

FDA Virtual Townhall

Moderator: Irene Aihie

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12:15 pm ET

Irene Aihie: Today Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostic 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 also 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.

Dr. Timothy Stenzel: So thank you Irene and welcome back. Yes we look forward to having today's call and doing our best to address developers questions. I did want to go over to topics first before turning it over to Toby. And we will go through selected questions that were received prior to the deadline for this call and for which we formulated answers.

First I want to go over our current priorities. They remained largely obvious and unchanged. Of course we've issued new amendments recently pooling and screening asymptomatics. And for those tests that qualify for those

amendments those are obviously priorities for us because they're both designed to increase access substantially for testing.

And of course our continued focus on particularly on diagnostic tests for point of care in home and home collection of diagnostic tests remains top priority and as well central lab tests that are extremely high throughput tests.

All of these again are designed to increase access to testing and hopefully decrease turnaround time and better and folks are better able to manage this virus and in particular as they go to work and go to school and as we prepare going back to school in the fall.

The second topic has to do with regular full submissions to (ARGOS). So we are now in the process of removing all the MDUFA files that for full authorization that were on hold. The vast majority have already been taken off hold. And going forward we're not going to place files on hold due to workload issues.

There is one area though where we still do not have the bandwidth to handle currently for regular submissions. And this has to do in the category of what's called Pre-Submissions or Q-subs.

And we are reviewing a select categories of Pre-Subs. These are not pre-EUAs. These are normal well submissions sort of pre-submissions. And they include COVID related pre-submissions. So for those developers who want to see feedback on their proposed plans for converting to full authorization we are accepting Pre-Subs and we are reviewing Pre-Subs.

We would ask as with all other full authorization sort of submissions typically we're doing our best to hit our MDUFA guidelines for times but we are

swamped and we're going to do our best to try to hit those usual timelines but in some cases if not many we're going to have to go a bit longer due to the workload and continuing workload for COVID.

So the other piece that we we'll be continuing to review are breakthrough requests, IDE requests and companion diagnostic requests. So the whole point of bringing up MDUFA is to, you know, generally let people know about what we're doing on that front but also to encourage those test developers who want to have a COVID related test on the market for long-term that we're open for business on Pre-Subs for COVID and our full submissions for COVID.

Of course for molecular, for the lion's share of molecular tests we've already authorized one De Novo and that means all subsequent molecular submissions for SARS CoV-2 whether they be single analyte for SARS CoV-2 or a multi-analyte panel, they all, you know, they meet the other criteria, fall under that, the new pathway, continue with the 510(k).

For serology and for antigen tests, the first submissions will be De Novo. Thereafter the lion's share of those will then also be 510(k)s. So we do actually urge folks developers who want to be in the market long term with the SARS CoV-2 test to begin turning their attention to this and preparing for full authorization and in particular making sure that they have the samples needed or banking of samples is allowed to do all the analytical work as well as the clinical validation that we expect for those full authorizations.

So now is the time I think to not delay to turning attention to that. We hope that the, you know, there's what of about 40,000 new infections a day in the US right now, it's still substantial. We do hope that that continues to fall and it falls greatly.

So we have seen following prior emergencies where developers when they turn attention to moving towards a full authorization, the positive samples fell off and they struggled at times at forgetting positive samples. So I just bring that up because I think, you know, the FDA is obviously interested in full authorizations and I think developers are too and I wanted to bring this up. And I will be probably reminding developers of this relatively frequently going forward.

Okay those were the two topics I wanted to cover. Now over to Toby. Thank you.

Toby Lowe: Thanks Tim and thanks as always to everyone for joining us again this week. We do have a few questions that came in that we're going to address before we open it up to the phone lines.

So the first question that we have is asking about saliva collection devices and whether a saliva collection device or a specimen is added to VTM prior to testing need to have an EUA?

There are - and the answer is yes. There currently are no FDA cleared or approved saliva collection devices intended for use with viral RNA. Since these are not 510(k) exempt devices FDA authorization either through full premarket review or through EUA is required for these saliva collection devices.

