

Virtual Townhall

Moderator: Irene Aihie

June 30, 2021

12:15 pm ET

Coordinator: Welcome everyone to today's conference call. At this time, your lines have been placed on listen-only for today's conference until the question-and-answer portion of our call, at which time you will be prompted to press Star 1 on your touchtone phone. Please ensure that your line is unmuted, and please record your name when prompted so that I may introduce you to ask your question. Our conference is being recorded, and if you have any objections, you may disconnect at this time. I will now turn conference over to our host, Miss Irene Aihie. Ma'am, you may proceed.

Irene Aihie: Thank you. Hello, this is Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA 62nd 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. As a point of information, we will not be hosting a town hall on Wednesday, July 7th. We will resume on July 14th via Zoom with updated login and dial in information to follow.

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 development and the validation of tests for SARS-CoV-2.

Please remember that during the town hall, we are not able to respond to questions about specific submissions that might be under review. Now, I give you Toby.

Toby Lowe: Thanks, Irene. Thanks, everyone, as usual, for joining us this week. I have a couple of updates, and then I will go through some of the questions that we received by email before we start the live questions. So, first, I know we've had a lot of questions about the decision summary for the BioFire De Novo. That decision summary has now been posted on our website. It was posted last week, I believe, on the 26th. And that can be found on the De Novo summary page, as well as the - with the BioFire De Novo authorization as well.

And then I also wanted to update that we just recently added three tests, three EUAs to the pooling and serial testing amendment. So, that is the amendment that we put out recently to allow for a streamlined addition of pooled serial screenings to previously authorized RT-PCR tests.

So, an email went out earlier this week about the three tests that were added. And those can also be found on the EAU page, the molecular EUA page, where they'll be noted under the amendment itself, as well as the authorization documents for those three tests specifically. That will be available - or that are available, rather, on that page.

So, to get into the questions that we received by email, I do want to note, as we have before, that we've received some questions that are a little too detailed or test-specific or case-specific, to address on the call. So we won't address those individually on the call.

So, those questions, we will try to send a response in writing within a few days. And if you submitted a question and don't hear it addressed on the call, and don't receive a written response in the next few days, please feel free to reach back out to the CDRH-EUA-templates@FDA.HHS.gov mailbox for an update.

So, the first question that we have today is regarding an EUA submission for a professional use diagnostic assay, where they're pursuing a clinical performance

study using retrospective samples stored in viral transport media, and as well as collecting prospective samples in VTM to complement that data set.

However, they also note that they have a proprietary assay buffer that they intend to supply with the kit. And they're asking about matrix equivalency study to demonstrate compatibility with the proprietary buffer, and whether they need to repeat all the validation studies, or just the - or just do a limit of detection analysis as an acceptable matrix equivalency.

So, generally, the matrix equivalency study should be performed to compare the assay performance in the VTM and the proprietary assay buffer. So, we would recommend testing be performed in parallel at the same target levels in both simulated and naturally occurring matrices.

And to demonstrate equivalency, you should observe the expected proportion of positive results at each target level in both sample types. The LOD can serve as an acceptable matrix study, and if determined to be equivalent, repeating the other validation studies should not be needed in most cases.

Dr. Timothy Stenzel: And I would just add that this is kind of a little bit of a special case, but, you know, where banked samples are used for central lab test validation, it's always been acceptable for molecular tests, for specific potential issues with antigen tests. And we want to work through that. So, but the same thing goes for point of care.

So, we are accepting banked samples for point-of-care and for molecular. Typically, we would like you to use whatever buffer remains in your actual test, if there is going to be a transport buffer. Just kind of bridging study about cross-validation is perhaps a special case.

We do know that using banked samples and banked positives, is going to be important for many, now that test positivity rate in the US is going down. And still, say an antigen point-of-care test, you know, we would like to see and we've done this before, in fact, the first antigen authorization was allowed completely banked samples VTM frozen, but we also recommended that they do at least five positive fresh

samples demonstrating, you know, good results on those five prospective fresh samples.

