Virtual Town Hall
August 25, 2021

Moderator: Anike Freeman

Anike Freeman: Hello, and thank you for joining us today. I'm Anike Freeman, a Senior Consumer Safety Officer in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be moderating today's program. I'd like to welcome you to our virtual town hall meeting for SARS-CoV-2 test developers. This is meeting number 68 in our series in which we'll discuss and answer your questions about diagnostic tests in the fight against COVID. Please note that, after today, we are switching to a biweekly format. The next town hall will take place on September 8.

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 Dr. Kristian Roth, also from OIR. We will begin with opening remarks from our speakers and then we'll answer your questions about the COVID test development and validation process.

To ask a question, please select the Raise Your Hand icon at the bottom of your screen. Please note we are not able to discuss specific submissions that are under review. Now, I will hand the program over to Tim.

Tim Stenzel: Thank you, and welcome everyone to another weekly webinar and virtual town meeting. And we will be moving to every other and see if that works. We always have the flexibility to go back to weekly if that's important. So, I had a few brief opening remarks. And then I'll move into the answering the questions that were submitted prior to the call, and then we'll go into live Q and A.

First of all, our clear priorities for review are diagnostic tests that greatly expand access. These are very high volume central lab tests or point-of-care tests and home tests and home collection for diagnostic assays. There are some serology tests that are clear priorities. And they are fully quantitative serology tests that are traceable to the WHO international standard.

This will really help us move forward and inform on whether or not there's a level of antibody that is able to provide complete immunity and/or protection. Neutralizing antibody tests are also a clear priority as well, although that may not always correlate with the development of some immunity or protection. So I also want to say that most of the questions today that were submitted ahead of the meeting have been answered, some of them even last week. But I do want to apologize for going over these topics again. But perhaps clearly, repetition may be needed.

So apologies in advance. So with that, we'll move into those questions.

The first question has to do with-- I'll just read it. For those groups trying to model the changing demand for COVID diagnostic testing, there is an increased concern about a spike in demand for COVID point-of-care and home tests as a result. What is the FDA doing during EUA process to help meet the increased demand for these tests? Are these tests prioritized? Will the FDA shift focus to these types of tests?

So for anybody who's a regular attendee of these town halls, you know that diagnostic tests in particular and those that are point-of-care and home have been a clear priority for a very long time and even home collection. And we have authorized quite a few of these, of course, already. And there really is no

reason that manufacturing volumes of these already-authorized tests cannot be scaled up. But unfortunately, that is not something that the FDA is in control of. We certainly can encourage, but we have no such authority. And as I've said at the beginning, we continue to prioritize these types of reviews.

Next question is from a company that's working on a total antibody test and is recruiting subjects into the clinical validation study and are asking -- and of course, the templates of the sample size should be 30 positive and 75 negative samples for the clinical study.

But however, they state that they will likely encounter vaccinated and unvaccinated individuals in their recruitment process. Does this change the sample size consideration? Or does FDA have recommendations for the distribution of positives and negatives required if we were to include both?

So our recommendations are recommendations, not requirements. And if you want to move away from what we recommend, we do encourage you to check with us first, the pre-EUA process. However, the sample size of 30 positives and 75 negative are pretty much the bare minimum.

We approached EUAs relatively early in the EUA process. That's why we moved, for example, for diagnostic assays, for prior pandemics, we often asked for 50 positives and 50 negatives per EUAs. And we moved relatively quickly to 30 positives and 30 negatives, since samples were not available. And we allowed contrived samples.

I know that there are, unfortunately, a lot of samples available now. And in the past, we moved to actual clinical samples. So those sizes are set based on statistics and being able to, at least at a bare minimum under the EUA authority, establish performance estimates for those tests.

Just a bit of a preamble to responding to this question in a little bit more detail, as has been communicated by the FDA and other agencies, the results of the currently authorized SARS-CoV-2 antibody test should not be used to evaluate a person's level of immunity or protection from COVID at this time, especially with regard to COVID-19 vaccination.

