

**Virtual Town Hall #89**  
**July 27, 2022**

**Moderator: CDR Kimberly Piermatteo**

**CDR Kimberly Piermatteo:** Hello and welcome everyone to Virtual IVD Town Hall Number 89 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.

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 Number 7, or OHT7, in CDRH's Office of Product Evaluation and Quality, or OPEQ; and Dr. Kristian Roth, Deputy Director of the Division of Microbiology Devices, also in OHT7.

For today's Town Hall, we'll begin with some opening remarks and a few reminders, followed by answering your previously emailed questions, and then proceed to address your live questions.

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 June 29 IVD Town Hall recording and transcript have been posted.

We will continue holding these Town Halls monthly on the fourth Wednesday of the month. Therefore, the next scheduled IVD Town Hall will be on Wednesday, August 24, 2022 from 12:05 to 1:00 PM Eastern Time, followed by one on September 28 and one on October 26.

Future dates for Town Halls after that will be announced once they have been confirmed. Please refer to the virtual Town Hall series web page for details on upcoming IVD Town Halls. A link to this web page is provided on the bottom of this slide.

And lastly, for those 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 Kris, who will be providing our opening remarks. Kris, the floor is yours.

**Kristian Roth:** OK, great. Thank you, Kim. Appreciate that introduction. Just four quick items from me today. Listed here, you see July 8 the FDA did authorize two new over-the-counter antigen rapid tests. This is the Watmind Speedy Swab Rapid COVID-19 Antigen Self-Test and Genabio COVID-19 Rapid Self-Test Kit. So these two products are now available and the latest to come out of our antigen review team.

On the 14th of July, we did update the SARS-CoV2 Viral Mutations Impact on COVID-19 Tests web page. This update included information about a new type of SARS-CoV2 test, which can identify and differentiate SARS-CoV2 variants or lineages and sub-lineages. It's important to kind of check back with

that web page, as most folks are aware, the virus does continue to mutate and new mutations do have various impacts on diagnostic tests. So this is just the latest update on that web page.

On July 15th, we published a Safety Communication titled For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results. The Safety Communication recommends the use of lesion swab samples only for monkeypox virus testing. This is to avoid false results and provide additional information for test users, caregivers, health care personnel, test developers, and laboratory personnel more information on sampling for monkeypox testing.

On July 21, we did update the at-home OTC COVID-19 Diagnostic Tests web page. This is a update which added images of the exterior box labels for consumers and other test users. So there is a reference, a visual reference, that folks can use to make a decision about choosing the right test for their needs. There is a variety of reasons folks may want to confirm that the tests that they're buying and have in their possession match those images, and now that resource is available for everyone to use.

And that's all for me, and I'd like to hand it over to Tim for some additional remarks.

**Timothy Stenzel:** Yes. Thanks, Kris. And welcome, everyone, today. So my reminders have to do with monkeypox, which continues to be ongoing in the United States and in many countries around the world. Just a reminder that LDT, Laboratory Developed Tests, are still under enforcement discretion per the FDA so the labs can develop and validate and begin testing without even notifying the FDA.

Also I'd like to highlight that the FDA-cleared CDC assay is currently being run at four major reference labs, and a fifth major reference lab is offering an LDT.

Next, the FDA does continue to support the CDC with options for the FDA-cleared CDC tests, the non-variola orthopox test that's being used in scores of LRNs [Laboratory Response Network] as well as at four of the reference labs with updated options that are able to increase the throughput of testing and with hope that it does also decrease the turnaround time even further.

For developers, LTD developers and others, there are controls available from both the NIST, the National Institute of Standards, as well as Twist Biosciences. And perhaps there are others that are on the market now as well. And with that, that ends my updates or reminders about monkeypox and we can move into the next section. Thanks. Over to you, Kim.

**CDR Kimberly Piermatteo:** Great. Thank you, Tim and Kris. We will now answer your previously emailed questions. Please note, we do receive some questions that are too detailed or test case-specific that we will not address today.

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 here to 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 [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) mailbox for an update.

Kris, I'll be directing these questions to you. The first question is, can FDA clarify if Flu A and RSV samples from outside the U.S. are acceptable to use in analytical test studies?

