

**FDA Virtual Town Hall Series –
Immediately in Effect Guidance on
Coronavirus (COVID-19) Diagnostic Tests**

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only.

This call is being recorded. If you have any objections, you may disconnect at this point.

Now, I will turn the meeting over to your host, Irene Aihie. You may begin.

Irene Aihie: Hello. I am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's 60th in a series of Virtual Town Hall Meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today, Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and

Radiological Health, both from CDRH, will provide a brief update.

Following opening remarks, we will open the line for your questions related to the development and validation of tests for SARS-CoV-2. Please remember that during this Town Hall we are not able to respond to questions about specific submissions that might be under review.

Now I give you Timothy.

Timothy Stenzel: Hello again. Thanks for joining us. We hope you find today's call helpful and instructive. Couple announcements and then I'll hand it over to Toby who will go through the questions received by email ahead of this meeting. First off is did want to discuss serology testing a little bit. We've had numerous inquiries about using serology to measure immunity and/or protection either from natural infection or following vaccines. This is a hot topic for our office. We are awaiting data from U.S. Government-sponsored immunity and protection studies to understand what are the factors that determine and can be relied on to make these assessments.

You know, sponsors, test developers are free to generate that kind of information, although, it seems like it would take fairly large studies to see what a certain level of antibodies, for example, offers in the way of immunity because you are looking at outcomes.

So, you know, as soon as we have definitive information about how to measure immunity and protection, we will be able to provide some more help to developers as far as what our recommendations are for validation of serology tests for this purpose.

So stay tuned. We can't - we don't know when that information is going to be made public. We expect we'll see it, you know, and pretty much real-time. And it will probably be made public pretty much in real-time as well. So we're waiting on pins and needles.

Next topic is priorities. Our current priorities remain the same. We are focusing on ways to expand testing opportunities, making it more accessible. We do think it's important that there are lower-cost opportunities. And so over-the-counter and home diagnostic tests and collection devices are our priorities, as are really high throughput diagnostic central lab tests and point of care tests.

Finally, I wanted to make a few statements about our current workload. We are still receiving a high volume of submissions for COVID. And however, we are keeping up with the volume even with reducing the surge, mainly to pre-surge, almost to pre-surge level as far as staffing goes. But we are staying ahead of it. We are closing out our files more quickly than we are receiving them. But there is still a bit of a backlog. In particular, the pre-EUA backlog is not insignificant.

And Toby and I have been making recommendations on recent calls for certain callers to check-in through the pre-EUA process. So we - you know, the pre-EUA process is not a required process. And it's designed to try to be helpful and make sure that we're aligned on what the recommendations are from the FDA.

So test developers can, you know, not do something and find out it doesn't quite work. Developers are always able to go ahead and submit and do the work and submit their EUAs. However, there are certain things that, you know, that may not be known. So we really are hoping only to advise your pre-EUAs, those things that are unique and different from what are present in the template. So, you know, look at our prior decisions. Look at - that are public. And look at, you know, our templates.

And hopefully, that meets the lion's share of pre-EUA requests. We know that there's questions that don't quite neatly fall in the template. You know, it is our priority to get through those pre-EUAs. It's just that we have a significant number of submissions, as I said. And we're doing our best to work through them.

Okay. With that, I will turn it over to Toby so that she can get into the questions.

Toby Lowe: Great, thanks, Tim. And as usual, thanks to everyone for joining us again this week. I'm going to go through the questions that we received by email. And I do want to note that we have received some questions that are a little too detailed or case-specific for addressing on this call. So for those, instead of trying to get into them on the call, we will try to send a response in writing within a few days.

So if you've submitted a question and do not hear it answered on this call, please look out for a response. If you don't get one in the next few days, maybe by the end of the week, please feel free to reach out to the CDRH-EUA-Templates@fda.hhs.gov email box for an update.

And with that, I'll go into our first question. So the first question is asking, once the COVID-19 emergency has been lifted, will FDA entertain the use of pooling in cleared FDA devices intended to detect SARS-CoV-2? They note that pooling was authorized as a way to speed up testing during the pandemic, but wondering whether FDA would consider clearance for tests indicated for both individual and pooled specimen testing.

So, yes. We would consider that. The type of claim for pooling would need to be supported by appropriate validation data and a positive benefit-risk analysis. So we would ask that you include that in your 510(k) submission. And we are open to considering proposals for that.