There are many ongoing longitudinal studies looking at outcomes investigating whether we can use SARS-CoV-2 antibody tests in the future as an indicator of protection. But we do not yet have that data available in order to make that decision. And we look forward to seeing the results of those studies. Those studies are not under the control of the FDA.

So this remains a topic of continued discussion. As new information becomes available, we, the FDA, will, of course, consider the scientific evidence to inform our recommendations to support such claims. And so back to the original question is, because there are many people vaccinated, what do you do? Well, unfortunately, there's many people who are not vaccinated. So we do recommend that you exclude vaccinated individuals from your clinical studies for serology for SARS-CoV-2. For negative samples to establish the negative predictive -- or negative percent agreement, or specificity, we recommend that you take advantage of bank samples that were collected prior to the pandemic. I'm sure there's been a huge demand on those samples over time. So I’m not sure how readily those are yet available, but you can collect fresh samples now. Feel free to send an email to the templates email EUA box to request further FDA think on additional testing approaches to support clinical studies if you continue to struggle with that.

Next question. Does the FDA plan to end the EUA pathway for any SARS-CoV-2 related test diagnostics, serology, et cetera, prior to the official end of the public health emergency? The short answer is no.

If so, what would be the criteria for ending the EUA pathway? The FDA is actually not the one that would declare an end to the emergency. That's the brief answer. I'll go into a longer answer here shortly.

Also, would tests previously granted EUA be allowed to remain on market if the EUA pathway is ended? And the answer is there is a short answer, is yes. Let me go into more detail on this. We have covered this before on this call, but we'll go over it again.

While we can't comment on the timeline, we're working on a transition plan for devices offered under EUA. But we still are encouraging full authorization submissions to the FDA soon as you want. We are accepting Q-Subs, Pre-Subs for those. And we're accepting full authorization applications. For molecular, that mostly would be 510(k) submissions now, since we've already granted one submission. And then for serology and antigen, it would be-- the first one would be a De Novo application. And then subsequent to that, most of the antigen and serology tests would be 510(k) submission. So the transition plan guidance is on the Center's, CDRH's FY '21 priority list.

And additionally, revoked EUAs are in effect until the public health emergency is terminated. This does not typically happen for quite a while, and as can be seen from previous public health emergencies that still have not been terminated, like Zika and Ebola. So there are still non SARS-CoV-2 tests that are able to be sold and used under EUA authorities.

We cannot anticipate when the public health emergency will end. However, the FDA is committed to helping ensure the public has access to a wide variety of test options for COVID. And we'll continue to review the EUAs to address public health needs.

Moving to the next question. With the recent surge in the Delta variant cases and the recommendation by the Biden Administration that some Americans receive a third dose of vaccine, is there any renewed interest from the FDA in serology testing that is for screening for eligibility for a vaccine? If so, should we expect any modifications to the serology template in the near future? Is there any particular type of serology tests that would be prioritized over others, neutralizing total IgG, et cetera?

So I've already spoken to this multiple times on this town hall call before, and I also talked a little bit about this already today. And again, just in brief as mentioned already, at this time, SARS-CoV-2 antibody test should not be used to evaluate a person's level of immunity or protection from COVID-19. The current agency, multiple agency recommendations and medical association guidelines currently recommend against using these tests for vaccine eligibility. Any updates from the FDA regarding serology test indications, templates, and review priorities will be made public on our website. And also, I'm likely to announce it here on these town hall calls.

Moving to the next question. Understand that for the clinical studies supporting 510(k) submission of a multi-analyte PCR assay comparative method for targets other than SARS-CoV-2, that is flu, RSV, et cetera, should be a 510(k)-cleared assay. Is this also true for discrepant method analysis? Or can a multi-analyte EUA authorized test be used? For a clinical study to support 510(k) submission, we recommend using a cleared comparator for test for targets other than SARS-CoV-2. And this would be true for discrepant analysis as well.

