Virtual Town Hall 8-4-21

Moderator: Elias Mallis
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Elias Mallis: Greetings, everyone, and thanks for joining us today. I'm Elias Mallis, director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be your moderator for today's program. Welcome to the CDRH Virtual Town Hall Meeting for developers of tests for SARS-CoV-2. This is meeting number 66 in our series during which we'll discuss and answer your questions about tests in the fight against COVID.

Our panelists for today's program are Dr. Timothy Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health, or OIR, in CDRH's Office of Product Evaluation and Quality, and Toby Lowe, associate director also from OIR We'll start today's program with some opening remarks and updates from our panelists, and then we'll spend the rest of our time today answering your questions about the development and validation of COVID tests.

Please note, we're not able to discuss specific submissions that are under review. To ask a question, please go to your name on the Zoom meeting and select the Raise Your Hand icon. Now let's turn the program over to Tim for some opening remarks and updates. Thank you, Tim.

Tim Stenzel: And thank you, Elias, and welcome again. 66, wow, that number keeps coming up and will continue to. And we already have a number of attendees, and thank you for joining us again. Again, our purpose here is to assist you in order to assist the nation's response to the ongoing pandemic.
And obviously, testing needs to persist with the Delta surge in the US that continues to go up. The amount of testing is going up, and obviously, the positivity rate is pretty high compared to earlier this summer and is hovering nationally around 10% right now. And there are certain areas where it's-- currently numerous areas where it's much higher than that even.

I just wanted to again go over some key current priorities. As I mentioned, the importance for testing is ongoing, and the demand's ongoing. And so it's very important. And our key focus is to do anything we can to significantly expand access to testing through a high-volume test to support high-volume testing. And so that is the best use of our public resources, public health

resources, is to focus our attention on that. And we're trying to stimulate development of those kinds of tests.

So tests, particularly I would say diagnostic tests, in high-volume central lab tests systems that can run through a ton of samples in a shift, and they're manufactured in high volume. And then point of care and home tests, so diagnostic tests that, by virtue of their higher distribution, being performed in a lot more sites than, say, a high complexity lab, tens of thousands of CLIA waived labs and hundreds of thousands actually of CLIA waived labs and obviously potentially tens or hundreds of millions of home sites.
And so to supply those over 100,000 point of care labs and as many households there are in the United States, that does require a high manufacturing volume of point-of-care tests and in-home tests. So for those that want to know if they qualify and meet the high volume considerations, they can reach out to the FDA and ask if their technology will meet that.

I also wanted to briefly cover the bar that the EUA provision allows her to use to make decisions on authorization decisions on tests, and these are primarily focused at SARS tests and diagnostic tests, and that bar is that the likely benefits outweigh the likely risks.
As we move through the pandemic and as the virus mutates and new variants show up and others recede, this balance between likely benefit versus likely risk can alter. And so that is a fluid sort of bar that we apply going forward. It hasn't changed drastically, but it does enter into our thinking. It is the standard that we use for making authorization decisions.

And of course, the target is SARS. That's what the EUA provisions are for. They aren't for other viruses, but we have-- obviously, the FDA has shown a good deal of flexibility to allow other viruses and panels to be submitted to the FDA. And those panels when produced in high volume are able to be tested in labs in high volume do remain a priority. All right, enough on priorities. We've covered all that before.
Also, we have recently obviously switched to a new platform, the Zoom platform, and there are clear advantages to it. But in moving over to this platform, we have had a challenge of dealing with transcript generation. And the awesome team that we have here at the FDA has been working on that, and we are working as hard and quickly as we can to restore the previous timelines for posting transcripts after calls.
And we do see a light at the end of the tunnel and hopefully in the relatively near future. So in the interim, we do ask for your patience until we get back to those previous timelines for transcript posting. With that, we can move into the phase of the call that we usually go to, which

is we address the previously submitted questions, and for that, Toby, I will turn it over to you. Thank you.