And the intervening negatives that happen with the collection of those fresh positives or fresh negatives and fresh positives, we expect that fresh negatives are going to be easy to obtain. And - but, you know, a complete data set on using bank samples, particularly for antigen tests, is good to establish performance. We just want to see those five - a minimum of five fresh positives, and then the remainder of the fresh positives will be placed into a post-authorization requirement study. Thanks, Toby.

Toby Lowe:

Great. Thanks, Tim. All right, the next set of questions that we have is related to antigen studies. Regarding previous statements that we've made on the town hall about allowing inclusion of data from outside of the US for point-of-care, as long as the sponsor can define how those sites qualify as point-of-care and asking whether any countries are excluded from that, whether variants which exist in certain countries, is a concern. So, labeling limitations and specifically asking whether, for example, they could use 80% of data from a point-of-care site in India or 10% in the UK, and the rest in the US.

Then they're also asking about using previously frozen samples for point-of-care studies, as long as a freeze-thaw study is performed. So, it is correct. We have previously stated that it may be acceptable to use data from outside of the US. However, we would want to see that the sponsor has demonstrated that the point-of-care operator in the OUS setting is adequately representative of a point-of-care operator here in the US.

This could be done by providing a detailed protocol describing how the proposed setting and intended users represent the point-of-care sites and users in the US. We would want to see that the instructions for use are in English, and provided in English to the point-of-care operator to perform the testing. So, that may present a challenge in countries where English is not the primary language.

But we would recommend that the sponsor submit a pre-EUA that includes a detailed protocol, including details on the site users' educational background, professions, et cetera, to demonstrate comparability or representability of a US point-of-care site.

And then the information that is provided in the labeling, ultimately would depend on the data obtained in the clinical and analytical studies. We do have information in the viral mutation guidance about expecting test developers to consider the potential impact of genetic mutations and variants that are in circulation in the US, as well as a plan to routinely monitor for new genetic mutations and viral variants, and to assess the impact of mutations or variants on their test performance, considering the potential of a given mutation or a variant to impact their tests.

And regarding previously frozen samples, we have previously discussed incorporating archived specimens into your validation. We would want to see that the testing is performed on your device in the point-of-care settings with the intended users, and that the supplemental banked specimens should be integrated into the daily workflow of each user, rather than included as batch testing.

We would want to see that the archived specimens were prospectively collected, and have a documented history of previous test results, including all test dates. And we would also want to see that there is well-documented information on the storage conditions of the samples from the time of collection.

And then also, as previously discussed, a fresh first frozen study should be performed to demonstrate that the test has similar performance with both fresh and frozen specimens. And then we would generally also expect a post-authorization study using freshly prospectively collected samples, if frozen samples are used for the pre-authorization study.

Dr. Timothy Stenzel: And as I mentioned before - thanks, Toby. If it's antigen, we do want to see those fresh collected samples by a minimum ahead of time. The importance of how you sample a bank is important. We want to eliminate bias, you know, collecting only the high positives or other such things. And we want to see normal distributions in banked samples as well.

And then back for the topic on rest-of-world studies for point-of-care. We recognize this isn't necessarily a preferred method, because we really like to see how it works in the US for US authorizations. But we know, because of the low positivity rate, that

it's very challenging to collect samples quickly enough, positive samples quickly enough in the US.

In regards to the English IFU, I also want to clarify that if users are not fluent in reading and understanding English, that's not an acceptable participant in the study. We've seen some sponsors for some point-of-care even home use instruments and tests that have provided local language translations of the IFU that are used primarily by users. And that has not - and that is not something that we recommend. We are testing the English language IFU as part of the test. And so, it does need to be with folks who understand English. All right. Thanks, Toby.

Toby Lowe: Thanks for adding that detail, Tim. The last question that we have to address right now is also regarding the use of banked samples for point-of-care validation of an antigen test. This is specifically asking about the use of a set of banked samples that includes all required information identified in the EUA template, except for the number of days post onset of patient symptoms. And asking whether they can still use that cohort of banked samples for initial EUA authorization without that information.

