CDRH Virtual Town Hall #100
mpox and COVID-19 Test Development and Validation
January 11, 2023

Joseph Tartal: Hello and welcome, everyone, to today's Virtual Town Hall number 100 for mpox and SARS-CoV-2 test developers. It's been almost three years since the beginning of the COVID pandemic in 2020, and the Center for Devices and Radiological Health has now held 100 of these IVD virtual town halls, reaching over 58,000 attendees. Thank you all for joining us at these town halls and engaging with us in the development of these important tests in the pandemic fight.

Today, we'll discuss and answer your questions about diagnostic tests in response to the mpox and COVID-19 public health emergencies.

I am Joseph Tartal, Deputy Director in the Division of Industry and Consumer Education in CDRH's Office of Communication Education, and I will be your moderator for today's Virtual Town Hall.

Our panelists for today are Toby Lowe, Associate Director for Regulatory Programs in 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; Dr. Kristian Roth, Deputy Director of the Division of Microbiology Devices in OHT7; and, Dr. Noel Gerard, Branch Chief for Bacterial Respiratory and Medical Countermeasures in OHT7.

For today's virtual town hall, we'll begin with opening remarks. Then we'll answer your previously emailed questions. And last, we'll address your live questions. As a friendly reminder for those of you participating live in today's virtual town hall, please be sure to have joined us via the Zoom app and not through a web browser to avoid any technical issues.

Our next virtual town hall will be held on Wednesday, February 15, 2023, for both mpox and COVID-19 test developers. You may refer to our web page titled, Medical Device Webinars and Stakeholder Calls, specifically our virtual town hall series, Test Development and Validation During Public Health Emergencies web page for details on all past and upcoming virtual town halls. Links to both web pages have been provided on this slide.

The presentation and transcript for our last virtual town hall, which was held on December 14, 2022, have been posted to CDRH Learn. A screenshot has been provided on this slide on where you can find those materials within CDRH Learn.

I'd now like to welcome Toby, who will provide today's opening remarks for mpox and COVID-19. Toby, the floor is yours.

Toby Lowe: Thanks, Joe, and thanks, everyone, for joining us. As Joe mentioned, this is our 100th IVD town hall since the beginning of the COVID public health emergency. And we're pretty excited that we've had these opportunities to connect with so many stakeholders. And we have found these town halls to be quite valuable and hopefully you have as well. So, thanks to everyone who has joined us over these past 100 town halls, for helping to make them so successful.

So just a couple updates today regarding monkeypox. We've discussed this before. We just want to remind everyone that we have responded to some of the pre-EUAs that we've received for mpox to let sponsors know whether or not we will be prioritizing review of their test. And we've begun to review some of those EUA requests accordingly.

If you have not yet received a response on your pre-EUA for mpox, please be aware that we are still considering some of them in the context of the shifting needs of the public health emergency, and we will get back to you with a response as soon as we can.

So now we can shift to COVID-19 updates. We did make some updates on our website last month that happened after our last hall, so we can give a quick rundown of those. On December 14-- actually, right after our last town hall, we posted a new web page called "Understanding Home Antigen Tests" that provides information to help users and public interpret their COVID-19 at-home test results with an easy step-by-step guide.

So that web page includes information about when and how many times to test, what the OTC results mean, what they don't mean, what the tests don't tell you, step-by-step guide on what to do if you test positive or negative, as well as a link to the over-the-counter home test web page that includes the list of FDA-authorized at-home OTC COVID-19 tests.

So then related to that, a few days later, we updated the COVID-19 OTC home test page to add three additional OTC COVID-19 antigen tests that received authorization, as well as to link back to the new "Understanding Home Antigen Tests" web page.

The OTC home test page is also the page that includes expiration date updates, and we are now requesting that manufacturers include an abbreviated link to that web page on their box labeling so that users are aware that they can check there to see whether their expiration date has been updated.

And then on December 28th, we updated the SARS-CoV-2 Viral Mutations web page to add an additional test that is expected to have reduced performance for the Omicron variant and subvariants. And that is the DxTerity SARS-CoV-2 RT-PCR CE test. So information on the specifics on that reduced performance can be found on that web page. And with that, I will hand it back over to Joe and we can move into some questions.