Toby Lowe: Thanks Tim. Thanks, everyone, for joining us again this week. The first question that we received actually goes nicely with Tim's talk about priorities. The first question is about an EUA for a multiplexed molecular assay that includes Flu A, Flu B, and COVID and specifically asking if it's possible to request an EUA for over-the-counter use of a multiplexed molecular assay.
And as Tim indicated, we do prioritize multiplex, multi-analyte panels when they're sufficiently high volume, but we have not currently authorized any tests either under EUA or traditional marketing pathways for over-the-counter flu tests. And that's because there's just generally not a need to screen asymptomatic individuals for influenza.

So Tim was talking about the benefit-risk calculations that we take a look at, that impacts the benefit-risk calculation. So for flu tests, we have not determined that there is a benefit to over-the-counter flu tests. So that means that while we are considering multi-analyte panels for EUA, we are not currently doing so for over-the-counter.

We are reviewing and authorizing over-the-counter tests for SARS-CoV-2 under EUA because there is a need for asymptomatic screening for COVID-19. But for multi-analyte tests, we are generally just considering prescription use tests since they're only needed for symptomatic individuals or those otherwise suspected of infection.

The next question that we have is regarding a point of care clinical evaluation and conducting-- so the clinical evaluation at a CLIA waived site with testing patient specimens, and then there's a portion of the template that also talks about testing with samples prepared with SARS-CoV-2 near the LOD of your assay in clinical matrix.

And the question is asking for the contrived sample testing discussed in the template, do all of the clinical sites have to participate, and do all of the operators in each site have to participate? If they're having difficulties with that, can they find other sites which do not participate in the initial clinical study to do the contrived sample testing?
So an efficient way to execute that study would be to incorporate the contrived testing into the workflow of the clinical test sites that are performing the clinical validation study. But using

clinical sites that were not part of the clinical validation study is also acceptable if they meet the recommendations noted in that section of the template.

Specifically, we don't require that they be tested at the same site, and they can all be tested at one site, but we do expect the operators to be actual point of care operators and not employees of the sponsors or the clinical investigators. And we do typically request the educational backgrounds and professions of the operators to ensure that they're representative of the intended user.

The next question that we have is about clinical evaluation of an over-the-counter home-use antigen assay that can be interpreted either visually using paper instructions or using a smartphone app on either iOS or Android-based smartphones asking about the target distribution of enrolled participants who use the paper instructions versus the app and asking whether a certain number of the 30 positives have to come from participants using paper versus the app.

So generally, for a situation like that, we would expect to see 30 positives and 30 negatives for visual interpretation and another 30 positive and 30 negative for the app interpretation since those two methods may lead to significantly different performance. And we would also expect to see usability for both approaches.

The next question we have is also for home-use rapid antigen testing. The question is regarding the template indicating that home tests should either have an internal control to verify that adequate sample is collected or mitigate the risk of sample collection error by having another feature like a video observation, and they're asking if that recommendation is still in effect. And yes, that recommendation is still FDA's current recommendation.

We consider each test individually and consider the mitigations that are included to enhance the robustness of the test when we do our benefit-risk evaluation. We do continue to recommend an internal control or other medication to ensure that adequate human sample is collected. And at a minimum, we recommend that there be an internal procedural control to ensure that the sample adequately flows up the test strips for lateral flow test.

The next question we have is regarding the use of contrived samples in a clinical trial for home-use test. This one is specifically asking about a home-use over-the-counter multi-analyte molecular diagnostic test. So as we discussed for one of the previous questions, we are not

generally considering over the counter for multi-analyte tests since there is no need to test asymptomatic individuals for flu at this time.
However, we can address the other questions that came in this inquiry which are generally about the use of a combination of prospectively collected positive fresh samples and positive contrived samples in a clinical study or the use of banked or archived samples. And at this point, the rate of new confirmed cases in the US is very high unfortunately so patient samples are readily available, and we do recommend acquiring and testing patient samples during the clinical evaluation validation studies.

