

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

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time, all participants are on listen-only mode until our question-and-answer session. At that time, if you would like to ask a question, please press star then 1. Today's conference is being recorded. If you have any objections, you may disconnect at this time. And now I would like to turn the meeting over to Ms. Irene Aihie. You may begin.

Irene Aihie: Thank you. Hello. I am Irene Aihie or CDRH's Office of (Communications) and Education. Welcome to the FDA's 35th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today 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 today's discussion. Please remember that 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 for joining us, everyone. I hope everyone had a nice Thanksgiving although this year is much different than normal Thanksgiving celebrations I'm sure. So just a couple updates today. This morning we updated two of our FAQs, one regarding antibody tests and what their purpose is, and one regarding testing supplies for extraction platforms for use with the CDC assay.

An email blast went out this morning as well. So most of you probably received that already. This morning we also updated the data on our reference panel Web page. An email blast went out with that one as well. But check that out. Some additional tests were added to that page.

And last week, we updated - or we posted two serology templates, EUA templates on our EUA page. One is the serology template for test developers and that replaced both the serology template for commercial manufacturers and the serology template for laboratories, so it's a single template for test developers now.

And we also added a home specimen collection serology template for finger stick dried blood spot. So those are both available on the IVD EUA page. And with that, I will turn it over to Tim for his update.

Dr. Timothy Stenzel: Oh, thank you, Toby. I hope everybody had a great Thanksgiving last week. And we stayed very busy, all of us. We see continuing increasing

demand for testing, to reduce turnaround times for results, which we have seen have crept up recently, due to the overwhelming demand for testing. And I did want to reiterate our current thinking on the top, top, top priorities.

And still probably mainly overall, for the office, although it doesn't functionally matter because we have separate teams for antigen, molecular and serology. So it doesn't mean that there's necessarily strong competition across those buckets for submissions.

We do try to balance the review staff to the workload. Those silos or buckets, operate independently of one another, all the way through authorization and other decisions. What we're hearing and what we believe is absolutely needed, is more availability for point of care tests, more availability for prescription home collection and prescription home tests, as well as OTC collection and OTC testing. And so those basically are our top priority.

Panels that include flu and other respiratory viruses also are a priority. As are truly steps forward in throughput capability for central lab tests. And so probably none of those are surprises to anyone. And we remain eager to authorize good tests in those categories as soon as possible.

Just some pointers - Toby mentioned that we made available a template now that was cleared. And we have been providing advice on a case by case basis, for serology home collection by blood spot. And so we're happy to make that that is cleared and that is on our Web site and available for developers who are interested in that.

You know, there are perhaps volume requirements for home serology collection and home serology testing. So we advise developers to pay attention to what those volume requirement are. Obviously, we've got to have

enough of a sample in order to get an accurate result. And how that - and how to make that as easy as possible, for end users for the patients and those who would buy an OTC test for those studies.

Just a heads up to pay attention to those needs for your assay and then how you make the validation, you know, in the home use either by prescription or OTC environment in the most expeditious study manner.

Okay. I wanted to spend a brief time on talking about particularly for I think molecular assays, we've authorized some semi-quant and quant assays. We spent - we've already authorized some serology quant assays. You know, we really have either few or none depending on the category in non-serology quant and semi-quant submissions. We do think that this is going to pick up because there seems to be an interest in having it, you know, semi-quant and quant molecular assays and perhaps antigen assays.

So that, you know, clinicians have an additional tool to make some assessments. Now what exactly the quantitative results or semi-quant results will translate into as far as clinical benefit is unknown. But we're very interested in as an office, to make good tools, as accurate and precise tools available, for those who would like it.

So obviously in molecular assays, people have been looking at cycle thresholds. Of course cycle thresholds have a relationship to the amount of intact virus in the sample. Due to sampling variabilities, other issues having to do with viral stability, exactly how that precisely and accurately correlates to what's going on in the patients, maybe a different question.

On a case - individual patient by individual patient basis, there are potential challenges in interpreting CT results. There are also technical hurdles with

CTs. So CTs across molecular assays that aren't made semi-quant or quant, so that you're actually not really focusing on CTs but you're focusing on actual viral target levels.