Joseph Tartal: Thank you, Toby. We'll now answer your previously emailed questions. Please note, we do receive some email questions that are too detailed or to 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 MPXdx@fda.hhs.gov mailbox for mpox questions, or the COVID19dx@fda.hhs.gov mailbox for COVID questions for updates.

Also, we received some specific questions as a follow-up to FDA feedback from pre-EUA, emergency use authorizations, or pre-submission requests that we will not address during today's virtual town hall. For those questions, we encourage you to contact your assigned lead reviewer to discuss or submit a supplement request.

So as we move on to our mpox questions, there are no previously emailed questions about mpox development, so we'll move to the previously emailed questions related to COVID-19 test development.

So for the previously emailed questions about SARS-CoV-2, I will be directing these questions to Toby. So the first question is, can SARS-CoV-2 test developers use plasma and serum that has been depleted of anti-SARS-CoV-2 antibodies as a negative control material for development of new serological tests and for negative controls for serology and neutralizing antibody tests that have already been granted approval?

Toby Lowe: Thanks, Joe. So generally we recommend that developers who hold an EUA authorization would first attempt to-- or who are seeking authorization would first attempt to obtain samples collected from prior to December 2019 from vendors and pull them to have enough volume for their testing.

We would be concerned that depletion of SARS-CoV-2 antibodies from samples may change the sample architecture or the antibody or protein content depending on the depletion method used. So sponsors would need to validate those controls to ensure that false results would not be reported as a result of changes to the composition of the controls.

And significant changes to the control's chemistry or composition would need to be submitted to the FDA for review for those tests that have already been granted an EUA-- or issued an EUA.

Additionally, we recommend that sponsors review the current policy to consider the FDA's current EUA review priorities, and if the changes that you're looking to make would not meet those review priorities, we would encourage you to pursue a traditional premarket review pathway, such as a De Novo or a 510(k).

Joseph Tartal: OK. Thank you, Toby. Our next question is, to support a multi-analyte flu and COVID antigen respiratory panel for De Novo or 510(k), could a molecular influenza COVID multiplex emergency use assay be used as the comparator assay?

Toby Lowe: So to support a multi-analyte antigen respiratory panel, De Novo or 510(k), we recommend that the comparator method for flu be a highly sensitive FDA-cleared RT-PCR test that was cleared within the past five years. We may consider one that was cleared prior to that time frame, if you can demonstrate that the test performance is expected to remain unchanged with the currently circulating flu strains. That could be done with in silico analysis of the primers and probes.

For COVID-19, the comparator method should be an EUA-authorized or FDA-cleared highly sensitive RT-PCR test that uses both a chemical lysis step and solid phase extraction of nucleic acids such as silica bead extraction. And further, the comparator test should be one that is validated with clinical samples and that generates CT values and has established a clinical performance of at least 95% PPA.

Generally, if you're looking to pursue a De Novo or 510(k) pathway, we recommend that you submit a pre-submission to discuss your approach for analytical and clinical studies.

Joseph Tartal: OK. Thank you. We'll move on to our next question. We received FDA feedback and recommendations for submitting a 510(k) for a COVID-19 antigen test. The FDA recommends including

serial testing in the intended use and referenced the NIH-sponsored Serial Antigen Testing Study. Can FDA confirm that developers seeking a serial testing indication for their COVID-19 antigen tests in a 510(k) do not need to include serial testing as part of a prospective clinical evaluation to support the premarket submission?

Toby Lowe: So, we've discussed serial testing and antigen tests quite a bit. So to just refresh that, we do continue to work to reflect the need for serial testing in antigen test EUAs. The results of the NIH-supported UMass study have been published, and we are leveraging that data in support of serial testing indications for EUAs.

And that means that we've generally not requested additional studies to support serial testing for EUAs. One of the goals of that NIH-supported UMass study was to provide broadly applicable data to avoid the need for individual developers to perform large and expensive studies. And this has generally been quite successful for tests under EUA.

For traditional marketing submissions, we have not yet granted a De Novo or cleared a 510(k)-- excuse me-- cleared a 510(k) for a COVID-19 antigen test. And so we do continue to recommend submitting a pre-submission to discuss your proposed validation strategies if you intend to pursue a 510(k) or De Novo.

Joseph Tartal: OK. Thank you for that great information. Our next question is, FDA recommended that test developers with clinical performance of a percent-positive agreement or negative percent agreement greater than 95% provide a risk assessment for why it is acceptable for a test performed in a CLIA-waived site to have a lower accuracy than 95%.