**Kristian Roth:** Thanks, Kim. So again, I just want to highlight this is analytical test studies. So, well-characterized Flu A and RSV strains with certificate of analysis or other such assurances of identity and quality from reputable institutions or sources outside the U.S. could be considered as acceptable for conducting analytical studies. We recommend that you document and, if needed, demonstrate that the strains tested were well-characterized.

**CDR Kimberly Piermatteo:** Thank you, Kris. Alright, our next question has two parts. I'll read them both, and then I'll turn it over to you, Kris. So that first part is, can FDA provide additional recommendations that can be used to calculate performance within the 10% to 20% target? The second part is, can multiple positive percent agreement calculations be used if a prospective clinical data set for a home use antigen test has greater than 20% low positives?

**Kristian Roth:** Sure. Thanks. So if you have completed a clinical validation study with confirmed omicron positive samples, and you have collected more than 20% low positives in your prospective clinical study, then we recommend submitting all of your data, including all the low positives, and we can work with you on a data 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. However, this should not delay the start of your clinical study since the study protocol details, such as enrollment criteria and the number of positives needed, is not impacted.

**CDR Kimberly Piermatteo:** Thanks, Kris. That wraps up our previously submitted questions. We will now take your live questions. So as a reminder, 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 do 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.

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

Joshua, I've unmuted you again, if you can look for that prompt to unmute yourself.

Alright, Joshua, I'm going to come back to you. Keep an eye out. I'll try to come back to you after we go to our next caller.

Annie, I am unmuting your line. Please unmute yourself and ask your question.

**Timothy Stenzel:** Kim, I don't usually see the mute function still on. I'm just wondering if you're really unmuting these folks or if they're muted.

**CDR Kimberly Piermatteo:** Yes.

**Timothy Stenzel:** OK.

**CDR Kimberly Piermatteo:** So I'm going to ask Annie to unmute again.

**Timothy Stenzel:** Hope we're not having technical difficulties.

**CDR Kimberly Piermatteo:** Yes. Let me.

**Timothy Stenzel:** Could you try the next person? Try to get somebody who's live.

**CDR Kimberly Piermatteo:** Yep. So we're going to go ahead and move down to Anjali Zimmer. I'm going to allow you to talk. Please unmute yourself and ask your question.

**Anjali Zimmer:** Hello, can you hear me?

**CDR Kimberly Piermatteo:** Yes, I can. Great.

**Timothy Stenzel:** Yes. Thank you.

**CDR Kimberly Piermatteo:** OK.

**Anjali Zimmer:** Thanks for taking my question. This is Anjali from Color Health, and I was curious if the FDA has any recommendations or advice for saliva-based antigen home tests.

**Timothy Stenzel:** So we've seen quite a bit of attempts at saliva-based antigen tests. I don't know exactly why it's been such a challenge. You know, there are a lot of advantages if it would work, but it may be that there's a concentration that's needed, such as with a molecular test.

So some of the molecular tests have not worked quite well in saliva, but that may be due to the concentration effect in extraction. So if you want to attempt it, you would just follow the recommendations, if you want, for antigen test validation. The comparator for saliva would be a nasopharyngeal swab using a high sensitivity molecular central lab test.

I would double check with the FDA before using a comparator test to make sure that it's high sensitivity enough. And then thirty positives and thirty negatives if you're going for symptomatic individuals.

We have recommended to others that want to pursue saliva. If this is a new test, we would recommend that you also consider as a backup and anterior nares swab. So that if you should have any issues with saliva, at least you have anterior nares.

**Anjali Zimmer:** Thank you.

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

**Paul Chapman:** Hi. Can you hear me?

**CDR Kimberly Piermatteo:** Yes, we can.

**Paul Chapman:** Super. Just curious to know if there's-- Oh, sorry. Paul Chapman from Domus Diagnostics. Where the guidance is for LOD for at-home or point of care nucleic acid COVID tests, and I see there's in terms of copies per mil, copies per swab, copies per reaction, is there definitive guidance on the target LOD?

**Timothy Stenzel:** Kris, would you like to maybe take this one?

**Kristian Roth:** Sure. We don't have a kind of recommendation for the LOD level or the LOD value. Of course, we have an LOD study design recommendation. That is important, because that LOD actually drives the concentration, which you'll do your other analytical studies and the cross-reactivity and interference studies.