But if you just try to compare CTs assay to assay and you haven't controlled for variables, that's an imprecise, inaccurate, challenging correlation. And even for a given assay there could be - there absolutely is the chance and many times there is the variability around lot to lot variability.

So every time you take a new lot of master mix you can upset the delicate balance a little bit and alter the readout ever so slightly. So when selecting CTs for cutoff I mean hopefully that's, you know, there's a fairly flexible within the variability range, to set that.

And you're not, you know, you're not getting false positives and you're not getting unintended false negatives. And - but this is a highly technical area to move towards true quantitation probably through the process of developing a semi-quant assay. First, since we don't have yet a recognized international standard which is really ideal and/or necessary for a true quantitative assay, so that all assays can be harmonized around that international standard and compare results assay to assay, lot to lot, et cetera.

So for the serology assays, we've been authorizing semi-quant because there isn't yet an international recognized standard for serology. We anticipate that for those that are interested that - in the molecular and antigen space for developers to come in for EUA authorization of semi-quant perhaps leading to the quant assay.

Then we'll go through those who want it now before the international standard is available and we'll go through a semi-quant authorization pathway. And of

course you need calibrators for that, probably at least a two point. And so there's an important development of those calibrators and it's important development of how you're going to assay the semi-quant and what sort of meaning it is.

We're also potentially challenged on the science around, you know, intended use for semi-quant and quant assays, to actually show say correlations on important clinical factor. You put in there what you want. Could involve to generate the data that supports that, could involve a significant clinical study.

You know, in order to authorize a semi-quant or quant assay, you know, I think we're going to be as flexible and adaptable as possible. And we're not going to be overburdensome on what those claims are at least as far as they don't claim things that aren't supported by actual data.

So that's where I think a lot of discussion will surround this topic, is okay, can we first of all, prove that our assay is semi-quant or quant; is it linear over a certain, or claimed, dynamic range, upper limit of quant, lower limit of quant, you know, that thing, really a blank limit detection, stability and reliability of your calibrators from run to run, etc., batch to batch, lot to lot.

We'll try to put, you know, we'll try to be as flexible and least burdensome as possible upfront, for authorization. There may be some post-market commitments just to make sure everything is sound and accurate. But, you know, we're getting a lot of questions about hey, can I compare this CT to that CT or this assay and that assay, and those in the know, know that that's very problematic.

And so probably the best next step forward is to encourage developers who are interested to come in with semi-quant and quant assays with their actual

standard. Okay. Next topic. And these are having to do with submissions of pre-EUAs and EUAs. And we're obviously still getting a lot of them.

We have surged our reviewers; we have a surge of effort bringing reviewers from other areas into this effort, to try to, you know, make decisions much more quickly and reduce the list of open submissions. I'm happy to report that as of the end of last week, we have turned that corner and we are reducing the overall amount of open submissions, both originals and supplements.

So the surge is working. We hope that it will accelerate. We do ask for your help. You know, due to the overwhelming interest by developers still, in pre-EUAs and EUAs we want to try to limit our feedback on pre-EUAs and EUAs, to one round. I know this is challenging. We want to be fair to all developers; we want to move through applications as quickly and expeditiously as possible, to come to a decision point.

And so we would ask that you work closely with us and when we have questions you completely address those after say a first round of questions, if there are some. And then we want to really close those applications out. In pre-EUAs we're going to use templates to the greatest extent possible, or prepared language to the greatest extent possible.

I want to make it clear that our templates and our thoughts in these communications even on EUAs, are recommendations. If something goes a little off recommendation it is going to slow us down. So while they're not firm and fast requirements necessarily, our recommendations are well thought out, they're streamlined. We're dealing with this volume of applications and we want to be fair to all.

So, you know, those that follow our recommendations, they could have a more expeditious pathway through to the decision point. And we're also starting to get questions about conversions from EUAs to full submissions. Those are coming in as QSUBs.

As is generally probably known for our office, we are trying to close QSUBs in most areas except for select areas, as quickly as possible. We'll do a similar thing for QSUBs for conversion of EUAs related to SARS-2 to full submissions. We have our thoughts now that we can share with developers who ask.