We have to date issued three EUA as I believe for saliva collection devices for use with SARS CoV-2 tests. And we recommend that you look at the authorization documents for those three EUAs as a reference point. Additionally, the home specimen collection molecular diagnostic template

includes some recommendations including four analytical and clinical studies that may be applicable even if the selection - or sorry a (unintelligible) saliva collection device is not intended to be used for home specimen collection specifically.

The next question that we have is regarding bringing a lateral flow rapid antigen test to the market for asymptomatic self-collection with serial testing using anterior nasal samples. The question is regarding the clinical protocol. And the just developers preference would be to do their clinical study in the home setting with mailed kits rather than in a simulated home environment.

And they're asking about using an FDA authorized comparator test but noting that the - there's a concern with the - well this question is asking about using an antigen test for the comparator which we'll get into. That is not recommended and there's a concern about collection from both anterior nares and concern that if the comparator sample is drawn first it would reduce the sensitivity of the subject device.

So the question is asking whether FDA would allow use of a saliva base comparator even though the test in question is using a nasal sample. So we'll address a couple of the different points of that question.

So first performing the study in a home setting instead of a simulated home environment is potentially acceptable. However we do recommend a high-sensitivity PCR using a nasal specimen as a comparator. Neither saliva specimens nor antigen tests are acceptable comparators. You should select a high-sensitivity PCR that is authorized for home collection and use the home collection kit with which that selected comparator test is authorized.

In order to address the concern of which sample is taken first, we recommend that the collection of swabs should be randomized so that the antigen and PCR tests are not consistently drawn in the same order and that both anterior nares should be sampled for each test. We would also recommend that you send in a pre-EUA with your study design and check the comparator selection with FDA prior to initiating your study.

Dr. Timothy Stenzel: Thanks Toby. I'll just add a little bit on the concern about losing sensitivity for the test device. We have seen developers do this and do it successfully. We would recommend that there is a gap between the first collection and the second collection of probably a minimum of ten to 15 minutes.

And when we worked with developers before and have done this, we haven't seen a drop off in sensitivity for either the comparator or the test device. Thanks Toby.

Toby Lowe: Thanks for that addition Tim. The next question we have is asking about the availability of the NCI laboratory to validate antigen test kits. So we want to clarify that NCI testing is not currently available for antigen tests and all validations studies should be performed by the test developer to validate the proposed intended use population.

The NCI test evaluation program is actually for serology tests. And if you have specific questions about that program, please send them to your lead reviewer if you have one or to that EUA mailbox if you don't yet have a lead reviewer and we're happy to answer those questions.

Dr. Timothy Stenzel: Yes and I'll just add that I mean it's a great idea to have banks for antigen tests. The challenge is that direct swabs are usually the sample type here for

antigen tests. And, you know, banking those in significant volume where there's consistent - consistency between swabs in a bank is quite challenging.

You know, for those tests that use VTM it's a little bit easier to use bank samples. But since most antigen tests don't use VTM in their usual workflow that presents the challenge for having panels for antigens. So we are working with RADx and other programs to see what we can do. The primary focus right now with these sort of banks is assessing finding better ways to assess the potential impacts of mutations and variance on antigen test performance. Thanks, back to you Toby.

Toby Lowe: Thanks Tim. Our next question is about analytical performance testing for an antigen test first asking whether recombinant or purified antigens spiked in negative clinical media can be used, so antigen in negative nasal media for example.

And the answer there is no, that we don't consider the use of recombinant or purified antigen to be acceptable for any validation activities. It - since it doesn't test the extraction step of your test. And we found that performance with recombinant or purified antigen does not correlate well with real-world performance. The second...

((Crosstalk))

Dr. Timothy Stenzel: I will add...

Toby Lowe: Oh go ahead.

Dr. Timothy Stenzel: Oh, go ahead Toby. No, no Toby, go ahead I'll - I interrupted. I'll say that again.

Toby Lowe: Sure. The second part of that question is asking whether laboratory-based analytical performance testing such as stability, limited detection can be performed outside of the US? And that answer is yes. Lab-based analytical testing can be performed outside the US but we do expect to see the full detailed protocols for each validation study as part of the EUA submission.