There are a variety of sources for virus and the variety of quantification methods, digital drop PCR, PCIV 50, regular PCR. So without a common standard or really measuring that LOD and IUs per mil, something of that nature, it would be difficult to set a LOD target.

So that's why we don't set a target, but it is important to appropriately define your load with the recommendations that we provide, because that does allow for a robust evaluation of those other analytical studies.

**Paul Chapman:** Great. Understood. Thanks.

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

Neil, I'm going to unmute your line one more time. Make sure you look for the blue prompt in Zoom.

**Neil Pankau:** Now can you hear me?

**CDR Kimberly Piermatteo:** Yes, we can.

**Neil Pankau:** Hi, this is Neil Pankau, JENLO Compliance, and my question is more general in nature, but generally on granting an EUA, is that based more on the particular diagnostic tests that's been submitted, or are you looking more at the disease state, or still kind of doing the combination of both?

If you want to get more specific, obviously COVID's been declared a public health emergency, but I'm wondering now if the assessment changes with the monkeypox designation as well for those types of tests.

**Timothy Stenzel:** So WHO has declared a public health emergency of EIC and international consequence [International Concern]. And we are awaiting word about whether such an emergency is declared for the U.S. But for right now, to my knowledge, unless it happened in the last few minutes, there is no emergency in the U.S. for monkeypox.

So regarding, COVID test development validation, we have templates and recommendations for developers that they can use to help them develop their test and validate their tests and guide them on how to get that test submitted to the FDA for review. If you have a follow up question, probably ask one.

**Neil Pankau:** Am I still unmuted?

**Timothy Stenzel:** I can hear you.

**Neil Pankau:** OK. Yeah, the follow up question isn't really on so much the particular types of diseases. I was just using those as an example for you. But in terms of whether or not to grant an EUA, does the current state of the disease play a part?

So I used COVID as an example, because obviously with it being declared public health emergency within the U.S. I understand that monkeypox has not been, but given the increases or anything, does that change the assessment equation the FDA would apply for granting an EUA or not?

**Timothy Stenzel:** So the EUAs we're talking about today are for COVID. And on November 15, 2021, we established our priorities for review, and that guidance applies only to COVID. And so those are the tests we're talking about today. We're not talking about any other disease.

So the EUA statute doesn't apply to monkeypox, and so this pathway doesn't exist for monkeypox right now. Nor does it apply for any other disease state that doesn't have an emergency declared.

**Neil Pankau:** Got it.

**CDR Kimberly Piermatteo:** Thank you, Tim.

**Timothy Stenzel:** Yeah. Thanks.

**CDR Kimberly Piermatteo:** Thanks, Tim. Thanks, Neil. Alright, our next question is coming from Christina. Christina, I have unmuted your line. Please unmute yourself and ask your question.

**Christina Zhou:** Hello, everyone, and good morning, Tim. This is Christina Zhou from Thermo Fisher Scientific. I have a question about the transition plan for medical devices issued EUA during the COVID-19 public health emergency. I would like to understand if FDA has any plans to publish the transition plan guidance this year.

**Timothy Stenzel:** So the FDA has publicly stated that we're working on transition guidance, and there is a process to that. People are urged to comment on the guidance, on the draft guidance. And then when the comment period closed, or will close, I don't remember the date, the FDA will review those comments and make any needed updates to the guidance.

It then goes through a clearance process. And once it goes through clearance, then it is made public. The FDA is unable to project when that might happen.

**Christina Zhou:** I see. Thank you.

**CDR Kimberly Piermatteo:** Thank you for that question, Kristina.

**Christina Zhou:** Thank you.

**CDR Kimberly Piermatteo:** Yeah. Our next question is coming from Cynthia. Cynthia, I have unmuted your line. Please unmute yourself and ask your question.

**Cynthia Merrell:** Good morning. This is Cynthia Merrell from Clip Health. As we plan our multiplex clinical trial, obviously we would like to be able to reuse this data for any future 510(k) work. Is there a target number of positives and negatives for COVID flu A and flu B for a 510(k) application?