So, generally, while we have indicated that banked samples may be acceptable, we would need to see that all of the data associated with the samples is available. And that does include the number of days post onset of patient symptoms. So, we would not think - we don't think that this data set is likely to be acceptable since it does not have that information.

Dr. Timothy Stenzel: Those banked samples could be used for analytical studies perhaps, if appropriate. This is an antigen test question, and one of the challenges of using bank samples that don't have data after onset of symptoms, we do not want developers picking samples based on the CT value.

The selection should be unbiased. And if it's unbiased and we don't know the days after the onset of new infection, you can end up with a lot of very low positives, high CT samples, and it will not put your device in good light, if - particularly antigen tests. I just don't - we don't have an expectation that, you know, 80% low positives are

going to be able to - or up to 90% or 70% of all positives, from being able to be detected at a sufficient sensitivity.

We just don't expect that of the antigen technology. It may be easier for molecularly to do that, but it also puts your molecular device, particularly if it's a point-of-care device, it might be a little bit less sensitive at risk if you use such banked samples. So, we've clearly seen some examples where - of developers and test developers that have gone to bank samples and ended up with a skewed sampling because they don't know the days after testing.

And then, you know, they harvest a lot of - too many really for the device to look well in comparison to the test - to the comparator test, because there was an unexpected balance or imbalance in the number of low positives that were included. So that's the danger and risk of using bank samples.

And so, it's important for us to know the days for which an antigen test is viable as a test. And so, we need that information. It also behooves developers to protect their investment by carefully using banks that record this information. Thank you.

Toby Lowe: Great. Thanks, Tim. With that, I think we can move on to the live questions.

Coordinator: Thank you. At this time, if you would like to ask a question on the phone, please press Star 1 on your touchtone phone. Please ensure that your line is unmuted, and please record your name when prompted to be introduced. Once again, please press Star 1 at this time. And we have a question from Greg Slabodkin. Your line is open.

Greg Slabodkin: Thank you. If I could get someone to comment on the NIH-funded study that's out today. It was announced. It basically builds the case for frequent COVID-19 antigen testing. The study basically says that antigen tests, if they're given every three days, are on par with PCR tests. And I'm just noting here also that I think there was 43 people in the study who were infected with the virus. So, I don't know. Tim, is that something you could comment on, just the whole building of this case that antigen tests are on par with PCR test?

Dr. Timothy Stenzel: Yes, no, exactly. I think this is the full journal and publication of this data. It was out as a pre-print months ago and the data was shared confidentially with the FDA before the pre-print came out as well. We use that data, which was not done in - always in a traditional FDA study sort of manner, but we used that data to primarily inform our recent policy, which allowed serial testing to support the provision of serial testing, to support an asymptomatic screening claim for authorization without having any asymptomatic data.

So that policy was based on that data which was available to us months ago. And so the basis for our serial testing program for any assay that showed at least an 80% sensitivity PPA in symptomatic individuals, and had a lower bound of the 95% confidence level of at least 70%.

And so, we had good indication that the test was performing well enough in symptomatic, and the mitigation for expanding the claim to asymptomatics without pre - without data on asymptomatic individuals prior to authorization, would be an acceptable risk for the agency. So, we allow that.

And then we did have a post-authorization commitment by the companies that use this, that they would do a serial testing program after authorization, to demonstrate adequate performance when the - particularly when antigen tests are used in serial testing, two or three tests a week.

So, you know, there are several antigen tests that utilize this, and we allow that - and then allowed us to make those tests, rather than prescription home use for those suspected of COVID to authorize them based on that paradigm for an over-the-counter, which also would test asymptomatic individuals as well. So, that particular study was done with only one of the lateral flow tests, and one of them that might be more sensitive to instrumented lateral flow test.

And so, we don't know that we can generalize that to all developers as far as basing where those hard decisions only on that study. So, that's our current thinking. Hope that's helpful.