Our next question is, let's see, asking for feedback or noting that on a previous round of feedback on a submission, they received information, feedback that an over-the-counter molecular test should not include a hazardous substance. And the question is asking whether that's true for all over-the-counter tests, including antigen tests or just for molecular tests.

And I think, Tim, you were going to address this one.

Tim Stenzel: Oh yes. So thanks, Toby. So we have seen the use of hazardous chemicals in the development of certain tests. These typically fall into three different categories or uses. One is preservatives to prevent microbial growth in buffers. There are materials that are used to lyse cells or virus. And then there are materials to stabilize RNA.

And as we began authorizing at-home tests and at-home collection devices, it became clear to us that this was an important review for the FDA to do. We would prefer that no hazardous materials enter the home. And if there are potential hazardous materials that they're of the type, that a dilute version of them as is the case in many examples, for example, detergents are usually in very low percent. It's only in high concentrations of detergent that, you know, say it splashes into the eye or could potentially cause harm to the patient.

Others, some preservatives such that are being used, you know, are potentially hazardous substances. So we, in an effort to make testing as widely available, we know that developers sometimes cannot avoid some of these components.

So we do a Hazardous Chemical Substance Toxicology Review. We encourage developers to, you know, to submit documentation that says, you know, whether or not the chemicals that are in their test are hazardous, especially at the concentrations that are being used in the test.

So a number of these reviews have happened. And we look at. And some of them have turned out to be safe to use without special considerations, mainly because they're fairly dilute.

But we continue this review. And we ask that developers send MSDS sheets, literature studies. You know, in particular, the literature studies look at lower concentrations of some of these chemicals. MSDS largely looks at the undiluted forms and in many cases, the MSDS's are not appropriate for full hazard analysis. We look at, you know, if there is something that still remains

in a range where it may not be entirely safe, we look at other mitigation, such as wearing gloves or eye protection. We prefer not to have to go that route. We also look at labeling, very strong labeling.

So, yes, we would prefer that non-toxic materials are used. We know that in the effort to get tests out there that it may not be possible to move away from them at this time. So we just look for mitigations. And we look at the available data to make the best decisions. Hopefully, that's helpful. Back over to you, Toby.

Toby Lowe: Thanks, Tim. That's really helpful. All right, so we'll move onto our next question. All right, so we received a question regarding antibody tests for use after vaccination focused on asking whether the FDA intends to provide a template or other guidance regarding an antibody level that demonstrates protection so that healthcare providers can track patient protection levels.

So we did note in our recent safety communication, titled the Antibody Testing, is not currently recommended to assess immunity after COVID-19 vaccination.

And also this topic was discussed by the CDC that more research is needed to understand the meaning of a positive or negative antibody test beyond the presence or absence of antibodies, including in people who received a COVID-19 vaccination and people who have been exposed and have SARS-CoV-2 antibodies, and in people who are not fully vaccinated.

As the science progresses in this area, we learn more about the potential correlation between the development of a specific level or concentration of antibodies and protection from infection, we'll consider the appropriate validation approaches for tests for use in monitoring such protection.

And Tim, did you want to add anything on this one?

Timothy Stenzel: You know, for certain things. If developers are having a hard time getting the

positives and negatives they need, you know, they always have the opportunity to reach out to the Review Team for any alternatives that we might be able to suggest or that you suggest and would like to run by us. Thank you.

Toby Lowe: Thanks, Tim. All right, so for our next question, this one is about validation of a point of care COVID antibody test and the difficulty and I think Tim was just getting into this one a little bit too, the difficulty with achieving the sample size that FDA has requested to obtain an EUA given the dropping positivity rates and the rising vaccination rates.

So they're asking whether FDA would consider reducing the sample sizes or requiring fewer samples.

So as Tim has said, previously as well, if sponsors - we do want sponsors to attempt get the requested positives through a prospective study. But if a sponsor is not able to do so, we would ask that they reach out to the Review Team or to the mailbox for additional input on alternatives.

Then our next question is about pre-EUA review timelines, which Tim did talk about a little bit earlier. You know, as Tim noted, we do start to review both pre-EUA and EUA requests as quickly as we can. We do communicate with each sponsor regarding their submission as soon as possible and provide updates as much as we can, including while a submission might be sitting in queue waiting to be assigned to a reviewer.

If you have additional questions, you can always send a follow-up email to the point of contact that has been corresponding with you or to the EUA email box. And we also do have some information on our FAQs in the COVID-19 Test Development and Review Section about timelines.