Would additional data such as serial testing data collected as part of a prospective clinical evaluation of the candidate tests serve as a suitable mitigation for the risk assessment? And additionally, are there specific requirements for serial testing in such a case?

Toby Lowe: Thanks, Joe. Just to clarify, this is for test developers with clinical performance with a PPA or MPA of less than 95%.

Joseph Tartal: Oh, less than. My mistake. Yes, that would be--

Toby Lowe: [LAUGHS] So the-- and this is looking for-- or looking at the difference between an FDA clearance or approval and a CLIA categorization. So, the standards for FDA clearance or approval and the standard for CLIA categorization are different, though FDA is responsible for the administration of both of those.

So, FDA clearance or approval is based on a demonstration that there is a reasonable assurance of safety and effectiveness for the device. And categorizing a test as CLIA-waived is based on a determination that the test is so simple and accurate, that there generally is a negligible chance of an erroneous result or no unreasonable risk of harm to the patient if performed incorrectly.

Therefore, when considering a test that would be CLIA-waived-- for example, a test seeking an intended use that includes home use or use at a CLIA Certificate of Waiver site, such as a clinic, it's important to consider the accuracy of the test. In situations where a test has a lower accuracy, such as a PPA or MPA

lower than 95%, we then consider whether there are appropriate risk mitigations to prevent an unreasonable risk of harm to the patient.

As previously discussed, these risk mitigations may include serial testing in the indication to increase the likelihood of an accurate result, as well as labeling, such as warnings, limitations, reporting negative results as presumptive, and potentially other labeling mitigation. And just to reiterate what I've said a couple of times, we do continue to recommend submitting a pre-submission to discuss your proposed validation strategies if you are intending to pursue a 510(k) or De Novo.

Joseph Tartal: Thank you, Toby, for that response. And it sounds like you guys want to hear from people about their clinical validations before they go submitting. So I hope that message has been made loud and clear. We've got one more of our pre-submitted questions. Can the BioFire Respiratory Panel 2.1 DEN200031, that is intended for individuals suspected of COVID-19, be used as a predicate device for a device that claims which will-- for a device that claims which will have both symptomatic and asymptomatic claim?

Toby Lowe: Yeah, so we have gotten a number of questions like this about specific tests asking if they can be used as a predicate device. And any test that is cleared or granted a De Novo can be used as a predicate, which is different from what can be used as a comparator for the clinical study.

So again, this would fall to the previous comments where we would recommend a pre-submission or Q-submission with specific information about your device and design and your study proposal so that we can make sure that we're giving specific feedback that's appropriate for your situation.

And I think we can-- I can hand it back to you, Joe and we can go into the--

Joseph Tartal: Live questions. Yep. Thanks-- thanks again for that clarification and for all the responses. That wraps up the previously emailed questions for both mpox and COVID-19 test development. And we'll move forward now to our 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 and select the blue button to unmute your line, then identify yourself and ask your question.

Please remember to limit yourself to asking only one question. If you have additional questions, you may raise your hand again to get back into the queue and I can call on you as time permits to have that question answered.

So our first question is from Annie Wright. Annie Wright, I'm unmuting on your line. You're unmuted. Please unmute yourself and ask your question.

Annie Wright: Hello, my name is Annie Wright, and I'm from Wondfo USA. Thank you for taking my question. So my question has to do with the-- now that we're going to go for a De Novo 510(k) for an OTC product, in regards to the clinical study and randomization, before when we were doing-- we were preparing for an EUA study, the position of the Agency was to essentially conduct-- have them conduct the self-test first prior to doing the collection for our RT-PCR so that there is no-- basically

minimal to no risk of the learning from the health care professional. Is that still the case? Or does FDA require us to have randomization now in regards to collection of samples for OTC?

Toby Lowe: Kris, do you want to take this one?

Kristian Roth: Yeah, sure, thanks. So I think the issue of users being taught how to collect an appropriate sample was something that we were concerned about earlier on in the pandemic. I think now we're in a different type of situation where literally a billion tests have been distributed to folks in the US, and certainly finding folks that are naive to self-swabbing is difficult and that's not something we are recommending.