Dr. Timothy Stenzel: Yes.

Toby Lowe: Go ahead Tim.

Dr. Timothy Stenzel: I'll just add something on question one. So absolutely correct what Toby said about authorization decisions. However it may be easier for some developers who want to monitor performance with respect to certain mutations and variants to use engineered antigens, you know, recombinant antigens in particular because they can engineer in the mutation.

I'm not sure if that's going to be sufficient only in assessing change and potential performance with mutations, but certainly it's a good thought and we're open to that just, you know, for verifying performance on mutations. So that's one area where recombinant antigen production may be entirely useful in addressing concerns.

And we look forward to having conversations with developers on this to make sure that's addressed in any potential concerns the FDA may have. Thanks Toby. Back over to you.

Toby Lowe: Thanks Tim. That's really helpful. The last question that we have prepared here is about antibody tests and about monitoring the performance of a lateral flow antibody test in relation to variants. And they're asking how many

variant - how many of each variant sample are required to be evaluated and whether there's a specific method required for confirmation of positive?

So for the first - at this time we don't have specific recommendations for the number of SARS CoV-2 variant related serology samples that should be evaluated by wet testing to monitor the performance of SARS CoV-2 serology test.

In your EUA request we would like to see your plan for monitoring for a new and emerging SARS CoV-2 viral mutations and variants. And we would expect your plan to include assessing the potential impact of mutations and variance that have been identified as prevalent or clinically significant on the performance of your test.

Testing is not expected for every variant that you monitor, but for mutations, the variance that has been identified as prevalent or clinically significant, you should provide information on the potential impact on your test performance considering your specific captured antigen and test technology or explain how the risk associated with the unknown performance of your device in samples from individuals with the variant can be adequately mitigated.

And then when variant data is provided we would expect you to describe how the serology samples were selected and characterized and described the sequencing map is used to cross specific variants. That should be included and it should include describing the sequencing method validation such as inclusivity and limited detection and describing the sequence analysis step used to call mutations.

Dr. Timothy Stenzel: All right, thanks Toby.

Toby Lowe: And that is it for me.

Dr. Timothy Stenzel: Yes. I think we can open it up for live questions. Thanks Toby.

Toby Lowe: Yes, sure.

Coordinator: Thank you. At this time if you would like to ask a question please press Star 1 on your touch-tone phone. Please ensure that your line is unmuted and please record your name when prompted so that I may introduce you. Our first question is from (Franco Calderone). Your line is open sir.

(Franco Calderone): Thank you for taking my call again. My first question is regarding a paper that I read from last week regarding mutations 1051 and D399N. This was a study done by the University of Washington and regarding how these mutations affect the end protein. And they took two tests, Sofia 2 Quidel and I believe the Abbott BinaxNOW and they measured their performance regarding these mutations. And they found some interesting results I believe, affecting the Sofia 2. The question is is FDA going to be updating the template, the antigen test template because of the development even though the prevalence of these mutations at this time appears to be very low?

The second one is regarding our ability to use labs outside the US to do the analytical work which I really appreciate. The question from my lab is whether FDA expects that the lab be GLP or ISO 17025 would be okay?

And let's see, and regarding the number of matrices that we need to test for a nasal swab antigen test for at home use how many are we expected to do? How many matrices because it's not clear to us on Part J Part 1 of the template?

Dr. Timothy Stenzel: Yes those are a lot of questions. I'm not sure that I - we'll I know I didn't capture all of them. I captured the D399N mutation in the first question. What was the other mutation?

(Franco Calderone): The other mutation is the - well the first one is the T2051. The second one is the one that you mentioned.

Dr. Timothy Stenzel: I'm not familiar with the T2051 so off the top of my head but I'll look into it. But the 399N it is in very low prevalence in the United States right now, well below 1%. And so and we know that - we know about the report that Sofia SARS and any of the Sofia SARS tests may not detect this mutation.