**Timothy Stenzel:** So for a 510(k), or if it's not been granted De Novo yet-- so for molecular—

**Cynthia Merrell:** I'm sorry, this is an antigen test.

**Timothy Stenzel:** OK. So the first antigen authorization will be a De Novo. And so we're accepting De Novo submissions now for antigen tests. And you can submit a Pre-Sub, or Q-Sub, and we will review it, asking this question, and we can provide you with information there.

**Cynthia Merrell:** OK, so there are no published targets like there are for the EUA?

**Timothy Stenzel:** No, for full authorization, we have developed recommendations and we can inform you of those through the Q-Sub/Pre-Sub process and those are not published.

**Cynthia Merrell:** OK, thank you.

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

**Dennis Shay:** Hi. Thank you. Dennis Shay from [INAUDIBLE] Health. So this is referring to a molecular at-home test that as a non-patient contacting component that houses all the reagents and chemistry. And that's sealed and everything, and all the reagents in there are well below any limits of acute toxicity.

So we're just wondering, we've been asked to do or satisfy or to look at tox assessments. And we're wondering, is that a full extractables and leachables, or is the FDA accepting rationales for these non-patient contacting tightly sealed types of containers?

**Timothy Stenzel:** So we do a safety review for all tests, including home tests. There are additional safety considerations for a home test, because of the location of the testing and the fact that consumers are using the test rather than medical professionals.

And so in submission, we want to know what's in your test. And we'll do a toxicology review when we see that.

And, you know, if there were toxins in there, but there are mitigations that prevent access by a consumer, we would assess the mitigations for that situation. So that would be handled by our routine home test review.

**Dennis Shay:** OK. Thank you.

**Timothy Stenzel:** Mhm.

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

**Robert Di Tullio:** Yeah, hi. Can you hear me?

**CDR Kimberly Piermatteo:** Yes, we can.

**Robert Di Tullio:** Yeah, hi. And thanks for taking my question. This is Robert Di Tullio I have a question about the choice that a company might have with regard to going for full authorization, or continuing to try to file an EUA.

In terms of the response time for a pre-EUA versus a Q-Sub, is there any benefit for continuing the EUA process to get a quicker response? Or can you get any kind of light on the timing, please? Appreciate that.

**Timothy Stenzel:** Well, we continue to get, on average, 100 new IVD EUAs and other related submissions a month, though our team continues to be swamped, and our Q-Sub/Pre-Sub review times are still extended due to the overwhelming amount of COVID work and now our work with monkeypox.

We have personnel now dedicated to monkeypox review. So that has eroded some of our capability as we respond to this outbreak. So I can't give you review times. We are recommending that people go for authorization. We have a lot of recommendations in the templates, so I would restrict pre-EUAs for an EUA, a pre-EUA.

We have an EUA tip to very narrow questions rather than broad questions that have been answered through our templates and our template recommendations. And especially as things have updated, the transcripts that we've had in the last weeks and months on COVID.

So unfortunately, I can't tell you the best route. There's going to be more samples required for a full authorization. The EUA process, at the moment, at least, still is easier to get through to get onto the market.

**Robert Di Tullio:** OK. Thanks very much. That was a very good pointed answer, Tim. I appreciate that. Thank you.

**Timothy Stenzel:** You're welcome.

**CDR Kimberly Piermatteo:** Alright, thank you, Robert, for that question. Our next question is coming from Michael. Michael, I have unmuted your line. Please unmute yourself and ask your question.

**Michael Zhang:** Hi there. Can you hear me?

**CDR Kimberly Piermatteo:** Yes, we can.

**Michael Zhang:** Hi. This is Michael Zhang from Thermo Fisher Scientific. I have a question regarding the EUA transition draft guidance. I just wanted to confirm whether a manufacturer can start a transition plan and submit to the FDA based on the draft guidance, or is it needed to wait until the transition guidance is published in order to start the transition.



**Timothy Stenzel:** The transition guidance is intended to provide a period between the end of the emergency and the end of the EUA authorities, and allow test developers to prepare and submit their full authorization package. And so that's the point of the transition guidance.