Moving to the next question. I had a question regarding predicate device for 510(k) submission related to SARS-CoV-2. We'd like to conduct clinical validation for our SARS-CoV-2 only assay and a multiplex assay that includes SARS-CoV-2 using the same specimen. Would it be acceptable to use the BioFire RP2.1 assay as the predicate device for both assays? Yes. It would be acceptable to use the BioFire RP2.1 assay as the predicate device for both assays.

Second question is also related to the first question. If RP2.1 is acceptable for the SARS-CoV-2 only assay, could we also compare the performance of the assay with interior nasal swabs versus BioFire RP2.1 anti-swab results? One second, please. To expand our claim to include anterior nasal swabs?

Ah, yes, comparing anterior nasal swab performance on the candidate test to anterior swab on the comparator test, in this case, RP2.1 appears to be acceptable to support an anterior nasal swab claim. There may be additional information requested to ensure that your SARS-CoV-2 test has been validated with samples having low viral load.

Moving to the next question. As the vaccination rate increases and the approval of vaccine boosters, we anticipate a decrease in the demand for COVID tests in 2022. We want to know if the COVID test demand continues to decrease, will the FDA change their review policy of the EUA or stop reviewing new EUA submissions and only keep the re-authorization of EUA? We want to know if there will be a cutoff date for new EUA submissions next year and if FDA will give any transition period.

As we've stated earlier, unless revoked, EUAs are in effect until the public health emergency is terminated. And we will continue to review EUAs that address the public health needs. Those priorities could shift, and we'll make those very public if they do.

Moving to the next question. In light of the recent news that a third booster shot for the Moderna and Pfizer vaccines will be available in the fall, has consideration been given for using a neutralizing antibody test, qualitative and quantitative, for determining the need and prioritization for a third booster shot? As I've previously stated, SARS-CoV-2 neutralizing or binding antibody should not be used to evaluate a person's level of immunity or protection for COVID-19 at this time. And with the ongoing studies, we'll evaluate the data that comes from those studies to see if we can make any further recommendations and updates at that time.

Next question. We would appreciate your guidance on the following. The molecular diagnostic templates for commercial manufacturers recommend that specimens representing a wide range of viral load, including low positive samples, should be tested. We note that the FDA has requested approximately 25% of comparator positive samples to be within two CTs of the comparator assay LoD. However, it has been indicated that it is very difficult to obtain these low positive samples. Please let us know if it'd be acceptable to use clinical specimens diluted with negative specimens or VTM as low positive samples for clinical evaluation? So this is something that we have heard. It may be because delta has such a high viral load.

And so but we do want to clarify that low positives are currently defined by the comparator test as those samples with CT values no more than three CTs below the target with the highest CT of LoD for the comparator test given a multi-target comparator. For example, if the comparator target one has a CT of 27, for target one, and for target two has a mean CT of 33 at LoD, then low positives would be any sample with a CT of 30 or greater for target two. We do still recommend acquiring natural low positive

clinical samples rather than diluting high positive samples, as we've seen data that low positives are available still.

A couple of thoughts about how to get these low positives, you can try to collect samples further out from the onset of symptoms. Or you can test newly-exposed individuals after an appropriate incubation period. And initial viral loads may be lower in those cases.

Moving to the next question. If an OTC antigen test received EUA using paper instructions and manual reads, and the developer wishes to use a smartphone app to interpret results, we understand a second clinical evaluation would be recommended. For the second clinical evaluation, is it acceptable to include only subjects that agree to use the smartphone app and exclude subjects that only want to use the paper instructions? If not, are 30 positives using paper instructions needed for the second clinical evaluation along with 30 positives using the smartphone app?

So if a test is already authorized for OTC with visual interpretation with paper instructions, it is not recommended to repeat your clinical validation on this cohort. But yes, if you are validating your test with the use of an app interpretation of the lines for positivity and negativity, you should only enroll those that use the app for interpretation in a prospective study and obtain at least 30 positives and 30 negatives. Regardless, you will want to conduct a usability study for all IFUs, that is, both paper IFU and our smartphone IFU and submit your app labeling for FDA review.