Our current recommendations for multi-analyte tests, which again, would not be over the counter, can be found in the molecular template, and for multi-analyte tests where the non-SARS-CoV-2 analytes are not previously cleared, we recommend providing data from testing positive patient samples from at least 50 positive patient samples to validate an RSV detection claim as part of a SARS-CoV-2 multi-analyte test. And you can take a look at the instructions for use that we've posted on our website for more information on the validation that we've been looking at for molecular tests, which include RSV.
And banked sample can be used for point of care moderate and high complexity molecular tests but not for home tests. And antigen point of care and moderate high complexity molecular tests can use banked samples with point of care testing a minimum of five fresh positive samples for a fresh sample claim and authorization with a post-market commitment to complete the fresh study.

Tim Stenzel: Yeah, just to clarify, the antigen point of care [INAUDIBLE]. But if they can use banked samples and frozen samples, we would like to see a clean set of fresh negative samples and a minimum of five fresh positive samples. But again, almost half the samples for home test, whether they may be molecular, antigen, we do need to see fresh samples for home authorizations. Thanks, Tony.

Toby Lowe: Thanks for adding that clarification, Tim. The next question we have is regarding a clinical study to support a five ten case submission of a SARS-CoV-2 multi-analyte PCR molecular assay using the BioFire RP 2.1 as a reference method. And they're saying that their current understanding is that a minimum of 50% of the prospectively collected specimens need to be tested fresh with the candidate test and asking whether they also need to be tested fresh with the reference method, or can samples be tested frozen provided that testing aligns with specimen stability in the package insert.

We do recommend that testing the comparator method using fresh samples, but testing using previously frozen samples is likely acceptable for molecular tests if an appropriate freeze-thaw study is available. The comparator method testing frozen samples is a risk since samples can degrade over time or if improperly stored.
Next question we have is--

Tim Stenzel: I didn't unmute fast enough. I just want to make clear that we do want to see a prospective fresh study. It's only if you're unsuccessful in getting samples that we'll be open to using particularly banked, banked deposit samples, too. And we want you to have a dialogue with our review team at that point just to make sure everything is going to be good. But we do understand that hopefully flu and other respiratory virus will stay low for a very long time. That would be awesome. But that does present challenges for full authorization of tests, and we want to be flexible as possible. Thanks.

Toby Lowe: Thanks for adding that, Tim. The next question that we have is another question about an over-the-counter COVID plus influenza A/B test. So again, we'll reiterate that we generally do not think that the benefits of an over-the-counter multi-analyte test outweigh the risks. So we would limit the multi-analyte tests to prescription use since health care professional involvement is generally needed to ensure that test results are interpreted correctly and that appropriate action is taken.

The rest of this question is asking about the recommendations to include 20% to 25% of samples with low viral load plus or minus 3Ct of the LOD of the comparator device and expressing some confusion about how to define those low viral load samples. So to clarify that, the low positive samples return a CT value within plus or minus 3 CT of the LOD CT of the comparator test. The LOD of the candidate test does not impact the evaluation of a low positive sample tested as part of a clinical validation. So again, it is low positive as tested by the comparator test.

And then the last question that we have here is asking about FDA review priorities for COVID-19 IVD sponsors who would like to submit a de novo or 510(K) instead of an EUA and asking if the FDA is encouraging non-EUA submissions for COVID-19 IVDs. But for tests that will most benefit the current public health needs, EUA remains the fastest and least burdensome route to authorization, especially considering the level of evidence that we're asking for for an EUA versus a full marketing authorization. But sponsors that are interested in pursuing full marketing

authorization through de novo or a 510(K) are also welcome to do so. And Tim, unless you have other things to add there, we can go to the live questions.

Tim Stenzel: Let's go to live questions. Thanks.