Anybody who wants to come in now with the full authorization submission or molecular, test most of them can come in through a 510(k). Serology and antigen tests would need to come through a De Novo. And we've been encouraging developers to do that. And if you want to engage with us on what's needed for that, which we do recommend that you come in with a Pre-Submission or a Q-Submission to discuss your validation plans for full authorization.

So we would encourage developers that want to be on the market long-term to get started now, or even a long time ago. There is, unfortunately, a lot of COVID out there in the United States right now. So this is, in some ways, helpful in the aspect of being able to do the clinical studies, the additional clinical work to get your submission up to a full authorization submission.

**Michael Zhang:** I see. Thank you very much.

**Timothy Stenzel:** Mhm.

**CDR Kimberly Piermatteo:** Thanks, Tim. Thanks, Michael. Alright, our next question is coming from Sue. Sue, I have unmuted your line. Please unmute yourself and ask your question.

**Sue Hart:** Thank you. This is Sue Hart from Hemex Health. Previously, it was important to provide sequencing data for clinical studies when omicron had come out, and now, BA4 and/or BA5 are running. Is it important to provide sequencing data specific for BA4, BA5? I'm wondering about that.

**Timothy Stenzel:** No. No, as long as your samples were collected on or after March 1st, 2022, you do not need to sequence those samples, as of now, as long as we are still in 100% essentially, if not completely, omicron situation. We have been working with NIH, or RadX Variant Taskforce, to look at the evolution of the virus and its impact with various sublineages on testing, both using bioinformatics at the FDA for molecular tests and antigen tests.

And when indicated, we've been able to confirm, or in the process of confirming, performance on the sublineages. So there is no recommendation right now for sequencing omicron.

**Sue Hart:** OK. So if you have an EUA that was submitted previously before March 1, is there any requirement to go back and provide additional data?

**Timothy Stenzel:** So if your submission does not include 30 verified omicron samples via sequencing prior to March 1, then our review does take a look at that, as stated multiple times on this call and previous calls.

**Sue Hart:** Certainly.

**Timothy Stenzel:** Omicron has apparently greatly degraded performance of especially antigen tests, likely due to a great increase in the number of low positives. So it's imperative during this omicron period that we know the performance of your test prior to authorization on omicron samples.

**Sue Hart:** Certainly. But you wouldn't need to run anything on any new variant running now?

**Timothy Stenzel:** No. No, not—

**Sue Hart:** And update the submission

**Timothy Stenzel:** --not unless something comes up, because there might be an issue identified. But it's not standard.

**Sue Hart:** OK. Great. Thank you very much.

**CDR Kimberly Piermatteo:** Thank you, Sue. Thank you, Tim. Alright, our next question is coming from Tom. Tom, I have unmuted your line. Please limit yourself and ask your question.

**Tom Cirrito:** Great. Thank you. This is Tom Cirrito with Y2X Life Sciences. I have a document that I received probably over a year ago on breath-based tests considerations for EUA. I wanted to know, now that there's been a breath-based diagnostic that's been authorized, if there have been any changes to that, and if there's any plans or timelines of formal guidance for breath-based diagnostics.

**Timothy Stenzel:** So it's always good if you're going to develop a test to take a look at if we have templates posted, or take a look at the transcripts from this call to see if there's any updates.

As far as breath tests go, that was an evolving science to understand its ability to detect COVID. And looking at the documents on that authorized test on the FDA website, looking at the instructions for use and the conditions of authorization, letter of authorization with the conditions of authorization, are pretty up to date as far as our current thinking for any sort of similar test.

But just like any test, there are variations on how you would approach, in this case, breath tests. So if the technology is different, we may have different questions. So it's best if you want to engage in developing or validating such a test that you reengage with the FDA and make sure that our recommendations are still current.

**Tom Cirrito:** OK, great. Thank you very much.

**CDR Kimberly Piermatteo:** Thank you, Tom. At this time, we have no more raised hands [INAUDIBLE]. OK. [INAUDIBLE] Please.

**Nikita Robinson:** Hi. Nikita Robinson from BioGX. I was wondering, when we process our COVID EUA, if it's possible to target two different groups, such as one workflow for a CLIA waived status, as well as a workflow that is for high and moderate complexity labs.