Second question from this person is, for an OTC antigen test that can be interpreted using a smartphone app running on iOS and/or Android, are 30 positives needed per operating system in the clinical evaluation or 30 positives total? No. As long as the IFUs are identical, you would not need to test 30 positives and 30 negatives for each operating system in the clinical study. But we would expect that you conduct appropriate software validations to ensure that performance is equivalent across systems. And specifically from the template, quote, "a summary of the verification and validation performed on your software/application. To validate use of your application with a smartphone, you should develop a set of minimum smartphone specifications. That is, memory, processor capability, minimum operating system requirements, et cetera. You should validate the software on smartphones with each OS that meets those minimum hardware specifications."

If you need new -- if you add new labeling via an app, you should submit that supplement with the revised labeling for FDA review. And this validation across platforms, not on a clinical study, but to ensure, on samples at the developer's site, that you get equivalent performance depending on the operating system is important. Because we have clearly seen that even within different models within a given brand using the same operating system, you can see a variability in results. And when you make your application, you can also request in a pre-EUA more details from our software review team.

Next question. For an EUA over-the-counter nonprescription COVID-19 rapid lateral flow assay with a serial testing claim that will eventually provide FDA with acceptable asymptomatic serial study data, is it a correct assumption that, for the transition from EUA to 510(k), no new asymptomatic testing would be necessary for the 510(k)? Meaning that only the acceptable asymptomatic serial study data is required to support the asymptomatic claim.

So currently, the serial testing program is only applicable to EUA tests. However, we will want to incorporate as much of the EUA data as is possible. And that's possible if the device does not change in any material way that can impact performance.

So but as far as the minimum recommendations for the number of samples, et cetera, you'll want to validate that according to FDA recommendations. And you can go ahead and submit a Pre-Sub or a Q-Sub with your proposed studies on specific questions. So depending on the size of that asymptomatic study, it may or may not meet the expectations for full authorization.

Second question from this person, for an at-home test by prescription multi-analyte COVID-19 and influenza EB lateral flow test intended for symptomatic individuals, presuming EUA authorization and eventual 510(k) clearance, is it correct that no testing of asymptomatic individuals would be required, either single or serial testing? If you're proposing a claim for a symptomatic population, which is the likely population, when you have a multi-analyte test other than SARS, we simply don't know what's going on with other viruses, respiratory viruses, in an asymptomatic population, you would not need to test asymptomatic individuals.

Next question from this individual, in general, when the performance of an assay isn't expected to exceed 90% PPA or sensitivity, does a test developer need to include symptomatic and asymptomatic serial testing in a clinical study to support 510(k) clearance for COVID-19 rapid lateral flow assay for over the counter?

So again, depending on what claims you want to make, we recommend you submit a Pre-Sub to get more information. And the final question from this person notes that in an August 12 article, in Agency IQ by Laura DiAngelo on the FDA transition from QSR to ISO 13485, that there are questions about the impact on EUA authorizations.

So yes, we are in the process of converting from QSR to ISO 13485. However, and we can't comment on the timeline for a transition plan. But again, we do not see an end anywhere in the near future to the EUA pathway for review of critical assays by the FDA.

Next question, and we are getting -- I think this is the last question of that submitted prior to the call. The FDA has stated many times recently for their review priorities for COVID related tests includes point-of-care tests. Does this review prioritization also apply to pre-EUAs and EUAs for COVID patients related to IL-6 tests?

So as I said at the top of the call, on diagnostic assay, they're currently the clear priority. IL-6 tests would not be priorities. And there -- however, I'll get to additional caveats here. There are three tests that are currently authorized for the management of COVID patients for IL-6. And we are continuing to review these types of submissions.

You should submit a pre-EUA to gain additional feedback, especially if those tests that have already been EUA authorized don't have-- and those authorizations don't have enough information for your pathway. But if you're simply following what was done by those before, there may not be a need for a pre-EUA. All right. And with that, we will-- we have a lot of questions today. We'll move to opening up for live Q and A.

Anike Freeman: All right, just wanted to remind everyone again to be prepared to unmute when your name is called. Our first question will come from Nancy Cheatham.