Elias Mallis: All right, thanks, Tim. Thanks, Toby. So again, if you have a question for our panelists today, please click the Raise Your Hand icon, and we'll get you on the list. So let's start off with our first question from Richard Montagna. Please unmute yourself and ask the question.

Richard Montagna: OK, thank you. We just finished preparing a presub for a multiplex PCR test for an expanded respiratory panel that will detect SARS-CoV-2, Flu A and B, RSV A and B, and we were uncertain as to how to actually submit it because since it's a SARS-CoV-2 related product, we weren't sure if we should just email it in through the OIR operations email or send it in formally through Document Control Center. So--

Tim Stenzel: This is for a full submission, correct, not an EUA?

Richard Montagna: Correct, yeah. It's to describe--

Tim Stenzel: I would use the traditional pathway for that. Toby, anything else to add?

Toby Lowe: Yeah, absolutely. If you're submitting it as a formal P-sub as opposed to a pre-EUA, we would ask that you use the normal processes for submission.

Richard Montagna: OK, so we'll send an electronic copy in through the Document Control Center.
Perfect. Thank you.
OK, thank you very much.

Tim Stenzel: And I would also add, I mean, we are starting to get an increasing volume of Q-subs, Presubs for full authorizations. When it's a molecular test, we've already made one decision, and so it would be hopefully the decision summary has been posted already. I don't know. But we do have recommendations. So by and large, we hope that you get everything you need from that.

And so because of the growing volume of Q-subs, Presubs, we are going to aim to probably be fairly succinct in our responses and focus on anything that might be unique. And we ask your patience with this because of the high volume. We're still getting more than 100 EUA applications a month, and obviously, we're still working on all our non-COVID work as well.

And then, we're going to endeavor to update the templates for molecular serology and antigen tests to make it very clear what the recommendations are for conversion and upcharge the team to make that a high priority now to make that available. I can't promise when. But then, it should minimize the need for Presubs and Q-subs and minimize any timelines for getting feedback from the FDA.

But in essence, we by and large, especially for molecular, have recommendations. We can provide our general recommendations pretty quickly. And then only if there are unique specific questions that we're focusing on working on. So I just want to let everybody know who is thinking about this and looking at this. So thank you for the opportunity to share.

Richard Montagna: Good. Thanks, Tim.

Elias Mallis: Richard, thank you for your question. Let's go to our next caller, Melissa [INAUDIBLE]. I hope I didn't mispronounce your name. Please go ahead and start your question.

Tim Stenzel: I think Melissa is muted. Yeah, now we can hear you. You were muted before.

Melissa Fertiguide: OK, OK. Thank you. Thank you very much. And here is the question is that there are a lot of COVID-19 variants. Which ones do we need to do verification by applying for EUA, and what specific verification do we need to do?

Tim Stenzel: What kind of test are you developing, molecular?

Melissa Fertiguide: Oh, no, just a OTC COVID testing.

Tim Stenzel: For molecular antigen?

Melissa Fertiguide: The antigen.

Tim Stenzel: Antigen test, OK. Well, when you do your clinical studies, if they're happening concurrently with your development and just prior to your submission, you're going to be testing the current circulating variant, and we don't necessarily ask you to identify which variant.

But if the test performs well with the current contemporaneous variant that are circulating during the time of the clinical study, that gives us an idea at least for what's currently circulating the performance if it was adequate or not. But we do also want you to do an assessment of sequenced variants and mutations and the potential impact of those on your test. And you can use bioinformatics to help you.

For an antigen test, knowing the epitope mapping for your antibodies and/or knowing the antigen that was used to raise your antibodies can give you a clue as to whether or not you should do any subsequent at least in silico investigation of potential impacts. And for any potential impacts that you identify or the FDA identifies, we may recommend some wet testing of those variants to make sure that you don't have a performance issue.