And then our last question, for now, is asking about the use of banked samples to supplement prospectively collected positive samples for molecular diagnostic tests. And this is specifically for point of care, asking whether FDA

has a preference on the type of banked samples to run on the candidate device and the EUA authorized comparator. Specifically, they are noting that if they're pursuing a molecular diagnostic EUA for use with nasal swab samples, should they test bank interior nasal samples, or would it be best to use banked nasopharyngeal swabs since the FDA considers nasopharyngeal swabs to be the most challenging upper respiratory matrix?

So generally, we do want to see samples, whether banked or fresh tested that match the sample type that you intend to claim for your device. So if you are looking to claim anterior nasal swabs, we would recommend generally using anterior nasal swabs for your study.

Additionally, you know, we do - we have previously said that that nasopharyngeal is the preferred comparator and also that it is the most challenging upper respiratory matrix. And typically, if you do validate with nasopharyngeal, since we do consider that to be the most challenging provided there are no other concerns or issues, we would typically allow for a nasopharyngeal specimen to support an intended use also for nasal swabs and other upper respiratory specimen types.

And with that, unless Tim wants to add anything on that one, that is the end of our previewed questions.

Timothy Stenzel: Thanks. Thanks, Toby. Yes. We can move onto the - any live questions that may come in.

Toby Lowe: Great.

Coordinator: Thank you. We will now begin our question and answer session. If you would like to ask a question over the phone lines, please press star 1 from your phone, unmute your line, and speak your name clearly when prompted. Your name is required to introduce your question. If you would like to withdraw your question, press star 2. Again, to ask a question over the phone line, please press star then 1. One moment as I queue the first question.

Our first question comes from (Koto Moody). Your line is open.

(Koto Moody): Hello. Good afternoon. Thanks for taking my question. This is about the serology test. CDC mentions about the serology test. The antibody test should not be used to diagnose a current infection with the virus that causes COVID-19. Maybe similar thing has been stated by your center also. So even any of the existing antibody tests are really, I mean, as for this instruction, not diagnostic. When you are mentioning about coming with the immunity test and all those, I'm a little bit confused. What is expected out of the antibody test that can give about - information about immunity of a vaccine? Can you please elaborate on that, please?

Timothy Stenzel: Yes. So first, to clarify the first point. Yes, the FDA agrees with what you represented from the CDC that the serology test should not be used for - routinely for diagnosis. There are some situations, of course, lingering infection where virus may be negative. And clinicians want to know, particularly in long COVID situations, and you want to know if they've ever been exposed. And clinicians can order those for their purposes.

Regarding immunity and protection, of course, this isn't a diagnostic test. This isn't saying you are currently infected with SARS. What it's more designed to do, should we get there with this virus and there's every belief that we will get there. Our science will advance to the point where we understand what it means to be immune to SARS. That is, what level perhaps of antibody or what presence of different types of antibodies like neutralizing antibodies correlate with outcomes that's showing that folks with a certain level of antibody or type of antibody do not get re-infected or if they get infected, it's asymptomatic.

So those just - those studies require close observation of patients. And oftentimes, you know, it might be the best study conditions to monitor patients who have received the different types of vaccines and then monitoring antibody production after the vaccines and the levels. You know, the obvious

reason to use vaccine studies is that we know exactly when these patients have been vaccinated.

So we know the time course of the immune response and antibody levels and we can track those over time and correlate them with outcomes. That is, do they avoid getting sick? Do they avoid hospitalization? Is death from COVID prevented? Those are the important questions to ask.

And until we know the correlation or say, the quantitative level of antibodies with outcomes, we - it's really hard just, you know, to say what a given antibody response means.

(Koto Moody): I think all the things that you pointed out are really important questions. My - do we have any such test for any other infectious disease approved by FDA so far?

Timothy Stenzel: Yes. We have fully authorized some such serology tests for a number of vaccines and authorized, you know, them in a way that these are usually quantitative tests that can help clinicians make the determination on whether a person has, you know, achieved and/or maintains immunity for them.

So, let's see, it looks like rubella, measles, mumps are examples traceable to a standard that is established as a correlative protection.

(Koto Moody): Thank you. I think it will be nice if that thing is available at the table somewhere. It might be useful for developers so that they can use that as a guidance. Thank you.

Timothy Stenzel: Well, really what we need to know is for SARS, can we find a correlative production? You know, what is that measurement?

And once we know that, you can bet that the FDA, Toby, and I will do our best to get the word out about what that is and what developers can do with that information.