Greg Slabodkin: Got it. Just a quick follow-up, Tim. I mean, is it your perspective that PCR is still considered the gold standard for diagnosing COVID-19 infections? And is the FDA still recommending that if there's a positive result from an antigen test, that it be verified by a PCR test?

Dr. Timothy Stenzel: So, there is communications that are out on the FDA website and on the CDC website regarding all those. We support the use of any test that can perform adequately to receive regulatory authorization. There are use cases for molecular and there are separate use cases. And some of it's not overlapping for rapid point-of-care tests, many of them being antigen tests.

So, remote areas, areas that were turnaround time for a molecular central lab test, is not ideal use of antigen tests or other point-of-care molecular tests may be used, but antigen tests are - can be produced at many-fold access to what a molecular point-of-care test can be. And often those molecular point-of-care tests require an instrument, whereas a couple of the rapid antigen tests don't require an instrument at all.

So, that has clear advantages depending on the use case. And so, we don't have a recommendation over. Now of course, we want to know as close to truth when we're evaluating tests as we can. And we believe that central lab high sensitivity molecular assays with an extraction step, represent the closest information to truth about whether a patient is infected with SARS or not.

And so, we typically use that as the comparator test for all other tests and some sample types. And that just allows us to understand what the real situation is. And let's see what else that I wanted to add into this discussion. Yes. So, we clearly see a value for antigen tests.

As far as a follow-up to antigen test results, this is frequently the case with any test. We have specific language in the point-of-care antigen tests, as well as antigen tests that may be less sensitive than the central lab molecular tests. But antigen tests actually are presumed negative. And if they are presumed negative, we want clinicians to evaluate whether that negative seems real to them or not. And that's all in the authorized labeling that we have for those tests. You can go to the FDA

website and look at that labeling. But with any test, including central lab molecular tests, there can be false negatives and false positives.

A lot of the variability is also contingent on sample collection. So, or there could be a mutation that might be affecting an individual patient. We're not seeing any mutations or variants yet confirm that are significant risks to test performance, but we have seen individual cases in low abundance mutations or variants where a certain test does fail.

And so, it does require clinicians, laboratorians, everybody involved with SARS testing, to keep that in mind that they could have a false positive and false negative. We also said that if you have a very low incidence population, no matter what the test is, molecular or lateral flow, molecular has a little bit better specificity NPA than lateral flow, typically.

But in either case, you're going to start to see when the incidences of true positives is low, that you may see significant numbers of false positives. And we've also seen and heard reports that clinicians move positive patients on an initial result in a low incidence environment, into a COVID ward, and that's obviously risky.

So, we do ask that everybody involved with testing be aware of that. And if the incidence is low and you have a positive, unless that person is already at increased risk, as they're known to be exposed to a confirmed positive patient, that you consider that it could be a false positive and do a confirmatory test, which we would recommend be a molecular test. So hopefully, all that is useful.

Greg Slabodkin: Yes. Thank you.

Coordinator: Thank you. Our next question is from Dr. Girgis. Your line is open, sir.

Dr. Girgis: Yes. This is about the OTC and the usability studies, human comprehension. So we submitted the application. It seems to be applicable to point-of-care, but then up to the level of the over-the-counter. Since we are approaching testing populations from two years old to 99 years old, what does the FDA expect us to do for the usability studies? Can you comment on this, please?

Dr. Timothy Stenzel: Yes. So I think what you're saying is, for the younger age groups, what do we expect to see for the usability studies? So, it depends on whether you're going to have younger patients self-collect, or if you're going to have adults collect the sample.

So, if you're going to have younger patients, you know, you might be able to go down to grade school ages and have them self-collect. Then we would want to see usability studies that - down to the age group that you're going to say, down to the age that you're going to say they can do it, that we'd like to see usability down to that age and good representation in the kids.