And that wet testing could be if the specific invariant or variants of concern are present in, say, BEI Repository and have an activated virus and that functions in your assay, that's one potential pathway. Another potential pathway is to obtain residual samples that have been sequenced so we know what the mutations and variants are. And there are some labs out there that are routinely doing sequencing and have banked samples or can sequence the samples for you. And that should help you determine whether or not there is a real issue with your antigen test.

But this is a high priority to determine the potential impact of variants of mutations on all tests, EUA tests. It's an ongoing activity at the FDA, the CDC, and of course, NIH and RADx, and we've been working really closely together along with the developers of tests to assess impact. So hopefully, that more than addresses your question.

Melissa Fertiguide: Oh, thank you very much, sir. And also, the CDC has recommended the labs to perform the testing for the variant?

Tim Stenzel: I would look at the labs that are doing the sequencing routinely and approach them. I don't think that we maintain an approved, authorized, or suggested list.

Melissa Fertiguide: OK.

Tim Stenzel: But again, that's only going to be recommended if there's a potential impact of your test following your analysis of potential impacts and our analysis during our review of your test for any potential impact.

Melissa Fertiguide: OK, I see. So as we already submitted the pre-EUA application, so and later about two months for that review, after we get the first response from the review, we will see that if the FDA will request any additional testing.

Tim Stenzel: Yeah, I don't think so unless they're at least providing information of potential impact. If you know of potential impact, I would just go ahead and do that. And for those that are waiting, this is a test, an antigen OTC test where we have authorized, I think, six authorizations for OTC antigen tests already. And we're going to authorize more. So I'm not sure what you're asking in a pre-EUA that you need to wait on our feedback.

As I stated earlier, we are still seeing high volumes of pre-EUAs and original EUAs as well as amendments and supplements. So we're remaining extremely busy, and you really-- if you're following what others have done before and our decision summaries for those, I mean, it's really low risk. If you're listening on these calls and you're just doing the standard things, I would urge you to move forward in your development program on risk. We'll get back to you as soon as possible.

And if we can sort of move to a place where we're really only asking in pre-EUAs and in Presubs for SARS tests that we're only asking the unique questions up front. That would really help all of us to focus on just the most important questions here. All right, we do need to move on. We do have a long list of callers. Thank you.

Melissa Fertiguide: Thank you.

Elias Mallis: Thank you, Tim. Yes, we have a number of hands raised so let's get to these questions. Arvita Tripati, you are next to ask your question for our panel.

Arvita Tripati: Hi there. Are you able to hear me?

Elias Mallis: Loud and clear.

Arvita Tripati: All right, excellent. So my question is for non-lab test kits, how is the FDA differentiating between low volume and high volume with regards to the quantity of tests allowed in a given kit?

Tim Stenzel: Well, again, this is home tests?

Arvita Tripati: Yes.

Tim Stenzel: Yeah, for home tests, if it's authorized for a single test in a kit, there are various options there and pathways depending on performance and what studies you've done where a single rapid antigen test in a home kit is sufficient. However, where the authorization comes with a serial testing claim say for screening, then we want to see at least two tests in a kit.

So the high volume for that situation, same goes for point of care, isn't the kit size or the throughput of the particular test because these are more manual point of care and rapid antigen tests at home. And a given individual can only perform so many of these tests in an hour, and it's pretty low volume.

So what we do when we look at that is we look at your manufacturing capability and how many of these tests can you produce, manufacture for US distribution in a given amount of time. And those thresholds, we haven't publicly announced. We may, but right now, we're not because we want to remain responsive to the current situations, and that can change. So we don't want to set a bar publicly necessarily, and then have to go and change it more formally later. So it gives maximum flexibility.

And obviously, I think we've now authorized 27 antigen tests, I think, is the latest number, and that includes both home and point of care largely. There's maybe a few that are higher complexity, but those providers are producing tests in relatively high manufacturing volumes, and that's what we look at for our priority reviews. So if you want to know if you meet the level for review of priority, then you can reach out to the FDA and let us know that information, and we can let you know. OK?