But because it's in so low abundance it does not reach - if in fact it is confirmed that Sofia test doesn't detect the 399N, you know, we won't be updating the Web site because we're reserving updating the Web site where we think that the prevalence of certain mutations that could impact performance is high enough that it warrants a Web site update.

So we're really looking at either individual mutations or a combination of mutation for antigen tests that would drop performance by 5% or more same goes for molecular tests.

And so we do have guidance on the what developers should do regarding variants and we are very active in monitoring the variants obviously in talking to developers. And when it becomes important to make that information publicly available, in our Web site we'll post the information there. Toby do you have anything else to add on variants and mutations?

Toby Lowe: No I think you've covered it all.

Dr. Timothy Stenzel: The second question I think it had to do with analytical studies and the type of lab that you do the analytical studies in. We do waive for EUAs and much of QS are regulations, and that's spelled out in the letter of authorization.

So while we always love it when developers even for EUAs do it fully within QSR compliant facilities and methods and everything, we are more flexible. So I don't believe and Toby correct me, I don't believe we have a specific laboratory requirement. We do recommend that, you know, you properly design your analytical studies and you form your study plans and document it before starting the studies and, you know, because we will want to see those study designs for that, the studies and for their appropriateness and then so that we can measure the effectiveness. Toby do you have anything to add, correct on my (unintelligible)?

Toby Lowe: No, no that's correct. That we focus on the protocol and the data so we do want to see those in detail.

Dr. Timothy Stenzel: And the third question I think had to do a different sample matrices that we recommend for a test and test developers. We really only need one that works, right? So if analytical, if anterior nares sampling, bilateral nares samples gives you an adequate performance to meet our recommended levels, you know, that's sufficient. And then it's really up to the developer or they want to do more.

And it could be an MP swab, could be a mid-turbinate swab, you know, for antigen test. But it's really what the developer wants part of the acceptable sample type and properly validated enabled (unintelligible).

((Crosstalk))

Dr. Timothy Stenzel: I hope I captured the third question because I wasn't sure that I was in time.

Woman: (Unintelligible).

(Franco Calderone): You did, thank you.

Dr. Timothy Stenzel: All right, we'll move on to the next caller please. Thank you.

Coordinator: It's from - our next question is from (Ella). (Ella) your line is open.

(Ella): Great thank you. My question is about antigen saliva test and the and cross read (unintelligible) at interferon study. So for a saliva test I'm wondering what would be okay to use as the clinic - clinical matrix? Can this be artificial saliva or does it have to be fresh saliva or could it also be from a commercial source? I understand that saliva the, bought commercially, because it's been stored for a while, it can degrade.

Dr. Timothy Stenzel: You know, I recommend submitting a pre-EUA for your saliva antigen test and your plans. Typically we won't allow, you know, completely artificial samples for anything right now including saliva. And the use of banked samples especially for analytical study is fine.

The use of contrived samples is generally okay for analytical studies meaning you take a negative patient saliva or pooled saliva and you spike in virus, whole virus inactivated will work. Or you can dilute a positive patient saliva sample into a negative pool in order to get the dilutions that you, you know, would want for your analytical studies.

But again we don't have recommendations out there on validation of saliva antigen tests. We do think that's a particularly challenging sample type for antigen tests. There's growing body of information that it is submitting less sometimes for saliva amount of virus.

By, you know, we're open to it. We're not saying don't do it. It's just I don't believe we've authorized one yet. And we haven't yet obviously then received an application for a saliva based antigen test that we could authorize.

(Ella): Okay thank you. Sorry, can I ask a follow-on question then?

Dr. Timothy Stenzel: Sure.

(Ella): For the clinical evaluation is it okay to use bank samples if you're having difficulty selecting enough positive samples? I understand from our regular test that's exactly what is - what I've tried to collect for two weeks. Is that the case for antigen tests as well?

Dr. Timothy Stenzel: Antigen tests are more challenging because we've observed that the freeze-thaw process seems to increase access shall we say to the antigen. And it's an artificial increase in assay sensitivity that is hard to control and understand. And we really want to understand real-world performance.