We'll also have a subset of questions that we know that some developers may have that we want to answer in those QSUBs. And but there will be some that we're going to ask that you rely on especially the most recent related authorizations as evidenced in the decision summary. And the specific SARS feedback that we are now giving to developers who asked.

We - dwelling on any one particular application and spending an overabundance of time only slows down our process and doesn't allow us to get to all developers as quickly as possible. So, you know, your understanding of this and your help with this would be greatly appreciate not only by me and our staff, but I think the other sponsors as well, because they want to get to this decision point as quickly as possible.

All right. So Operator and Irene, that pretty much closes out a longwinded and hopefully helpful update from me and from Toby. Thank you Toby. We can go onto Q&A.

Coordinator: Thank you. We'll now begin our question and answer session. If you would like to ask a question over the phone, you may do so by pressing star then 1.

If you need to withdraw your question, you may do so by pressing star then 2. Our first question comes from Shannon Clark. Your line is now open.

Shannon Clark: Good morning. This is Shannon Clark with UserWise Consulting. Thanks so much for the helpful update. So my question is about how to assess severity of various outcomes pertaining to antibody testing. So when running human factors testing we prioritize test cases and define qualitative usability acceptance criteria, based on severity of various outcomes to the patient and/or users.

And FDA has been really clear that antibodies - with respect to - it's unknown if the presence of antibodies confers protective immunity. And that's one of the most important things to know about antibody testing. So according to our preliminary analysis, the only high severity outcome that could result from incorrectly using a COVID-19 antibody test kit, is associated with understanding that the presence of the antibodies may not confer protective immunity.

So I just was curious what's FDA's assessment of severities associated with other, you know, false positive, false negative outcomes. Is this the worst case scenario associated with antibody test kits? Are there any other extremely concerning outcomes that I'm not thinking of?

Dr. Timothy Stenzel: False positives, false negatives and overinterpretation of the final - of the findings for serology, obviously no test is 100% specific or sensitive. Serology may be a little bit lower on the scale of the test that we authorize, being that we allow, you know, 90% for the IDG sensitivity PPA, and down to 70% for IGM sensitivity PPA.

And then obviously, sometimes for some devices, the specificity may be a bit lower than what we may have seen for other devices. Typically, molecular devices, you know, are highly specific. Typically, above 99% some can fall. Depending on the size of the trial and how the chance falls out who you test and how you test might be as little as 98%. Typically molecular assays are in those high 90s.

For antigen tests, what we have seen pretty consistently, is somewhere around a 98% specificity in the marketplace in real world situations. And then for serology, we do know that it can fall down to, you know, 95% for those that we may have authorized. Obviously we're still examining data, accumulating data, trying to understand performance.

So when you don't have - I think what you're asking is when you don't have a clinician involved say in the home, even though we do in our first home test and in our home collections, but primarily home tests because either by prescription, because, you know, it's difficult to enforce shall we say, that a patient will follow up with their clinician and to interpret the results.

But with an OTC there is no expectation that anybody will follow up with their clinician and we want them to properly interpret potential false positives, potential false negatives and not to overinterpret the result that they receive.

Shannon Clark: Yes. So with quantitative data it's very straightforward what to do and there's very clear thresholds. But when we talk about qualitative human factors data, for example, someone entering into quarantine unnecessarily because they misinterpret the test to indicate that they have an active infection, this is about antibody tests again, or they just believe that they're positive when they're negative or vice versa, leading to various actions.

All of those actions according to our assessment, lead to user inconvenience unless they misinterpret the under, you know, that antibodies do not confer protective immunity. Basically what I'm saying is you can have all of this quantitative data, we'll submit it. But then when you analyze the human factors data that is the only really high severity outcome that we're able to identify. And I was just wondering if FDA agrees.

Dr. Timothy Stenzel: Well, so interpretation of serology results is challenging enough for those in the know.

Shannon Clark: Challenging for me as well.

Dr. Timothy Stenzel: And, you know, I've issued I can't even count the number of warning letters in serology entities, serology testing entities, either developers or other entities. Who, you know...

Shannon Clark: Where they might be saying oh, this might...