If you're going to have adults collect, say kids under 14 or under 13, or if you go the exact top point is, and you want to include, you know, unlimited pediatric patients in your test, then we'd want to see usability of adult collection down to age two. And so, obviously, if you want to get a full pediatric range, you can involve some self-collection of older kids if you want, or it can be all adult collection.

But then whatever - say, you know, you don't have a grade two - you need to demonstrate that kids can self-collect down to grade two, then below grade two, you're going to have adult collection and we'd want to see representation that an adult, in a home test situation or, you know, that kind of setting, can safely and adequately collect under usability studies and also in your clinical studies, that the adults can see a plain adequately collect those samples, and those samples are apparently in the usability studies collected well, and in the clinical studies accurately.

So, that's a lot of information. It all depends on which route you want to go as far as what claims you want about self-collection for kids or adult collection. That's what we've done for all the authorizations to date. And if there aren't kids included in the study, you can't authorize kids.

And of course, in point-of-care situations, we know that clinicians can adequately sample kids. So we're not worried about testing it necessarily in kids, but you shouldn't exclude kids in your clinical study at point-of-care. It's just we don't need to

specifically see kids in the point-of-care study, unless there's something unique about your device that makes kids difficult. Hopefully, that's helpful.

Dr. Girgis: Actually what I'm looking for is that, can we get the - if the device is approved for point-of-care, and now we work with you on the usability studies, depending on the age group, because it's massive. We're going after a massive population at large, and we can't just - I think this is beyond whatever any company's ability, small companies specifically, to do that kind of studies unless they work with you on the usability and allow the point-of-care devices approved to be used to collect data. Is that possible?

Dr. Timothy Stenzel: No. So we're looking at usability in clinical studies that demonstrate performance in the home type situation. And this just can't be avoided. We need - we make our decisions based on data. And if you only have point-of-care studies, your healthcare sampled patients, healthcare worker sampled patients, and run by the healthcare workers. They are not sampled and run by home users.

Dr. Girgis: Agreed. I'm asking, if we have a point-of-care device, approved point-of-care device, and working with you on a usability study designed and collect the data, and depending on the age group, is that going to be usable, the device can be used for that? So, a full approval of point-of-care, we need this.

((Crosstalk))

Dr. Timothy Stenzel: Yes. I don't think we're actually communicating well in this forum. So, I would suggest that you reach out either through a pre-EUA or the template email address, because we're just not connecting on this. So, I'm not understanding your question well enough to give you a response that meets your needs. And I'd like that to happen, but I think we ought to - if there's another caller, I think we ought to move on to the next caller.

Dr. Girgis: Okay. Thanks.

Coordinator: Thank you. Our next question will come from Elliot Rosen. Your line is open, sir.

Elliot Rosen: Hello. Good afternoon. I have a quick question regarding the serology test for neutralizing antibodies. I know on the town hall call last week, it was stated that due to declining prevalence in the United States, FDA would now consider data from subjects enrolled internationally. And my question is, will there be updated guidelines released for serology testing for neutralizing antibodies, or can we utilize the minutes from the call last week in case a reviewer asks about that during our EUA submission?

Dr. Timothy Stenzel: Yes, you can certainly refer to the minutes and they're always - and the reviewers, if they have an issue with what I said on this call or Toby said on the call, they come to me and try and understand it. So, I don't believe the - I could be wrong, but I don't believe the neutralizing template says it has to be done in the US.

We've just been discouraging non-US because there was - prior to now, there's been unfortunately plenty of positive patients in the US. And given that our EUA bar is so much lower than the usual FDA test standard for numbers of positives and negatives and the amount of work done for an authorization, that we want to ensure that we best understand performance of the test on the relatively few samples we ask for in the US population, in US labs and point-of-care sites and home sites.

Due to the incredible success of the US to date and right now and in future. Our vaccination program and the testing program and all the other programs that everybody has been involved in, apparently has been highly successful. So for pockets right now that we're in a bit of a conundrum, you know, on test validation, and we're trying to be as flexible as we can. Toby, do you have anything to add?