So, you know, anything that doesn't follow sort of, you know, an, you know, our sort of standard recommendations for antigen tests, again I do recommend that you submit a pre-EUA and ask for any, you know, flexibility that you need to develop your test. But molecular is a little bit different because they typically have an extraction step and, you know, for those essays that - although we do examine about whether freeze-thaw does impact molecular as

well so we do ask for freestyle studies. But with antigen it's been pretty consistent that the sensitivity increases with the freeze-thaw cycle.

(Ella): Thank you.

Coordinator: Thank you. Our next question is from (Don Catheter). Your line is open sir.

(Don Catheter): Yes hello. Thank you for taking the call. You mentioned in several of the meetings of the desire to move towards full approval for COVID tests. And the only one that you've approved is the De Novo from BioFire.

And it would be most helpful I would think for developers to see the decision summary for that assay which is still not available according to the database. So I'm wondering if you could shed any light on when and if that decision summary will be made available?

Dr. Timothy Stenzel: Yes I mean Toby will know the exact protocol for these to get posted, but it goes through a process of looking for any proprietary information that about the assay that we authorized that shouldn't be disclosed publicly. So it leaves our office and it's go through this process and we're not entirely in control of it and we can't, just like guidance, we can't predict when it's going to come out.

However for those developers for molecular serology and antigen tests that want to pursue full authorization, as I said we're accepting Pre-Subs for COVID related applications. And as soon as we can post that that decision, we will. Toby do you - along with the special controls. Toby do you have anything to add?

Toby Lowe: Yes we have been working to expedite posting of that. It has hit some - you know, it does need to go through a (unintelligible) process and it is

unfortunately not the fastest process in the world but we are working to expedite it because we do need to know how valuable that would be for developers to have access to.

(Don Catheter): Yes I would reiterate that it would be valuable. And hopefully before two months is up we should be may be seeing it I would hope. Thank you for (unintelligible).

((Crosstalk))

Dr. Timothy Stenzel: Yes again, it's not in our full control. Otherwise it would be out.

(Don Catheter): All right, thanks.

Dr. Timothy Stenzel: Yes.

Coordinator: Thank you. Our next question is from (Richard Ferrin). Your line is open sir.

(Richard Ferrin): Hello. I have a question about bio repository and banked samples versus live samples. For molecular and antibody tests, can you restate the CDRH position as what's acceptable for a biorepository test versus a live specimen?

Dr. Timothy Stenzel: Are you talking about serology and molecular?

(Richard Ferrin): Precisely.

Dr. Timothy Stenzel: I think we for central lab tests and moderate and high complexity labs test authorization, frozen samples are largely acceptable for that. We'll want to see freeze-thaw studies to make sure that they behave the same, you know, seeing in paired samples.

When you move into point-of-care or home situations that's where it gets a little bit more tricky. I don't know if our current templates spell out the use of banked samples, but we always do recommend that if you're going to use bank samples for your analytical and/or clinical studies that you do check through the pre-EUA process and if you're going for full authorization through the precept process to make sure that your design of studies using bank samples, you know, mitigates completely or to the extent it can be any sort of bias. Toby anything else to add?

Toby Lowe: No nothing for me.

(Richard Ferrin): Okay as a follow-up to that what are the - what would you say would be the sensitivity limit requirements for a centralized laboratory, you know, test versus a home use or point-of-care test?

Dr. Timothy Stenzel: I'm not sure I understand the question. Can you restate the question please?

(Richard Ferrin): With regard to a home use test would the sensitivity minimum limits be different in for the home use or point-of-care test versus a centralized laboratory test?

Dr. Timothy Stenzel: Yes clinical sensitivity or positive percent agreement to a comparator or to the, you know, the test of record, you know, for molecular and serology they would be different answers for that.

I think we have - well I know that the home template for antigen molecular spells this out. And then I think we have a home collection template for serology. So you should be able to get a good idea.

Basically for serology testing we're really sort of have set levels of sensitivity or PPA recommendations as well as specificity or MPA. For - and for home - and for point of care molecular it's 80% is the floor that we recommend. We really like to see good concordance to central and molecular tests for all molecular tests whether they be in-home or point-of-care.