Arvita Tripati: OK, got it. What I was trying to clarify was around the size of the kit at which you would need a control. For example, we are going for a home use pathway, and so I've seen examples where there's one, two, I think up to six allowed in a pack for home use. At what point would we need to add in the control swabs? Would that be if we're making a Costco-sized pack that's 25 kits? Or is that a 100-kit pack? That's the high volume or low volume that I was trying to differentiate.

Tim Stenzel: Yeah, we set the minimum number for recommended kit size based on the use. So again, if it's a single-use application, it only needs one test. If it's serial testing for antigen test, it needs two. And as far as external controls go in the home environment, we are not recommending that you actually have that.
I mean, if your test requires for continued good performance to have external controls run, there could be some devices that require periodic calibration and/or check up calibration, that's more challenging in the home environment. And so it's ideal if you don't need those external controls.

And of course, for waived labs point of care, there are monthly quality control requirements, and for those professional use tests, we do like to see that controls are available for the professional use so the folks in those environments don't have to go try to find a source for control to meet their CLIA requirements. So there's no cut off for number of tests that then requires external controls. It all depends on the technology and the location where the test is performed.

Arvita Tripati: Got it. Thank you so much. That was really helpful.

Tim Stenzel: OK, all right, we'll move on to the next caller. Thank you.

Elias Mallis: All right, our next caller is from Greg S. Please go ahead with your question. Hey, Greg?

Tim Stenzel: Well, Greg dropped something. Oh, he's on camera. But his hand's no longer raised. I don't know what happened.

Greg S: OK, here I am. You there?

Tim Stenzel: There you are, yeah.

Greg S: Sorry about that. Tim, I know that you said the agency is monitoring commercially available COVID-19 tests to see if they're impacted by the Delta variant. I guess it's just a very general question, and maybe this requires specifics. But when you look at the dozens of commercially available COVID tests, can they detect the Delta variant? And can you parse that a little bit? Can test pick up on Delta but not necessarily say it's delta, and then does that matter, I guess, is the bottom line?

Tim Stenzel: Yeah, so let me just go through our process that we use. So first of all, through safety communications, we have asked developers to engage in this along with us, and we don't want it to fall entirely to the FDA or the US government, but the US government has stepped up, and because we've been asked by the US government to make sure, ensure that the EUA authorized tests are still performing in the face of mutations and variants.

And so on a weekly basis, we download the most recent sequences. We have all the proprietary primers and probes and other details about other types of tests like antigen tests, and we do our own bioinformatics search across all the tests and identify potential issues.

We have a scale for determining whether it reaches the level in which we want to investigate further. And then if we do, we engage CDC and NIH RADx. And they try to source samples, and they try to obtain the tests to perform the actual test, particularly for antigen tests in NIH RADx labs.

In addition, we do reach out to sponsors at that point, developers to do their own and for us to ask questions and for them to get back to us. And we do ask them to get back to us in a very timely way. And as soon as we have any sort of confirmed findings, we've been erring on the side of caution and posting results on the FDA website.

But we do maintain a variant mutation website. Currently, there's only four tests listed there, and actually, none of those four have demonstrated a loss of sensitivity of 5% or greater, which we're currently defining as a significant decrease, for any of the variants of concern and for any mutation in the US or combination of mutation that reach the 5% or above level.

So that's the good news, but we do have ongoing active investigations of potential issues. Fortunately, none are active for any of the tests that we would consider super high volume tests, and these are the super high volume rapid antigen tests, and we could come up with the list easily

of the handful that are in that category, and you read about them the time, and also for the central lab test.

So we do subdivide by whether it's lower volume, relatively lower volumes, moderate volumes, and high volume. Some of that is market penetration, too, as we're looking at how we grade the potential risk for the US testing activities, not that we don't investigate lower risk, but we want to be able to provide that kind of dashboard on a weekly basis to all our partner federal agencies.