All right. I think we should move onto the next caller. Thank you.

Coordinator: Our next caller comes from (Haromi Gardena). Your line is open.

(Haromi Gardena): Hello. Good afternoon. So my question is regarding the digital tools that were developed to capture and report rapid tests from almost any where, you know, people who are testing in schools and workplaces.

So, you know, as you know, the FDA had a design-a-thon, and we actually are a small startup that won the silver medal. And we have successfully transferred data to the HHS database. And we are doing this as a public service.

And we were wondering if the - you know, if this group could connect us to other - the test developers who might need the service where they don't necessarily have a mobile App or anything to, you know, capture and report data. So we have this product that's - can be deployed. And, you know, it's an App that, you know, they have to, you know, we are not charging anything for licensing or anything because this is a public health service. And so we were wondering if the FDA can make this connection for us or who should we talk to so that we can make this service available to the test developers?

Timothy Stenzel: Well, yes, first of all, thanks for reaching out. If you send an email to our Templates email address, EUA Templates email address and contact - and ask to contact Dr. Sara, S-A-R-A, Brenner, B-R-E-N-N-E-R. Sara heads up that part of our COVID response and has been involved with the prior and current Administration on data and connectivity. So she would know exactly who, you know, she could put you and or anyone else in contact with the right people to make the connections. That could be helpful.

So, yes, Dr. Sara Brenner. Just send an email and that will be forwarded to her. And she's really good.

(Haromi Gardena): All right, thank you so much.

Coordinator: And as a reminder, if you would like to ask a question over the phone lines, please press star, then 1. Our next question comes from (Kelly Turner). Your line is open.

(Kelly Turner): Hello. This is (Kelly Turner). I have a clarifying question related to the antigen template. The template recommends 10% to 20% low viral load samples for the SARS-CoV-2 defined as the CT value of greater than 30. Regarding the multi-analyte respiratory panels, does FDA expects a similar distribution for retrospective influenza samples, and if so, how does FDA characterize a low viral load influenza sample?

Timothy Stenzel: Great questions. So I want to clarify a little bit. We are in the process of harmonizing our recommendations across the board. That is for molecular and for antigen. So our antigen template may be updated in the future.

But we are really looking at 20%, 20%- 25% of samples, plus or minus 3 CTs from the LoD of the comparator assay rather than what's in the current template. We've been providing that information to antigen sponsors.

Toby, you can correct me if I'm wrong on any of those.

We are also interested in seeing low positive for any of the other panel analytes. And CTs for those, you know, would be helpful in the evaluation of those and it would be the same sort of thing. We would like to see some, you know, 20%-25% percent low positives, plus or minus 3 CTs of the LoD of the flu or RSV or other panel members as well.

Toby, you got anything to add?

Toby Lowe: No. Nothing else from me.

(Kelly Turner): Okay. Thank you.

Coordinator: We have no additional questions in queue at this time.

Timothy Stenzel: We have answered all the questions.

((Crosstalk))

Toby Lowe: Thank you. We did.

Coordinator: Please standby.

Toby Lowe: Please forward if you have any.

Coordinator: You got more questions.

Toby Lowe: Or you don't like our answers. Hopefully not. We're here to help. And we'll just pause a little bit to see if there's any questions that come in.

Coordinator: We do have a few more questions in queue. Our next question comes from (Christopher Patterson). Your line is open. (Christopher), please check your Mute button is not on.

(Christopher Patterson): Apologies. Yes. I had the Mute button on. Thank you for that. You guys can hear me okay now.

Timothy Stenzel: Yes.

(Christopher Patterson): Hello. Okay, sorry.

Timothy Stenzel: Yes.

(Christopher Patterson): Sorry about that Dr. Stenzel. I have a question about the review process for the antigen test. So we are in the review process. And we've been assigned a reviewer.

And it was kind of bizarre because after couple of months of waiting, which is fine, they asked us some questions. But a lot of the questions weren't really related to our submission or they were kind of almost an accusation, we didn't provide data that we clearly did. And so to follow up with that, we asked the reviewer, if you don't have this data, absolutely, please tell us right now. We'll submit it.

But then we never got a response back. So we're a little concerned about this. And we didn't really know who...

Timothy Stenzel: Yes.

(Christopher Patterson): ...to respond to or bring this up with.

Timothy Stenzel: Yes. Well, and in our office, the buck stops with me so.

(Christopher Patterson): Okay.