But we will authorize molecular tests between 80% and 95% PPA compared to a high sensitivity central molecular tests. And the same thing for home molecular tests.

And then there are various thresholds for different applications such as if you want OTC and there's different pathways for the OTC. And those are all laid out fairly clearly in our templates so I'm not going to go over those again right now.

(Richard Ferrin): Thank you.

Coordinator: Thank you. Our next question is from (Josh Profeto). Your line is open.

(Josh Profeto): Hi. Thanks for taking my call. My question is about your priorities. At the top of the call Tim mentioned that you were prioritizing asymptomatic amendments for the reopening of like schools in the fall. And I'm wondering whether that would extend to new submissions for asymptomatic testing?

We have - and we've had one of these assays, molecular, saliva based, high complexity that the review has been held up for like six months or so. It was always our intent to submitting a asymptomatic amendment once we got that authorization. But I'm wondering if we were to resubmit the new EUA now

with the asymptomatic validation whether that - or if that would be a higher priority? Thanks.

Dr. Timothy Stenzel: Yes with the central lab test we are also asking for, you know, it be a high throughput test. So a low-throughput test isn't really going to advance our capability as a country to address the huge numbers of tests that are needed for asymptotically screening our population.

And we're really driving development priorities towards those extremely high throughput tests. And those are the ones that we're prioritizing so simply a new submission, you know, adding asymptomatic screening that doesn't also meet our access.

Our access is point-of-care in-home. But if it's a central - if it's moderate to high complexity test and it doesn't have - and it doesn't meet the throughput template it's not going to be prioritized right now and it probably won't be going forward.

The regular full authorization pathway it is open to test developers who don't meet our pandemic priorities, you know, which are probably going to be, you know, pretty similar going forward. And so that pathway is open to them. We are accepting MDUFA applications as I said at the beginning of the call and we're not putting them on hold. They may take a little bit longer than we'd like and the same thing goes for pre-submissions.

(Josh Profeto): Okay thank you.

Coordinator: Thank you. Our next question is from (Maria Ramos). Your line is open.

(Maria Ramos): Hi. Thank you for taking my call. My question is in regards to the Quidel Sofia 2 instrument. You spoke about that less than 1% variant mutation that's not being detected. Is that why Medicare is declining payment for this instrument or re-categorizing it as moderately complex or high complexity?

Dr. Timothy Stenzel: I thought ...

((Crosstalk))

Dr. Timothy Stenzel: ...it was authorized for CLIA waived settings.

Toby Lowe: Yes.

((Crosstalk))

Toby Lowe: Tim, I can address this one.

Dr. Timothy Stenzel: Okay good, you know more than I do Toby. Go ahead please.

Toby Lowe: Yes. This has come up - I'm not going to be able to give you full information because it really is out of CMS and so we'll recommend that you reach out to CMS. If you email the CLIA program they'll be able to address your question.

There is what I understand from talking to our CMS colleagues is that there's a misunderstanding and there's not - they're - they haven't recategorized anything. The Quidel Sofia is authorized under their EUA for point of care which is CLIA certificate of waiver setting. And if you reach out to CMS they'll be able to clarify the payment side of things for you.

(Maria Ramos): Okay. Okay well thank you very much. They published a recent coding...

Toby Lowe: Yes.

(Maria Ramos): ...guidance on their - yes you know.

Toby Lowe: Yes there's something...

((Crosstalk))

Toby Lowe: ...about the HCSPCS codes that I don't fully understand and there's some add on to it that there' confusion over. But they're aware of the issue and are able to answer your questions much more eloquently than I would be able to attempt to do.

(Maria Ramos): Okay.

Dr. Timothy Stenzel: And if you haven't already, you know, it's good to chat with the specific developer of a test that you're having any sort of reimbursement issues with as they potentially can help as well.

(Maria Ramos): I have. I definitely have. I've looked everywhere and I found no foundation for this. So my next question is what was a bit confusing is what role does the FDA play versus CLIA in recategorizing testing devices? Can CLIA just come in and recategorize?