**Timothy Stenzel:** Yeah, that's a question that's probably best specifically answered through the pre-EUA process. I would say-- and Kris can correct me here-- but we want to be careful not to-- you said CLIA waived. OK, these are medical locations by and large. And I don't think there is a problem to have two different instructions in there.

We would want to assess with the FDA if those different workflows could impact performance and whether or not you need to validate each sort of independently. So it would depend on what modifications are made between one workflow and the other and what its impact on performance would be.

But having a central lab instructions separate from the CLIA waived instructions, that's a possibility. I mean, the CLIA waived instructions are usually super simple. They're almost like OTC instructions. So I think we just have to explore a way.

The worst-case scenario is you would just have two different kits. We would split your application into two different kits. You would have one labeled for CLIA and one labeled for central lab. Kris, do you have any other guidance?

**Kristian Roth:** Just one thought. For the POC part, or what you're calling CLIA waived, but it actually POC, we are going to want to see validation in the hands of those POC users. And then of course, if we get that POC EUA, that can be used at a high complexity laboratory as well. So there is an impact there on the validation.

**Timothy Stenzel:** Yeah. Yeah, good point. Yeah, yeah, you can't validate the CLIA waived version in a central lab.

**Nikita Robinson:** Thank you.

**CDR Kimberly Piermatteo:** Thank you, Nikita. I'm going to make another call out. Does anyone have any questions? Please raise your hand.

Alright, this is the last call out. If you have a question that you would like our panelists to address today, please raise your hand.

OK, we have another question coming in. Rainer, I have unmuted your line. Please unmute yourself and ask your question.

**Rainer Ziermann:** Hi. This is Rainer Ziermann. Thank you for taking my call. I was wondering, for EUAs in general, good manufacturing practices are waived. And we are currently evaluating a point of care test, but ultimately, of course, we want to move on to 510(k).

And my question is-- right now for the EUA, we use, for example, primers and probes that are not practically GMP. They are research-use only type of primers. And similar for the clinical trial that we carry out. We carry it out so that the numbers of samples would be sufficient for 510(k).

But I'm curious whether all the components that we use in the trial have to be GMP if we want to use the data later on for 510(k), or if there is some kind of leeway, because if you get an EUA first, and the trial is at least large enough. So that's really the question. Do all the components for an assay that is supposed to be an EUA later converts to a 510(k) have to be GMP?

**Timothy Stenzel:** So you're correct. For many tests, not necessarily all, we waive many of the 820 requirements. But when it comes in for full authorization, that is something that we'll want to see

eventually. For those entities that don't have full 820 compliance now, that's certainly something that is very appropriate to discuss in the Q-Sub or Pre-Sub submission.

But manufacturers can use RUO primers and probes if they bring it into their quality system and they have incoming QC, and they manage those components according to their quality system.

So by and large, the most important thing is that you're not making any material changes to your assay that would impact performance between your EUA and your full product. In that case, we're anticipating to be able to utilize all of the EUA data as long as it's on actual clinical samples for a full authorization.

Kris, anything you might add?

**Kristian Roth:** No. It is a good question. And we welcome that in a Pre-Sub. That would be fine.

**Rainer Ziermann:** OK, thank you very much.

**CDR Kimberly Piermatteo:** Thank you for that question. Alright. Again, does anyone have any other questions they would like to ask our panelists today?

OK, this is the last call. If you have a question, raise your hand. If not, Tim, did you have anything else that you wanted to mention today. Or we can go ahead and close today's Town Hall.

**Timothy Stenzel:** No, I think we can close. We're just closing just a few minutes early, but we had a lot of questions and we look forward to our next meeting.

**CDR Kimberly Piermatteo:** Great. OK, so I'll go ahead and start our concluding remarks.

As I mentioned earlier, a recording of today's Town Hall and a transcript will be made available on CDRH Learn within a week or two of today. 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. To access those materials, please visit CDRH Learn at the link provided on this slide.

For additional questions about today's Town Hall, and COVID-19 IVD topics in general, you may send an email to [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov).

And please remember to join us for the next IVD Town Hall scheduled for Wednesday, August 24, 2022, from 12:05 to 1:00 PM Eastern time.

Thank you all again for joining us today, and this concludes today's Town Hall. Have a nice day.

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