Toby Lowe: Yes. I just want to mention, I believe the template does specifically say US, and we want to make sure that the specimens that are used reflect the population that - the intended use population. So we would just want to see that justification that we've talked about on this call as well about when you're using, or considering using OUS specimens, outside the US specimens, that we would want to see the justification for how that is representative of a US population, including the circulating variants that are in the US.

Dr. Timothy Stenzel: All right. Thanks, Toby, for that clarification and correction. And, you know, we're constantly looking at updates to templates that will be helpful. It does - and Toby is actually primarily the one responsible for pulling all that together and marshalling it through all the authorizations within the US government. And she does a great job, but it can take some time.

And sometimes, you know, things are in process and we don't want to slow what's already in process to update. So, that's the incredible value, I think, of this constant weekly call that we have with developers, where we can update our most current thinking well ahead of what the templates reflect. And it's one of the main reasons why - one of the key reasons why we have this call, and why it's, I think, important for people to call in and/or check the transcripts. Thank you.

Elliot Rosen: Great. Thank you so much. Is there a plan right now to update the template or is that still?

Dr. Timothy Stenzel: I think it's a good thing to do. And like I said, we tend to accumulate updates and send them up at the appropriate times because it is a lot of work to get all the authorizations before we can post it.

Elliot Rosen: Thank you very much.

Coordinator: Thank you. Our next question is from Ariana Erickson. Your line is open, ma'am.

Ariana Erickson: Good morning. I have a question about an antigen lateral flow test. So, we're working on a point-of-care claim for our antigen test using a CLIA-waived drive-thru clinic. At the clinic, they use personnel who are certified to conduct nasal swabs and nasal pharyngeal swabs. And the same personnel will be collecting and running our tests. I just wanted to ask if you anticipate any issues with these personnel as part of our point-of-care claim.

Dr. Timothy Stenzel: No. But do double-check the template on - that we do want to see more than one individual, and we recommend more than one site be used for point-of-care. But sometimes it may be necessary to use one site. We want to see - I forget the number, five, I think it might be five or six different people, but, you know, at that one

site, so that we have a spectrum of users, and so we're not just going with somebody who's like expert and we're not seeing the typical point-of-care site.

Ariana Erickson: Absolutely. Yes. Thank you so much.

Coordinator: Thank you. Our next question is from Robert de Tullio. Your line is open, sir.

Robert de Tullio: Yes, thank you. Hi, Tim, and Toby. Thank you for taking my questions. I wanted to follow up on an answer that I heard to one of the previous submitted questions about POC ex-US, and qualifying the sites and the users. I heard the response that you should file an EUA to tell about the new study or the amended study.

If the sponsor is already operating under a previously submitted EUA, and because of the dearth of samples now, needs to pivot outside the United States, is the pre-EUA the right way to go because they - because you're so busy, don't - you don't get immediate responses? Is there a quicker way to verify something like maybe via email or something like that? Or do we need to refile a pre-EUA?

Dr. Timothy Stenzel: So, if you've already filed a pre-EUA for a device, and you're switching to this because you've tried a prospective study in the US and it isn't getting you where you need, I think it's very appropriate to go back to the same reviewer who reviewed your pre-EUA and ask them this question. You just go directly to them. They can just reopen the file, or we open a new file and address that question specifically.

For those that we haven't seen the technology yet at all, it's probably best to go through - directly through a pre-EUA process so that we understand the technology and we can address the questions accurately. I know we have - we still have a backlog of EUAs and pre-EUAs. I've made a concerted effort to mention that we need to make good progress on both pre-EUAs and EUAs.

The pre-EUAs are not required. And our recommendations in the EUA templates are not required. It's recommended - pre-EUAs are recommended and our templates are recommended validations. The value of the pre-EUA, as you know, just as the value of the Q-sub pre-submission, it reduces the risk to the developer.