So, the concern of finding naive folks or being concerned with folks being trained by watching a health care provider take a nasal swab is much, much less of a concern now than it was quite some time ago. So, I think we are open to a number of different approaches. Randomization certainly is acceptable.

I think what's important is to have a-- what we're calling a washout period or a sufficient period between the two samples being taken such that you're getting a good sample for both. In some cases, we have recommended taking the comparative first because that is really the most reflective of how a test will be used in practice. You're not going to take two swabs, you're only going to take one swab, so I think we would be open to that as well.

I think the take-home here is that there's really no strong recommendation at this time as far as swab order other than be sure that you have a reasonable time period between the two swabs such that you get a good sample for both tests.

Annie Wright: OK. So, I mean-- I guess based on what you're saying now, if we have a plan of assigning like numbers-- so odd would be—

Kristian Roth: Sure.

Annie Wright: --you do the-- you do the RT-PCR first, and then you would have-- that would be not-- that would be acceptable?

Kristian Roth: That would be acceptable, and I think we would also recommend just taking a look at the performance and making sure that the performance for the two tests is-- I'm sorry, whether it's the first or second test, making sure that that's similar. So if you're seeing-- if you do the comparative first, you get one performance, or if you do the competitor second, you get a different performance, that, of course, would raise some red flags. So just-- I would keep an eye on that if you are going to be the randomization approach.

Annie Wright: OK. So, I mean, in this particular case, in terms of if you were doing the study and you're doing 20 collections a day or whatnot depending on the thing-- and then they would basically—you're not going to see the performance until a couple of days for the RT-PCR because, of course, they have to be sent to the lab, right?

And then whereas-- so we would know. So basically what you're saying is just monitor it and then see how it goes and then potentially change your strategy based on the performance? Is that—

Kristian Roth: You could consider that. And if you were going to change the strategy, I think our typical recommendation would be that the patient would have the standard of care done first. Whatever the standard of care test is, and if that's the RT-PCR, then certainly that should be done first, of course. If we're outside of that standard of care setting, now there's a little bit more flexibility about how you can go about doing the swabbing.

Annie Wright: OK. But, I mean, I guess-- because we have to send our protocol to IRB, so I guess—

Kristian Roth: Sure.

Annie Wright: --it would probably behoove us to-- but I guess-- what I'm just trying to get at is if there is an expectation of randomization and that we need to justify how we randomized, would that be the position of the Agency once we get into the submission portion? Because I want to make sure that we're doing it-- performing our clinical study to the Agency's expectation.

Kristian Roth: Yeah. I think any randomization based on birth date, even and odd, anything that has that type of approach I think is acceptable.

Joseph Tartal: OK. Thank you, Annie, for your question. Our next question is from Roya. Roya, I'm unmuting your line. Please unmute yourself and ask your question.

Roya Khosravi-Far: Hi. This is-- can you hear me?

Joseph Tartal: Yes.

Roya Khosravi-Far: Hi, everyone. This is Roya Khosravi-Far for at Innotech Precision Medicine, and thank you very much for taking my question. One of the questions that I have is with regard to multiplexing-- multiplex tests with flu. And we were wondering if the Agency accepts a pan flu A, flu B test for a multiplex test that would be combined with SARS-CoV-2, agnostic SARS-CoV-2 test.

Toby Lowe: Thanks for that question. I can start it off, and then see if Kris wants to add anything. I think that we would probably want you to come in with a pre-EUA if you're looking to do this under the EUA or with pre-sub if you're looking at a 510(k) or De Novo since we would want to better understand what you're planning to look at and how you're planning to report. So Kris, do you want to add anything to that?

Kristian Roth: Sure. Thanks, Toby. I think this is an evolving area. For folks that are at home, this OTC test, that's something I think we can discuss with you in the context of how you envision your test being used and the performance. If it's something that-- if it's for professional use, I think we might have a slightly different recommendation and it be more in favor of tests that do differentiate flu A and flu B. So, if you're talking about OTC EUA setting, that's something I think we can certainly engage with you on.

Joseph Tartal: OK. Thank you for your question. We'll go on to our next question from Jordan. Jordan, I'm unmuted on your line. Please unmute yourself and ask your question.

Jordon Chaput: Hi, I'm Jordan Chaput with Cantor BioConnect, and I just had a question regarding organizing a multiplex antigen device trial. What is recommended for capturing influenza B samples when the rates are so low in the United States?