Dr. Timothy Stenzel: Or promoting things beyond what serology can support. You know, making a determination oh, you can go back to work now because you're antibody positive with one test. Oh, you are not going to be able to get it again. You know, you're not going to be able to pass along the infection. You know, or using it for diagnostic purposes.

Oh, you know you're positive, you know, you could be infectious. You know? It's not the right test for that. It's not the right test for that. So we're still working hard to understand the meaning of serology results. And overinterpretation is a huge danger and an inconvenience.

You know, our first home test was a molecular test. You know, I believe in that environment a positive probably ought to be in almost every case, followed up and confirmed and a negative shouldn't be trusted. But, you know, especially if someone is without symptoms in that environment, right?

They're without symptoms. If there were symptoms and they have a positive molecular result in a home test that was authorized, I don't know if they need a repeat test. I'd say that positive predictive value in that situation is going to be sufficiently high.

But where we've heard complaints from lots of folks is hey, I got a positive result, you know, with this test. I went and got it confirmed, it was really negative, but I still had to stay out of work for X number of days and it was a real inconvenience. They risk losing their job which shouldn't be the case, but that's what I'm hearing.

So, you know, our instructions that go along with our authorizations, should be followed. And those tests where clinicians are involved, you know, expert clinician involvement in interpretation results is so important. It's so important.

Coordinator: Thank you. And our next question comes from (Mark Hackman). Your line is now open.

(Mark Hackman): Yes. Good morning, Tim. Good morning, Toby. I hope you had a nice Thanksgiving holiday. I just have a follow up. You know, I appreciate you guys coming out with the new serology templates and things. I've been reading through them and I just have a question. And I know I'm probably pushing the envelope but I have to ask the question anyway because I've been told to.

When - we appreciate the over the counter - we appreciate that there are now serology tests that allow for finger stick blood samples, both the dried samples, as well as the opportunity to use wet finger stick blood samples. My question is, do you anticipate, or when do you anticipate it going from an RX device to an OTC device?

Dr. Timothy Stenzel: So we are waiting for clearance on the home - I think this is correct, Toby. We don't have clearance on the home serology test template yet. We've obviously drafted it and it's going through the clearance process. We can't predict when it will be made publicly available, but we - to developers we are providing our current thinking on that. We're not sharing the draft template but we are sharing our current thinking on the question that are asked.

So just like our first home molecular test and just like what will be for our first home antigen test and our first home serology test, whether it's RX or OTC, it's, you know, do we have sufficient information to make a good decision? And does that decision support authorization for the intended use?

So we're absolutely open to OTC and I would anticipate in the not too distant future, we're going to start making some OTC determinations and some that will obviously become public. And so we're well on that path I believe. So I can't tell you when. If you're interested in it, we're open to it. We can give you our current thinking around whether they - our recommendations for validation and our expectations in that situation.

Coordinator: Thank you. And our next question comes from (Brad Hemond). Your line is now open.

(Brad Hemond): Hi. Thanks for taking my question. The question is around the FDA's recommendation for manufacturers or developers validating a molecular lab assay on an IVD versus a RUO instrument, for instance, a thermo cycler that's already on the market.

Now what if any, difference is there for validation and use of authorization? And ultimately, is the FDA still accepting EUAs for RUO labeled instruments? Or are you preferring IVD labeled instruments? Thank you.

Dr. Timothy Stenzel: Yes. We're still open to the use of RUO instruments and - although it's ideal to have IVD instruments for obvious reasons. We will want to see the labeling, the RUO labeling for the instrument and do reviews of that. They are not all inclusive reviews of that labeling. But we want to make sure certain things are there and certain things are not there, in that labeling for those RUOs.

And then the rest of it is all dependent on the quality of the data. You know, is it supportive of an authorization or not? But realizing that there is still an expanding need for more testing access and that there's a limited pool of IVD instruments out there that can address these urgent needs, we remain flexible.

Coordinator: Thank you. And our next question comes from (Paul Joseph). Your line is now open.