Timothy Stenzel: I'm always...

(Christopher Patterson): All right.

Timothy Stenzel: ...available. I am quite busy, unfortunately. But in this case, do send an email to the Templates email box with some details on your submission.

(Christopher Patterson): Perfect.

Timothy Stenzel: The EUA number, the name. And ask for that to be forwarded to Toby and myself.

(Christopher Patterson): Okay.

Timothy Stenzel: Toby Lowe and Tim Stenzel.

(Christopher Patterson): Okay.

Timothy Stenzel: And we'll look into it and make sure that you get some communication back.

(Christopher Pattersron): Very good. Okay, thank you so much doctor and Toby. Okay.

Coordinator: Our next question comes from (Koto Moody). Your line is open.

(Koto Moody): Good afternoon. Thanks for taking the call once again. I'm asking this question is related to the resources available for the review. I think in the last two weeks ago when you mentioned the surge capacity, reviewers are going back to their respective previous level. And still, you have a large number of applications and then there is some backlog.

Do you have enough personnel to do the review? And is the review process by itself is different from when it was reviewed last year when these applications came versus when they are being reviewed after? I mean, obviously, many of the applications that are being reviewed now were considered as a low priority at that time. And now it is being reviewed. So is it these low priority applications are reviewed with a different standard than what was reviewed as high priority applications last year? If you can elaborate, I will appreciate. Thank you.

Timothy Stenzel: So there were definitely some lower priority applications that were put on pause and were assigned to some of our support staff to communicate with developers. As our reviewers have completed the work on the higher priority applications, there has been an opportunity to go back to some of the lower priority applications. The standards are still the same. The priorities are still the same. It's just as we've been able to work through the backlog, we are working in some cases into lower priority submissions now.

Now many of these were able to be marketed through the notification pathways. And since that pathway was open to them and they were deemed to

be a lower priority, that's why they were paused.

But we're going back to them now. There really is no different standard. We, you know, we do - when the applications come in, we do a quick assessment. And we look and see what it is in order to prioritize it. Then we also look at whether there are any obvious concerns about the application.

But we are not doing a complete review of those applications until it is assigned to a reviewer. And at that point, they do a complete review. And if there are issues, they will reach out to the developer and state those issues clearly.

(Koto Moody): Just like how the previous caller was mentioning, we also have seen when the data is given when reviewers come back and ask, they say that it is not given. So is it like the review has been consistent, like what was done previously or now, I'm not sure?

Timothy Stenzel: Yes. You know, so this is getting very specific and we try to avoid specifics there. So you can also reach out to me. I know that actually, I think I see an email in the last 24 hours or so from you. And I will take a look at that. I was on leave last week and there's a large volume of emails to go through.

(Koto Moody): Thank you.

Coordinator: Our next question comes from (Rhina Vemon). Your line is open.

(Rhina Vemon): Hello. Hi. Thank you very much for taking my question. And Dr. Stenzel, this is a follow-up question to the previous question you just addressed in regard to antigen testing.

So we currently have - my company has an active pre-submission, a pre-EUA submission for flu A/B, COVID. And we did get very precise feedback.

But I'm wondering about your comment about the desired number of low

positives also for flu, because, as you know, of course, it's tremendously complicated right now to get any positive flu samples at all, let alone those that are in the low titer range.

And so I'm wondering whether that's really a stringent requirement. We did not get this particular requirement in our FDA feedback. And I think it would really complicate the matter, you know, again, dramatically, if we had to hit this 20%, 25% figure, which I fully understand why you wanted it. It makes sense. But practically, it's really a very high hurdle. And I don't believe in previous 510(k) submissions, which we did, that was never a requirement before.

So can you just confirm that you really - that's a requirement for molecular point of care test as well? Thank you.

Timothy Stenzel: And so yes, our thinking sometimes evolves here. And this just reflects an ongoing evolution. And we - you know, in the case of panel tests that we've not reviewed before for EUA, we do have flexibility.

So, for example, banked samples can be used for - you know, and we know that there's very little flu circulating right now. And so we've made good use of bank samples. And those bank samples may not - they may not have, you know, a good distribution, say, of positivity and that's something that we had hoped to see.

So but, so we haven't in prior situations asked about that. So but we do have the flexibility to put in some commitments post-market. So I would not - if you're struggling to get those low positives for non-SARS targets, I would still submit and work with our team.

(Rhina Vemon): Great, thank you very much.

Coordinator: Our next question comes from (Robert Deterio). Your line is open.