Toby Lowe: Yeah, so we have talked about that a bit on here previously, that we would expect you to attempt to include flu B in your trial, and then if you're not able to collect a sufficient number of samples through your trial, you can come talk to us about different potential options for how to move forward there. Kris, do you want to add some more specifics to that one?

Kristian Roth: Yeah, thanks. So, you can take a look at two recent authorizations, one from Lucera, the other from Visby. So those--the data packages that are reflected in those instructions for use don't meet the recommendations for flu A, flu B. There are some other approaches in there. There's some banked sample testing. And you can also look at the conditions of authorization, and you'll note that there's a requirement to keep the study going and enrolling until you do get those recommended flu A and flu B positives.

Flu B, of course, is very, very low this year, and certainly we're not requiring companies to collect an impossible number of specimens with the understanding that this year is very low. Perhaps next year it's not low or in the future it's not low and at that time we may have different recommendations. But I think publicly, you can look at those two instructions for use and get a sense of where we're at right now as far as what we think is acceptable for flu for multi-analyte.

Jordon Chaput: Great. Thank you so much.

Joseph Tartal: OK, our next question is from Wenli. Wenli, I'm unmuting yourself-- I mean I'm unmuting you. Please unmute yourself and ask your question.

Wenli: OK. Thank you very much for taking my call, and this is Wenli XYZ Laboratory. And I just have a question-- thank you for the question about the randomization-- the method-- the clarification of the randomization. And I have a related question now because the OTC test is so popular and almost everyone will get some-- and test at home and see if they're positive or negative, in that case, some of the participants, when they come to the clinic side, they probably will already know if they're positive or negative with the symptoms. In that case, would that violate the prospective study, that part, if they-- how we can avoid that part.

Toby Lowe: So, we've talked about enrichment strategies on these calls before. And I think that's something that we've always generally said to come talk to us about. If you are looking for-- whether you need to make sure that individuals don't know their status at the time of the trial, I think that's typically what we expect for enrollment.

What you're describing seems a little bit like a unique case. So Kris, I don't know if you to weigh in or if this is something that we would want them to come in to discuss in a pre-EUA.

Kristian Roth: Yeah, I can partially weigh in. I think we understand that-- I just said, there's a billion tests that have been provided to the US, and testing is commonplace now. I think we understand that some of your clinical trial participants may know their test result from the previous day or day before.

And that's something that I think we are—we're willing to accept a portion of your study to be comprised of those people. We would have some guidance on trying to evaluate the bias-- the potential bias. Of course, if someone knows they're positive, they're really going to be looking closely for that positive test line on their visually read test.

So, I think we can talk about how many is acceptable, what kind of data analysis we would recommend to look for bias. Of course, if it's a machine-read test, that's a different story. If that does change the bias evaluation; folks don't have to determine their own positive/negative test result.

So like I said, I think a certain percentage, we're willing to kind of work with you on. But again, that would have to be in the context of a specific pre-EUA or test and clinical study plan just so we make sure we understand all of the different aspects of your study.

Wenli: Yeah. Great. Thank you, yeah, because-- so even though we don't advertise this, we don't see come, like people, they just-- they-- OK, they test at home positive or they come to the clinic, therefore, we have no idea whether they're already tested. But it looks like we need to ask them whether they're tested or not at home.

And also, I think it's-- this issue is more severe when it's-- when it gets to the borderline of negative or not or something like that. If it's a strong positive, it really should not affect them as much. But I think-- yeah, I understand now. Thank you so much.

Joseph Tartal: OK. Thank you. Our next question is from MC. MC, I'm unmuting yourself-- unmuting you. Please unmute yourself and ask your question.

Maria Cortez: Hello, I am MC. It's for Maria Cortez. Thanks for taking my question. I'm interested to know more about how it's going to be-- or if FDA is rethinking how the clinical studies for mpox are going to be complete, since access to positive samples is getting so challenging. It's worldwide, it's going down, and it's very difficult to get new positive samples.

Toby Lowe: Thanks for that question. Noel, do you want to talk about the mpox clinical studies?

Noel Gerald: Sure. I can just note in general that for molecular tests, we have allowed initial authorization with contrived samples, and that is still the case with the expectation of finding actual natural clinical samples post-authorization to demonstrate performance.

