Yes. Can you hear me?

CDR Kim Piermatteo: Yes, we can.

Allen Chun: Yes. Hi. My name is Allen. Thank you for taking my question. This is regarding COVID-19 tests. If we have an EUA in queue already and it's considered prioritized, would FDA still take pre-EUA, brand new pre-EUA?

Timothy Stenzel: Or is it specifically for the test that's in the queue?

Allen Chun: Yes.

Timothy Stenzel: If it's related to a test in the queue, then yeah, we'll continue to communicate. It doesn't necessarily have to go through the pre-EUA process, though.

Allen Chun: OK. Great. Thank you.

Timothy Stenzel: If it's directly related to a test that's in the queue, just reach out to your reviewer.

Allen Chun: OK. Alright. Thank you.

CDR Kim Piermatteo: Thanks, Allen. Our next question is coming from Rohit. Rohit, I've unmuted your line. Please unmute yourself and ask your question.

Rohit Polavarapu: This is Rohit. My question is, as far as EUA approved multi-panel tests for point of care, would that count as a predicate device if I were to file for a 510(k) for a multi-panel, let's just say, COVID influenza rapid for point of care? Would the currently EUA approved ones count as a predicate device?

Timothy Stenzel: So the predicate device has to be something that FDA cleared. And that's just the formality of the submission. I think what you're talking about is a comparison device.

Rohit Polavarapu: That's right.

Timothy Stenzel: The current predicate may not serve well as a comparator. And that's why we have expressed flexibility in using EUA authorized tests as a comparator. However, we do recommend that you check in with the FDA through a Q-sub or pre-submission to make sure that the comparator is appropriate for your test. Not all EUA authorized tests may be appropriate. And so that will reduce your risk of doing a study if you go ahead and are assured of that and any other questions you might have about your development of your test for submission. Kris, anything to add to what I've responded?

Kristian Roth: Yeah. Thanks. So if you do submit a Q-sub or pre-sub, we can respond to you with your comparator question. Just to let you know, there are-- I would say I think we have at least three options for comparators that you can consider.

Rohit Polavarapu: Great. Thank you very much.

CDR Kim Piermatteo: Thank you. Tim, I think we have time for one more question.

Timothy Stenzel: Go for it. Go for it.

CDR Kim Piermatteo: So the next person is Homer. Homer, I've unmuted your line. Please unmute yourself and ask your question.

Homer Wu: All right. Thank you. This is Homer Wu from Hopkins MedTech Compliance. I have a question about the application we already submit to EUA. If we decide to go to the formal process-- I guess, right now, we can only do De Novo-- We need to start all the validation, or we can leverage the validation we already done?

Timothy Stenzel: So anybody who has an EUA authorization or has an EUA submission in that can be reviewed, that data, especially if it's ultimately authorized, can be used for the full submission. And we haven't authorized an antigen test now. So the submissions now are going to be De Novo submissions until we grant the first De Novo. And then submissions after that date can be 510(k)s. But yeah, we are seeking for developers to fully utilize the EUA data that was reviewed by the FDA and successfully reviewed by the FDA.

Homer Wu: Alright. Thanks. I do have a follow-up question about the De Novo. So if there are multiple companies applying for De Novo, when then happens, whether FDA will approve multiple companies for the De Novo?

Timothy Stenzel: The first authorization will be a De Novo grant. And the subsequent authorizations will be a clearance, so those that have a De Novo submission in house right now.

Homer Wu: OK.

Timothy Stenzel: Or have or have one prior to the first granting.

Homer Wu: So if I understand correctly, if we apply for De Novo, it gets approved. But if there's someone else before us, they're always going to be just 510(k)? Is that correct?

Timothy Stenzel: It would be a 510(k) clearance.

Homer Wu: OK.

Timothy Stenzel: And if you haven't already submitted a pre-submission or a Q-sub, we do recommend that for those that are trying to achieve full authorization for their COVID test.

Homer Wu: OK. Alright. Great. Thank you.

CDR Kim Piermatteo: Thank you. That was our last live question for today. Thank you, everyone, for your participation. And I, again, want to thank our panelists, Tim, Toby, and Kris.

So for your information, a recording of today's virtual town hall and transcript will be posted to CDRH Learn under the section titled "Specialty Technical Topics" and then for now, under both the "Public Health Emergencies" subsection and the "Coronavirus (COVID-19) Test Development and Validation Virtual Town Hall Series" subsection, in a few weeks. So to access those materials, please CDRH Learn at the link provided on this slide.

If you have any more specific questions about monkeypox diagnostic development, you may send an email to MPXDx@fda.hhs.gov. And for specific questions about COVID-19 diagnostic development, you may send an email to COVID19DX@fda.hhs.gov.

Please remember to join us for our next virtual town hall for monkeypox test developers on Wednesday October 5, 2022 from 12:05 to 1:00 PM Eastern time.

Thank you all again for joining us today. This concludes today's virtual town hall. Have a wonderful day.

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