(Robert Deterio): Hi, Tim. Thanks for taking my call. Can you hear me?

Timothy Stenzel: Yes.

(Robert Deterio): Okay, great. I'd like to ask a clarifying question because I'm confused a little bit. It seems as if the CDC at this point has said that in many cases, except some limitations, once you are vaccinated, you are free to come and go without a mask and not socially distance like we were once doing.

But on the other hand, there's no correlation between antibody titer and immunity. And I know you're working toward that.

But I wonder if you can expand on that, please, for me.

Timothy Stenzel: Yes. So we're - you know, at the FDA we're looking at, you know, what uses and claims for a test can be supported by data. And what we're saying is we don't - we haven't yet seen the clinical data that supports immunity or protection claims.

And, you know, and I'm aware of CDC guidelines in these areas. But, you know, they're the experts on their guidelines. And, you know, we focus on what we can authorize for tests and the meaning of that.

So, you know, our missions are a little bit different. They - I mean, and I leave it to them to, you know, expound on their guidances.

(Robert Deterio): Okay, thanks very much. I appreciate it. And good job, everyone.

Timothy Stenzel: Thank you.

Coordinator: As a reminder, to ask the question over the phone lines, please press star 1 from your phone, unmute your line, and speak your name clearly when prompted.

Our next question comes from (Dana Hummell). Your line is open.

(Dana Hummell): Hi. Thank you for taking my call. I have a question regarding two items in the non-lab template and if they are required for the antigen test or only for a molecular test. So the first is the FDA reference panel. Is this one only required for molecular tests or is there also a panel for antigen tests?

And then the second one is the performance study in the non-lab template, which is called inclusivity analytical sensitivity. Is this one only for molecular tests because it refers to the molecular and the antigen templates for more details, but I don't see inclusivity in the antigen template? Thank you.

Timothy Stenzel: So it was - the two were inclusivity and what was the other? I missed the other word?

((Crosstalk))

(Dana Hummell): The reference panel. The FDA Reference Panel.

Timothy Stenzel: Oh okay. Okay. So okay, Reference Panel and inclusivity. Okay. So for - first of all, for the Reference Panel, so we do not have a Reference Panel for antigen test. We have one for molecular. And there were various reasons for that, largely because producing something that will work uniformly for antigen test is a little bit more difficult. And, you know, so there are thoughts about what we need to do there.

For antigen test, though, we are carefully monitoring as the molecular impact of mutations and variants. And so we'll continue those efforts.

And as far as inclusivity goes so, you know, we largely have relied on in silico inclusivity testing for molecular tests. And that's fairly straightforward for molecular tests because, you know, you have primers and your probes and you can do homology analysis to the known mutations and variants out there and detect if there's anything of significance that would lead to a false

negative. That sort of in silico analysis is at best very challenging for antigen tests.

You know, we are asking all developers, serology, antigen, and molecular to - through guidance that we issued on this to be monitoring indications and determine whether - when a situation exists where there may be an impact and they need to do more work. And more work can involve getting a hold of through various means and be able to test for mutations and variants that might impact the test performance.

For developers who are still developing their tests, we ask them to do the same thing. And antigen tests would fall into that category. So antigen tests should know, you know, which antigen was used to generate their antibody or antibodies and epitope mapping information as well for those antibodies so that they can look at the sequence data. Translate it to amino acid and see were there are any potential impacts. And if there are potential impacts, there are various ways to test in vitro the impact of those mutations on antigen tests. And we would ask the developers for those mutations or variants that may impact their test to be able to do that testing. That would be wet testing, rather than in silico testing.

So hopefully that helps out.

(Dana Hummell): Yes. Thank you very much.

Coordinator: And that concludes our Q&A session. I would now like to turn the call back over to your host, Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions during today's Town Hall. Today's presentation and transcript will be made available on the CDRH Learn web page at www.fda.gov/training/cdrhlearn by Wednesday, June 22nd.

If you have additional questions about today's presentation, please email

CDRH-EUA-Templates@fda.hhs.gov.

As we continue to hold these Virtual Town Halls, we appreciate your feedback. Following the conclusion of today's Virtual Town Hall, please complete a short 13 question survey about your FDA CDRH Virtual Town Hall experience. The survey can be found now at www.fda.gov/cdrhwebinar.

Again, thank you for participating. And this concludes today's Virtual Town Hall.

Coordinator: Thank you for your participation in today's conference. You may disconnect at this time.

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