But this is also in the context of assuming that there is a prioritization for review, and know that it will be reviewed. But I don't know if you have anything else to add to that, Toby.

Toby Lowe: No, that's great. I think that's a really good point that you just made there, Noel, about the prioritization and which tests we are prioritizing for review. So, taking a look at the templates that are posted on our website, as well as the guidance that discusses our prioritization, is a good first step.

Joseph Tartal: OK. Thank you both.

Maria Cortez: Thank you.

Joseph Tartal: Our next question is from Raul. Raul, I'm unmuting you. Please unmute yourself and ask your question.

Raul Arevalo: Hello, my name is Raul Arevalo from Thermo Fisher. And my question is, can the Agency share insight on when the SARS EUA termination notice is expected to be published?

Toby Lowe: Do you mean for the SARS-CoV-2 public health emergency?

Raul Arevalo: Yes. When do you anticipate the EUA will be terminated?

Toby Lowe: Yeah. So we don't have any data for that at the moment. We do have some information on our website that-- on our FAQ site, we do have some information about that. There are two different declarations. There's the 319 determination under the Public Health Service Act, and then a separate declaration under Section 564 of the FD&C Act. That's the EUA declaration. These are independent.

The 319 declaration is a three-month declaration, and then it has been extended every three months since it was first issued in January of 2020. And that will last for 90 days from each iteration, unless the Secretary extends it or proactively terminates it.

And then separately, the 564 EUA declaration is what gives FDA the authority to issue emergency use authorizations. And that is in effect until the Secretary of HHS proactively terminates it, and we do not have a date for when that may happen. You may be aware that there are many previous EUA declarations that are still in effect, such as MERS, Zika, Ebola. And so we don't have a timeline there.

Raul Arevalo: All right. Thank you.

Joseph Tartal: We currently don't have any more questions. I'll give it a few seconds for anyone to ask a question. OK.

It sounds like that is our last-- oh, nope, one jumped in there. Annie, I'm going to unmute your line. You're unmuted. Please ask your question.

Annie Wright: Oh, thank you so much. My question is-- this is Annie Wright again from Wondfo USA. My question is in regard to the sample type for the RT-PCR. I know that they need to have clinically validated samples. So for example, if you did have nasal swabs, I know that the antigen tests for cobas-19, the cleared version, has validated samples for nasal swab sample type.

Unfortunately, they're not commercially available yet, the reagents aren't. So we were looking at the EUA-cleared versions, and I know that one of the-- I think it was the duo or the cobas duo. It only has validation data for 15 positives. And so would that be considered acceptable for the Agency in regards to using it as a sample type for the RT-PCR?

Toby Lowe: So I'm not completely clear what you're asking, but it sounds like you're asking about specific comparator methods. And so we would recommend that you send that into the mailbox with specifics about your study design and what tests you're looking at for comparators so that we can provide feedback directly there.

Annie Wright: OK, OK, OK. I did-- we did send in a pre-sub and we have a name or of a reviewer. Would that be acceptable as well, going directly to the reviewer? Or would it be--

Toby Lowe: If you have a pre-sub--

Annie Wright: --the mailbox?

Toby Lowe: Yeah. If you have a pre-sub open, then you should absolutely reach out directly to your reviewer.

Annie Wright: OK. OK. Thank you so much.

Joseph Tartal: OK. Thank you. That was our last live question for today. Thank you for everyone for your participation today. And again, I want to thank our panelists, Toby, Kris, and Noel, as well your work and hard work in helping everyone understand the expectations of FDA and the requirements. I don't know how to give you enough credit for all the work you've done over these last 100 town halls and the information and the public impact that it's had during these unprecedented times during the pandemic.

So, thank you and all your colleagues at OHT7.

Today's Virtual Town Hall presentation and transcript will be posted to CDRH Learn under the section titled "In Vitro Diagnostics" and the subsection titled "Virtual Town Hall Series."

If you have additional questions about mpox test development, you may send an email to MPDdx@fda.hhs.gov. And for additional questions about COVID-19 test development, you may send an email to COVID19dx@fda.hhs.gov.

As a reminder, our next Virtual Town Hall will be for mpox and COVID-19 test developers, and will be held on Wednesday, February 15, 2023 from 12:05 to 1:00 PM Eastern time. Thank you and have a nice day.

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