All right. It looks like Nancy is not there. Our next question will be coming from Julie.

Tim Stenzel: And callers can please unmute. If you're using the phone, for example, you might have to do star 6.

Anike Freeman: All right. Looks like Julia's not there. Let's move to Tianyang Liu.

Tianyang Liu: Thank you. Oh, hi, Tim. My question is, if we formally submitted our materials to FDA of our OTC home test kit, and it has no major deficiency, how long should we expect the first feedback from FDA?

Tim Stenzel: So if we take a look at the assay, we do an initial review to make sure that the application is complete. If the application is not complete, we would, within a few days, I think up to 10 days, we would return comments with the fact that the assay, the application is incomplete.

Tianyang Liu: I see. Yeah, but--

Tim Stenzel: If you are beyond that period, then we take a deeper dive into the application. And those applications that have essentially no substantial questions get prioritized ahead of others. And that's because we can move those applications along more quickly. So it's important to submit a good application. Because if we've got questions, it will move an application down in priority.

So and it's probably evident to all on the call that the authorized another home OTC test, the BD Veritor. And that was late last night. And so that, obviously, was something that could move along the process relatively quickly.

So then we move to those that are next on the list. And it is our goal to get through that list as quickly as possible. And I meet regularly with the team, and we discuss all the applications. And we discuss priority within even the home OTC applications what are the top priority.

Tianyang Liu: I see. So --

Tim Stenzel: Hopefully that addresses the question.

Tianyang Liu: Thank you, Tim. So in this case, if we submitted our OTC home test kit which is a priority two months ago, I mean, seven weeks ago, and we never received any feedback except that your application is under review. So in this case, you mean that--

Tim Stenzel: So yeah.

Tianyang Liu: We are --

Tim Stenzel: If we issued a-- oh, go ahead. I'm sorry. Go ahead.

Tianyang Liu: So in this case, you mean that so our application is under a deep dive look. And in this case, we should wait. Right?

Tim Stenzel: It depends on what feedback. You said, resubmission. So if an assay is resubmitted--

Tianyang Liu: No. It is the first submission. It's a first.

Tim Stenzel: Oh, a first submission. Oh, OK. Yes. It is under review, and it -- you should have already been assigned a reviewer and have somebody to contact. If not, you can send an email to the templates email box. And they can, on a periodic basis, give you an update on the status.

Tianyang Liu: OK. Thank you. Thank you. Got it.

Anike Freeman: Our next question is from Richard Montagna.

Richard Montagna: Thanks, Tim, for taking the call. I know you guys are up to your eyeballs in EUAs. But I'm wondering if you have any guidance as to when we might see meeting transcripts beyond the July 28 meeting. It seems to be the last one posted. Thanks.

Tim Stenzel: Yes, yes. We converted to Zoom and had a new process that, frankly, initially, didn't have a correct transcript. So we had to restart the process of the new transcription process. And that is nearing the end, and we expect to release transcripts in the very near future, ahead of the next call.

Richard Montana: OK. Thank you very much.

Anike Freeman: Our next question is from Diego Blandon.

Diego Blandon: Hi. So I have two, hopefully quick, questions. The first is we're currently working with a company that is validating a lateral flow antigen test for home use. And the company wants to validate the device for interpretation by both the user and a reader in the same study.

And so the study will first require the user to interpret the results themselves and then capture an image of the device with a smartphone to have the results interpreted by the software without any user input. So in this case, would FDA consider an EUA application for both user-interpreted and app-interpreted indications if the study was executed in this manner? And I can repeat how the study was executed.

Tim Stenzel: Let me read it back to you here, or even, I think, or saying back what I think is being said. You want to combine both manual and visual read and app reading of the test with the same study, with the same individuals to make that more efficient. So would the results of the app be evident to the individual performing the test?

Diego Blandon: Could you repeat that question? Sorry.

Tim Stenzel: So if they read it first visually, and then they scan it with the app, would the app results be available to the patient?

Diego Blandon: I believe so.