And the reviewers are still just swamped. So, we're doing our very best. So, developers can do things on risk. And so, it's why we give high-level guidance here on our recommendation. If it's point-of-care, we want to see it exactly mimic the point-of-care situation in the US. That's a busy clinical office practice or a busy ER. It's not a central hospital lab where you pull trained laboratorians off that line and say, oh, test some samples on this point-of-care device.

No, that's not testing on folks who aren't trained laboratorians. And we have seen those - without pre - without a pre-EUA, we've seen sponsors say, oh, here's our point-of-care study. And, oh, by the way, we did it in a central lab with central lab trained laboratorians as our point-of-care. You can get a moderate and high complexity claim, but you're not going to get a point-of-care claim. So, that's the challenge.

So, if you can get - do a good job on selecting point-of-care sites or home sites, because we've talked about those situations already, this call and many calls, that can reduce your risk if you follow our high-level guidance. But to eliminate, you know, complete risk of having to repeat some study, the pre-EUA process is still the best way that we recommend.

Robert de Tullio: Okay. Well, as usual, very helpful. Thanks so much, Tim. I appreciate. And I wasn't impugning the process that it was too slow. I was just saying the reality is, it takes a couple of weeks or so sometimes. And for developers, sometimes that's, you know, a long time.

Dr. Timothy Stenzel: I know. I feel for you because I've been on - I spent many years, 15 plus years on the other side of the clinical development community working with the FDA. And I know - and how important it is. And I track, at least weekly, all of the volumes for the various submissions, and work with our team to do the very best job that we can to get answers as quickly as possible.

Robert de Tullio: Yes. Well, keep up the good work. Thanks so much. Bye-bye.

Dr. Timothy Stenzel: I will. Thanks.

Coordinator: Once again, if you would like to ask a question, please press Star 1 on your touchtone phone and please record your name. We do have a question from (Kaumudi Venkat). Your line is open, sir.

(Kaumudi Venkat): Good afternoon. Thanks for taking the question. Thank you very much for all the hard work that your center is doing and you are doing your best. But if the best is not good enough, and especially when you really don't have enough resources to do it and that, is there anything that can be done better to increase the efficiency, make this process more transparent, to be more helpful for the developers, especially not the corporations who are small businesses, so that innovative methods and tests that can be made available during this pandemic?

Dr. Timothy Stenzel: We're doing our very best. We've authorized almost 400 tests now. And you don't hear about the ones that we don't authorize. And so, we have plowed through a lot more tests than that. And we believe we're doing a great job at meeting the public health need at this point. And with all those cuts authorized and, you know, we have our priorities.

We have our priorities, which is point-of-care, particularly diagnostic test point-of-care, and in the home diagnostic tests, and home collections, and high throughput central lab tests. So, those priorities haven't changed, you know, for a very long time. We always assess priorities, and the team is doing the very best they can.

We also moved 100 people from other areas recently on to COVID work. That surge - and it was - it had great success in clearing the backlog in many cases for priority reviews. And - but unfortunately, put - it put more than 100 regular non-COVID 510(k), De Novo and PMA submissions on hold or on pause, not hold, on pause. And that got to be a balance of our resources.

So, our office was not staffed, the center was not staffed prior to this pandemic to handle this volume. Our office again, and I'll say it again, in the past year, we typically see just under - we see about 1,900 applications a year. Our office alone receives over 5,500 applications in 12 months, with no substantial increase in staffing, because it takes experts to review this. So, we just had to do it faster and better than

we had ever done it before, which I believe the team did. And okay, I think it's time to move on to the next caller. Thank you.

Coordinator: We have no more questions at this time. So, I will now turn our conference back over to our host, Miss Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. Again, we will not be hosting a town hall on Wednesday, July 7th. We will resume on July 14th via Zoom, and we'll be sending updated log-in and dial-in information. 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, July 7th.

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 would 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 on www.FDA.gov/cdrhwebinar. Again, thank you for participating, and this concludes today's virtual town hall.

Coordinator: This does conclude today's conference call. We thank you all for participating. You may now disconnect, and have a great rest of your day.

END