Toby Lowe: So again they have not recategorized. Their - what they point out is specific to payment and is a coding issue. The FDA is responsible for, you know, outside of an emergency, we do a CLIA categorization. Under the EUA we don't do a formal categorization but we authorize for specific settings which is sort of

parallel to that CLIA categorization that we would do on a full marketing submission.

But their - that does fall under FDA, the determining what settings a test can be used in under that authorization. The CLIA and CMS side is, you know, authorized on the CLIA side authorizing or certifying the labs for a specific level of testing and on the reimbursement and payment side of things determining what gets paid for.

And I think that this really is a misunderstanding based on possibly the way that they worded their document, I'm not sure, and they'll be able to resolve that.

(Maria Ramos): Okay. (Unintelligible).

((Crosstalk))

Dr. Timothy Stenzel: And just for clarity under law, under federal law it's our office that is the office that under normal circumstances categorizes tests as high, moderate or waived. Under EUA, we are not making formal categorizations, but it is still falls to our office to do this. And so we're calling it deeming a test for categorization.

This most - mostly applies to those tests that we're deeming as waived and we're not currently till those tests come for full authorization we are not doing a formal categorization. And as Toby mentioned this test was, it sounds like appropriately deemed waived by the FDA, by our office and so this is some sort of paperwork problem and hopefully it quickly resolves.

(Maria Ramos): Perfect. Thank you so much for your time.

Coordinator: Thank you. Our next question is from (Lisa Homertz). Your line is open.

(Lisa Homertz): Hi. Thank you so much. I have a point of care question. Are clinical - do clinical research organizations sites qualify as a point of care setting? And the reason why I ask is that, you know, clinical research organizations sites often screen subjects before seeing them versus a typical clinic have all-comers where they would test, you know, as appropriate and for a clinical study let's say while providing patient care. Does that make sense?

Dr. Timothy Stenzel: I think so. I mean it depends. We're really looking in the point-of-care studies the typical setting is a typical busy, you know, primary care sort of facility. And we're looking for the ability of folks and, you know, healthcare workers who are not trained in laboratory and in the midst of their busy daily schedules to be able to use the test and get accurate results because in the real world that's what's happening.

And if you've ever been to a busy point of care clinic these folks, they're juggling a lot of balls. And want to make sure that the device is robust enough, the instructions are robust enough that they still get accurate results. So that is the ideal.

If you're contemplating settings other than what I just described I would recommend submitting a pre-EUA and describing it and getting and having a discussion with our staff on whether that's appropriate or not. We don't want you to go ahead and do a study and then it be lacking in some ways.

(Lisa Homertz): All right. Thank you so much.

Coordinator: Our next question is from (Jackie Chan). Your line is open.

(Jackie Chan): Just following-up on the previous question on priority. In particular if a developer has got multiple tests like the unmet needs such as the - a neutralizing antibody test or other type of technology they - it's not on the high throughput platform that so it is not - so it cannot test at least 150 tests at once but it can still test multiple tests at once. Is this of a lower priority than other POC tests or the bigger platform test?

Dr. Timothy Stenzel: Yes so again we're looking at access. And so it does - it's home, it's point-of-care or it's high throughput. It really needs to pass those bars right now first, those thresholds. Having a great neutralizing antibody assay that can't really help that many people is not going to address the country's needs right now.

So we are, you know, this is - you know, these priorities are out there for clear reasons. One is to inform developers of what we're not prioritizing. And it also is to hopefully stimulate developers to develop the tests that are really needed at this stage of the pandemic. Okay?

(Jackie Chan): Okay. Can you define high throughput? Is it at least 150 at one?

Dr. Timothy Stenzel: So, yes as we said before if you want to check and see if your test will meet current priorities, you know, do send in a pre-EUA with relevant information for us to assess that. You don't have to fill out a full pre-EUA if you're going to use the templates as in the template recommendations as intended. You can simply say our one question is do we need the high throughput at all?