Tim Stenzel: They have-- yeah, they have to be.

Diego Blandon: Yeah.

Tim Stenzel: So that could potentially bias the manual read. Because if they said negative, but the app says positive, the reader may switch their answer on the manual.

Diego Blandon: Mm.

Tim Stenzel: So we want to eliminate bias in these studies. So there might be a way to do that. We want to be as flexible as possible. But it might require an expert observer to make sure that they're not doing things out of order and changing their response.

Diego Blandon: OK.

Tim Stenzel: And then also there's the timing of the read. Presumably, it wouldn't be -- it would be less than a minute between the visual read and the app read. But we wouldn't want that window to be too long, because it could change the results.

So that's the sort of details, probably your best hash out through interchange with FDA review staff through a pre-EUA. So just submit your study plan. I would recommend that you try to eliminate any bias, as I just mentioned one obvious potential bias, which is going to be hard to do if you don't have an observer making sure that the person performing the test doesn't cheat --

[LAUGHTER]

And go with the app reading for their visual read.

Diego Blandon: OK. Thank you. And so the second question is we understand from previous IVD town halls that FDA is not requiring an app to be validated for a home use over the counter test prior to authorization. So this company is considering expediting the submission of the OTC EUA by submitting without an app validation completed. And so can you comment on the submission of an OTC EUA without an app and if it has any impact on the EUA's review priority. And this is kind of why the first question was asked, just because --

Tim Stenzel: Yeah. So the short answer is no. It will have no impact on the original submission and our ability to authorize that. We've done that already from such tests. But we do add in a postmarket commitment to develop such a reporting app.

A reading app would not be required at all. And developers can choose to use a reading app or not. It's not even recommended that necessarily the developer uses a reading app. But if you think the test will perform better with the reading app, or it'll be easier for patients to use, and easier to capture the data, and transmit data, et cetera, et cetera, yeah, you're free to do that.

But again, no. You do not need a reader or reporter app at the time of initial authorization. And then we don't even require a reporting app. We just want a postmarket commitment that at postmarket, you'll have a method of patients being able to report their results for their clinicians and as well as for public health surveillance needs.

Diego Blandon: Thank you.

Anike Freeman: Moving to our next question from Gordon Siek.

Gordon Siek: Hi. Thanks for this. We're in the middle of developing an over the counter at home COVID test for both antigen and antibodies. We would be interested in the FDA's position on that. And would there be an extra hoop we'd have to jump through?

Tim Stenzel: Is it a combo test?

Gordon Siek: Yes.

Tim Stenzel: Or were they two different tests?

Gordon Siek: It'd be in --

Tim Stenzel: I would recommend that -- mm?

Gordon Siek: Very quickly, it would be read in an automated fashion. It would be a cartridge put in the device, recorded in the automated fashion, and by Wi-Fi sent to our server and analyzed, and then reported back.

Tim Stenzel: So as previously stated in the call, particularly the diagnostic tests, so that would be the antigen component of those tests, are a clear priority for home and point-of-care. I would come in with a pre-EUA to discuss this with us.

Gordon Siek: Thank you.

Anike Freeman: All right our next question is from S Wells 7.

SWells7: Hi. Thank you. Can you hear me?

Tim Stenzel: Yeah.

SWells7: OK. So we're developing an assay that tests - it's a spike IgG point-of-care OTC, and we want it approved for the lab as well, detecting IgG antibodies to COVID. And there's this one kit that can detect-- has a procedure for fingerstick blood and then also a procedure for venous whole blood, serum, and plasma. For the procedure for serum, venous whole blood, and plasma, would it be acceptable to the FDA for in the clinical agreement trial to just look at whole blood, since that's the least specific?

Tim Stenzel: If you want claims for fingerstick or want to see fingerstick data--

SWells7: Right. We would do fingerstick as well.

Tim Stenzel: OK.

SWells7: That's where the one part of the procedure.

Tim Stenzel: So you're saying, can you just do whole blood and not serum and plasma?