So the good news is for Delta nor for any other mutation or variant do we have any significant concerns at this moment. We do know that sequence information is not as numerous as sometimes we would like as far as new sequences on a weekly basis. And obviously, for some mutations that may not be a variant of concern, we don't always know at what point they reach.

So we do continue to urge and recommend that for anyone performing testing, if they get a result particularly for a diagnostic test that doesn't match their clinical perceptions of what might be going on, that they reflex to another test, particularly a different test and particularly a different molecular test if the original test is molecular to confirm whether or not that original test result is accurate because any given test could, depending on whether it's three targets, two targets, or one target test, could have an issue, particularly the lower target test could have an issue with what I call a private mutation that isn't reaching significant levels, but obviously, it's critical for understanding what's going on with that patient.

Greg S: Can I ask a quick follow-up? I mean, would you say generally that PCR tests are more accurate and sensitive to genetic variations of the coronavirus say compared to antigen tests?

Tim Stenzel: Right now, all the EUA authorized tests are performing as expected that contain their EUA authorization or continue having EUA authorization. We don't have any information. Otherwise, we would not make that available or move to have them removed from the market. And as we've said before, and then we need to move on to the next caller, is that multiple target assays have a tendency to be more reliable than single target assays, and that's in our prior mutation coverage, and that makes good sense. So let's go ahead and move on to the next caller, please.

Elias Mallis: Thanks, Tim, and thanks, Greg, for joining us on camera. Our next question comes from Wenli Zhou.

Wenli Zhou: Hello, thank you for taking my call. So I have a question just to follow up with the previous conversation about the variants. So a couple of developers approach us because we are a CLIA lab and we do have a capacity to do some samplings or to do that to determine the variants, especially Delta variant right now. And the developer, antigen developer approach us and want us to determine if the sample specimen they're testing are Delta variants or not because they want to confirm their test can detect the Delta variant.

So the question that they ask is, is your test and variant test EUA authorized? As far as I know, there's no such of EUA authorized variant test. So I guess my--

Tim Stenzel: We have a couple of whole genome tests, sequencing tests. They can report out the genotype. It's not part of the EUA authorization so that certainly aid. Can you focus on your question because we do have a number of folks, and I want to try to get through them?

Wenli Zhou: My question is can we still do it? Can we still provide the test to them so they will use that for their submission or for their whatever their antigen development?

Tim Stenzel: Here is the thing. If you're assisting their submission and you want to help them provide sequenced results, well, that's fine. We'll want to know some details about how you did your sequencing, though.

Wenli Zhou: OK, so that have to be [INAUDIBLE]. OK, thank you.

Tim Stenzel: And let's move on to the next caller.

Wenli Zhou: Thank you.

Elias Mallis: All right, our next call comes from Ivory Chang.

Ivory Chang: Hello, this is Ivory Chang. Can you hear me?

Elias Mallis: All good.

Tim Stenzel: Yes.

Ivory Chang: OK, good. Yeah, my question is very simple just to clarify. You mentioned about the home use multi-analyte OTC is not encouraged at the home test due to the multiplexing. How about if we put a claim as a [? presubmission ?] use only, but we will hold the test still multiplexing and can be distributed to non-laboratory locations like the airport, anywhere? Is this one can be submitted, or it's a totally no, has to become the point of care?

Tim Stenzel: So I think you're talking about point of care testing rather than home testing, and we aren't limiting authorizations for point of care tests. Multi-analyte tests are fine in the point of care.

Ivory Chang: OK, so which means I'm not really asking for the point of care. I'm asking can we put the presubmission for home use multiplexing as a product claim, or this is totally no?
Tim Stenzel: Oh, Toby I think made that clear, right?

Toby Lowe: You're asking if you can have a prescription home use test for multi-analyte?

Ivory Chang: Yes. Yes.

Toby Lowe: We would consider that.

Ivory Chang: Oh, OK. Great. Sounds good, thank you.

Tim Stenzel: Yep, let's move on to the next caller. Thanks.