That is something that we're not publishing right now because as we go through the pandemic that may - they may elevate and if the needs change. So

it's best just to check with our staff through the pre-EUA process to see if your test would currently match our priorities.

(Jackie Chan): Thank you.

Coordinator: Thank you. Our next question is from (Dana Hummel). Your line is open.

(Dana Hummel): For taking my call. My question is regarding an antigen rapid test for home use. So for the usability study, the FDA recommends 50 patient self-test and 50 patients collect the specimen on another person. If we have someone enrolled who collects a sample from another person such as a child, can that same patient then run the test on themselves as well and be counted in the 50 as the self-test group or do we need 100 unique patients to perform the test?

Dr. Timothy Stenzel: I believe you can use that same adult to self-collect and to collect the child. And yes, so I think that's acceptable to make that a more efficient study. We're...

(Dana Hummel): Okay.

Dr. Timothy Stenzel: ...looking at usability of self-collection as well as usability of an adult in a home situation collecting a child and making sure that the adults can, you know, adults can do both things well and safely.

(Dana Hummel): Okay. And then a quick follow-up for the same test for an anterior nasal swab antigen test for home use for the clinical evaluation study you mentioned at the beginning of the call that the comparator should not be a saliva PCR test, correct?

Dr. Timothy Stenzel: Correct.

(Dana Hummel): Okay. So should it be only an anterior nasal swab PCR test or could it also be a nasopharyngeal swab PCR test?

Dr. Timothy Stenzel: It can be a nasopharyngeal swab. It can be a mid-turbinate swab. It can be an anterior nasal swab. We recommend both nares on the anterior nasal swabs.

What's most important is that it's a high-sensitivity molecular test that has the - an extraction step. And we do recommend that developers check in with the FDA to make sure that the comparator is going to be an acceptable comparator...

(Dana Hummel): Okay.

Dr. Timothy Stenzel: ...ahead of time so that there's just no having to redo anything, okay?

(Dana Hummel): Okay.

Dr. Timothy Stenzel: Just check with us. We want to make sure that you're using an appropriate test that will allow us to make an assessment on whether the test can be authorized or not.

(Dana Hummel): Okay. So even if the saliva test is a high-sensitivity PCR test just because it's not the same sample type that's why we shouldn't use that one?

Dr. Timothy Stenzel: Saliva continues to be a problematic sample. And we're seeing issues with it is a sample type. And so we're not recommending it is a sample type for a comparator test.

(Dana Hummel): Okay perfect. Thank you so much.

Toby Lowe: And just to add a little bit more on your question about the usability study since the intent of the usability study is to assess how well the user can follow the instructions while the, you know, having the same person perform both on themselves and on another individual would be assessing different aspects of those instructions, it would, you know, potentially impact the ability to evaluate, you know, how well a larger group can use the instructions.

So, you know, you're sort of reducing the size of your usability study effectively. So you may want to take that into consideration in case that may impact your analysis for the results and you may want to send a note to the inbox to discuss some of the further nuances there.

(Dana Hummel): Okay. That makes sense. Thank you.

Coordinator: Our last question at this time is from (Michael Zane). Your line is open sir.

(Michael Zane): Hello. Thank you very much for taking my call. I have a question on FDA policy for receiving EUA submissions. I've heard that the FDA has plans to no longer receive submissions for antibody tests in the future. And I just want to confirm if that's accurate as far as or whether there are any plans to phase out EUA submissions for certain types of tests in the near future?

Dr. Timothy Stenzel: That's incorrect on serology tests but we are on - if a test is not high throughput we are declining to review as part of a prioritization process. So if someone say has a lateral flow assay and they're only validating it for a high complexity lab that's not currently meeting our priority.

Serology tests that are point of care home collection we're still reviewing if they are complete applications. And if they are high throughput tests, central

lab tests as we've authorized a number of them, we are continuing to review those. So I'm not sure where you get your information but it's not correct.

(Michael Zane): All right. Thank you very much.

Coordinator: At this time I have no further questions.

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 Friday, May 21. If you have additional questions about today's presentation please email cdrh-ea-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