SWells7: Right, for the other procedure that is it involves the laboratory part of the test.

Tim Stenzel: I'm pretty sure we want to see each sample type which can be obtained from every patient, obviously, with -

SWells7: Right.

Tim Stenzel: The fingerstick, it requires a stick. And then whole blood requires having a venipuncture that you can collect in serum/plasma tubes at the same time you collect the whole blood too.

SWells7: OK. So you'd like to see each sample type for each patient?

Tim Stenzel: That's best, because sometimes, at least reported to us, for some developers, there's different performance on the different. At least, it's claimed to us that there's different forms, and they only validate certain types. So we would like to see all sample types validated for which you make claims.

SWells7: OK. Great. Thank you.

Anike Freeman: The next question is from Jack Fang.

Jack Fang: Hi, Dr. Tim. So this is Jack. As you mentioned that the home test is currently the priority, and we also noticed that recently all home test kits are experienced supply shortage. So for example, the school in my community just ordered Abbott rapid test kits, but they need like three weeks to get them.

So my question is that whether this kind of situation make the home test kits more urgent for FDA to review. Because we actually submitted our EUA of OTC home test in early July. So to date, we have not received any data requests or questions about our data.

So I think our reviewer was assigned a few weeks ago. And I also asked a question last week in the town hall, and you forwarded that question to our reviewers. And to date, we only received the response like, currently under review. So no further request. So what do we expect to do in this kind of situation?

Tim Stenzel: Yeah. So we have quite a few that we are reviewing. And I'll say this a little bit more clearly that, if an application comes in, it's complete, all our answers can be answered within the application, it's well-organized. We have all the information that we require. Those applications get moved to the top of the list.

And if there are questions, we move those down the priority list. So we will get to your application. And I can't promise you that there's going to be questions, but that's our current process right now. So we will get to it absolutely as soon as possible. But again, when everything is complete, we have all the information we need, those authorizations happen very quickly.

Jack Fang: All right. So because we haven't received any data requests, that means you downgrade our priority, because we have some issues? As you mentioned, even though we have a priority.

Tim Stenzel: I don't know the specifics of your application. I don't know the priority of your application. Your primary reviewer is the best person to interact with.

Jack Fang: All right.

Tim Stenzel: And they will get to it as soon as their leader has assigned your application as the top priority on their plate.

Jack Fang: All right. Thank you.

Tim Stenzel: I want to go-- yeah. I want to go back to the last caller. I gave a bit of incorrect advice. We do want to see validation, but we will allow matrix equivalency to support serum, plasma, whole blood per the template. So please refer to the serology template for that. I was correct in that, yes, we want to see separate fingerstick. But for serum, plasma, whole blood, there can be an equivalency study to support that and not necessarily in a clinical setting. All righty.

Anike Freeman: All right. The next question will be coming from Eric Penny.

Tim Stenzel: Eric, you should be able to speak.

Anike Freeman: All right. Well, then we will move to the next caller. That would be back to Tianyang Liu for another question.

Tianyang Liu: Oh. Thank you, Anike. Hi, Dr. Tim. The second question is that you already -- how long will be the— I mean, how does the EUA interactive review work? Could you give me that information? You're already doing the 510(k) application. There will be one month, I mean, 30 days reply time frame. So in the EUA application, do we have this time frame?

Tim Stenzel: So we don't have a specified time frame for the EUA interchange. We prioritize applications within serology, within antigen, and within molecular diagnostics according to our priority. And that priority get worked on first. And really, in all the areas, the better the application, the less questions that we might have, the faster it goes through.

And we are continuing to see, on average, more than 100 EUA applications and pre-EUA amendments, supplement, of all types still. This month. So we're continuing to see a large volume. And so that's why we prioritize. within that.

So again, we'll get to individual applications as soon as we can. In all likelihood, if you don't hear back from us relatively soon, there's probably questions. And we want to get back to you. But because others may not have those questions, we move forward with those first. Because the priority is to get assays authorized as quickly as possible.

Tianyang Liu: OK. Thank you very much.