Elias Mallis: All right, our next call comes from Xinyi.

Xinyi: Hello, thank you for taking my call. We are developing a neutralizing antibody test, and we were wondering what the FDA's review priority on that was. Thank you.

Tim Stenzel: So we continue to make that a priority, and we have a template now on neutralizing test. So follow the template, submit it, and we'll review it.

Xinyi: Thank you so much.

Elias Mallis: All right, our next question comes from Laura D'Angelo.

Laura D'Angelo: Hi, Tim and Toby. I assume you can hear me. I'm off camera. OK, anyway, so just in clarifying the documents that we're expecting, I thought that we were going to expect a guidance document on the transition, but are we going to update the templates instead or both?

Tim Stenzel: The guidance is still going through development and/or authorization clearance for us to release. We don't expect that there will be an end any time soon the emergency declaration, nor will we stop reviewing EUAs any time soon for at least for those for which we have priorities.
We are welcoming Q-subs and Presubs for the full authorization. The guidance and in fact, wouldn't go into-- the guidance is going to cover all potential EUA devices. And so we won't go into the details of what our recommendations are for individual devices that recommended validation. So that, we are going to provide separately as well.

And so you don't have to wait on the guidance. You can approach us now, and as I said, our teams particularly for molecular have a full set of recommendations for full authorization. OK, I think we want to move on to another caller. I think there's a repeat caller. Maybe we could go to the new caller, and if we have time, go to the repeat question.

Elias Mallis: Right. So Alex Weinberg, please ask your question.

Alex Weinberg: Hello, can you hear me?

Elias Mallis: Loud and clear.

Alex Weinberg: Awesome, thank you. So in previous town halls, you've given guidance saying that it's OK to perform clinical studies outside of the US. Is that still the FDA's stance?

Tim Stenzel: We would want you to start the study in the US right now for SARS. There's unfortunately a boatload of SARS right now. So there isn't still the need. When the volume was really low-- when the present positivity was really low earlier this year, we opened that up. We're still open to it, but we would like you to start the studies in the US because we would like to know how it performs in the US with US labs and/or consumers and/or point of care sites. And then only if you need to go outside the US that you do that, that would be our recommendation.

Let's see if we can't fit in the repeat question from Melissa as well. We have two minutes [INAUDIBLE].

Elias Mallis: Melissa, the floor is yours for the last question.

Melissa Fertiguide: OK, thank you very much. And I would like to follow up a question of a lady that asked before that for the high volume that could apply for that another level of priority, where could we submit our requests for the high volume priority, the template?

Tim Stenzel: If you submit a sample question to the template's email address about whether or not your volume qualifies, that should be good enough. If you're also submitting a pre-EUA, you can put it in there, but you might get a quicker, more direct response just submitting that question. All right with that, I think we can close out today's town hall. And thank you, everybody. Thank you, Elias. Thank you, Toby.

Elias Mallis: All right, thanks, Toby and Tim. This concludes today's town hall. I want to thank our panelists Dr. Tim Stenzel and Toby Lowe for joining us today. And I want to thank our audience for your participation and all the great questions that you asked our panelists today. Today's presentation and transcript will be available to CDRH Learn in about a week. As Tim said, we're working on some of the logistics involving getting the transcripts up for you.

Please visit CDRH Learn at www.fda.gov/training/CDRHLearn. Now note that we've updated the title of the section to make it easier to find. You'll find the recordings at a new subsection titled "Coronavirus (COVID-19) Test Development and Validation Virtual Town Hall Series." So if you've been to CDRH Learn in the past, please check out the new listing site.

For additional questions about today's presentation and topics, please email us at CDRH-EUA-Templates@fda.hhs.gov. As we continue to hold these virtual town halls, we appreciate your feedback about the program series. Please complete a brief survey which you may find at www.fda.gov.CDRHWebinar. Again, thanks for joining us today. We'll be back with you for the next town hall on August 18. Take care and see you next time.