Tim Stenzel: I think we might go to the last caller now. We can --

Anike Freeman: All right. This question's from--

Tim Stenzel: Actually, we have --

Anike Freeman: Laura --

Tim Stenzel: We have another five minutes. So I think maybe we can get more than one caller in. OK?

Anike Freeman: All right. Next question is Laura DiAngelo.

Laura DiAngelo: Hi there. I would like to follow up on myself on the 820 question. I think the last time we talked about 820 at these town halls was in February, when the plan was the transition guidance will address kind of the things that were waved out under EUA and the transition into a fully compliant 820 system.

And then forward looking, and the answer might just literally be we can't comment on the timeline. But my question was, if we're transitioning from EUA with some parts waived out in 820, to full 820, is there going to be another plan for? Or is this just we'll take as it comes for the transition to ISO, which I know is kind of in the hopper?

Tim Stenzel: So I don't I don't see any immediate change to how we have EUA and how we have full authorization in the near future. We are accepting Q-Subs and Pre-Subs for full authorization. We are reviewing those. We are getting back to folks as soon as possible. And all our areas antigen, molecular, and serology have ideas. Of course, molecular, we've already done it. So we have very clear recommendations.

We are going to work on templates, updates on what those full authorization recommendations are. I am recommending that, those that want to stay on the market long term, that they do start working on their full authorizations and submit Pre-Subs for us to review if needed. I mean, you can look at things in the molecular. You can look at what we've already reauthorized. You may not have any questions, and you can just go forward.

And so I really can't comment on the guidance. That's really not within my control anymore. It's going through the process to be able to be made public.

That document will not specify for IVDs the recommendations for conversions in all likelihood. It'll just be outlying things like timelines and general high level expectations. But our plan is to update the templates with specific recommendations for those.

Laura DiAngelo: OK. Very cool. Thank you.

Anike Freeman: All right. I think we have time for one more?

Tim Stenzel: We have time for one more.

Anike Freeman: Yep. And that will be from Diane B.

Diane B: Hi. I just have a question regarding human factors or usability testing. When you're doing the OTC or the home use testing, are you preferring to see -- can that be conducted at the time of clinical performance, the human factors in the simulated environment? And then also do you need English or English and Spanish? What type of translations are you looking at?

This is particularly for a fingerstick procedure that would be OTC. So I'm looking for some insight on that human factor. And then potentially, what type of quantities that you need to see, if it can be a relatively

small since the population for a fingerstick might be easier to do if you have a parent doing a child or a parent doing themselves? So just some insight there.

Tim Stenzel: So is this a home collection of a fingerstick? Or is this a home--

Diane B: This would be more like a lateral flow antibody test, not a dried blood collection.

Tim Stenzel: Performed-- OK, what I wanted to know. Well, we haven't released a home serology test template. So we would recommend that you submit a pre-EUA and get our input on such a plan for such a test.

Diane B: OK. Do you-- when we do that, do you have any suggestions as far as the English versus Spanish language requirements for that at all? Or just want to do that in the Pre-Submission?

Tim Stenzel: Well, for OTC home tests, we do like to see English language and Spanish but English primarily, but also include Spanish. Kris, you can correct me over here. But those are the two main languages spoken and written and read.

Diane B: OK. I think that's helpful.

Anike Freeman: All right. Thank you, everyone. We greatly appreciate your participation. Today's presentation and transcript will be available at CDRH Learn in about a week. You can visit CDRH Learn at www.fda.gov/training/cdrhlearn.

Note that we've updated the title of the section to make it easier to navigate. You'll now find the recordings in the subsection titled Coronavirus COVID-19 Test Development and Validation Virtual Town Hall Series. For additional questions about today's presentation and topics, please send an email to cdrh-eua-templates@fda.hhs.gov.

As we continue to hold these town halls, we appreciate your feedback about the program. Please complete a brief survey which you may find at www.fda.gov/cdrhwebinar. Finally, as a reminder, we are switching to a biweekly format. So please join us for the next webinar on September 8. This concludes today's town hall.

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