(Paul Joseph): Hi. Thank you. I appreciate you taking my call. My question has to do with a companion digital platform that may accompany some of the COVID tests that are out there. I think as I'm tracking the issue some of the apps will fall into the FDA's medical mobile app enforcement discretion policy, especially if they tend to just kind of store testing results and then allow it to be transmitted or encrypted or reported to CDC and other locations.

But if a digital platform does anything on the diagnostic side or interpreting results for example, or transmitting it for a non-cleared device to a lab, that becomes something that needs to be specifically, have a premarket approval either through an EUA or something more broader from FDA.

And my question is, is that accurate? And do you know if the FDA is considering a template for companion digital products?

Dr. Timothy Stenzel: So at a high level, you're spot on with our thinking. And there's obviously a gray zone between those two that sometimes makes it challenging to determine. I think if you have a question about whether your software is a device or not, software as a medical device, versus software as decision support, come in with a question to our templates email address if it's EUA related.

I believe Toby, you can potentially address this. I believe our update to serology template has the latest in our thinking about devices that would be used to say scan the results from - right off the assays, at least up to our current thinking, relatively current now, to assist developers of these devices, to enter into the market.

Of course these kind of devices could be very helpful in capturing electronically, the data so that it could potentially, more easily, be transmitted to public health authorities for tracking this pandemic in a more precise way and accurately. So obviously, we're supportive.

So I don't believe we're currently planning to have a specific template for these devices, but look to the individual templates for each of the different

technology, serology, antigen and molecular, for information about what we're looking for in those devices.

We're totally open to the different potential business models that companies may employ. There could be press such as yourself, developers of imaging, scanning technologies or recording technologies that aren't developing their own assay. And therefore, there does need to be a link up to a specific test to get the ball rolling. And then, you know, perhaps other test developers want to get onboard as well.

And there's also a US government effort, a design-a-thon around software in apps to capture, record, and transmit data until there's another pathway. I'm not sure when that design-a-thon closes. We're getting close to closing that design-a-thon that was a couple of weeks ago. And so far we've obviously seen a lot of interest in that and we look forward to moving through, you know, review of those design-a-thon applications.

Coordinator: Thank you. Our next question comes from (Alison). Your line is now open.

(Alison): Hi. Thanks so much for taking my call. So we know that a large portion of hospitalized patients with COVID also have diabetes. With the recent prescription recommendation for steroids we realize that diabetics have a worsening of their diabetes when they are treated for COVID.

Our company currently markets an FDA cleared SAMD, software as a medical device, that's used by clinicians in the hospital, for management of diabetes. And we're looking to add some new features that will improve the quality of care for these patients. This is done through improved treatment recommendations and really better management of their insulin intake.

I'm not sure if this something that FDA would recommend an EUA submission since it doesn't treat or manage COVID directly. I know you spoke early about the PEUA as well. I guess my question is what would FDA recommend so we can get this software update added to the current product?

Dr. Timothy Stenzel: Yes. So obviously diabetes is a risk factor for a severe COVID disease and for death. So it has an important relationship and I was invited to give a keynote talk a couple of weeks ago, at a national diabetes forum. And we talked about some of this interplay between diabetes and COVID and our desire to be of assistance.

It would not likely qualify under an EUA provision as we understand it. So if you - the QSUB, pre-SUB process for non-COVID applications, is - promotes non-COVID applications is challenging. It sounds like you and your company are very expert at this. So if you're looking for an assessment about whether it's SAMD, software as a medical device, or doesn't support software applications, we can probably provide some input on that.

But if you already know it's a software as a medical device update I would recommend if you know what to do and you feel comfortable about it, that you just go ahead and do the work and you submit it in the normal application. We do have the surge where we moved folks including from the diabetes branch, into COVID activities. We didn't move everybody.

And we're still reviewing many, in fact most, non-COVID application submissions in the office. We're not talking about QSUBs or pre-SUBs. Most of those are being rapidly closed down. But actual 510(k)s, de novos, PMAs, we are still accepting and reviewing most of those. If COVID activities impact your submission you will be notified relatively quickly in written form what the potential impact is.

The surge is a 90-day targeted surge and - but we're not looking at - we're not anticipating pulling back from the surge until the beginning of the new year and will obviously affect us on a frequent basis.

Coordinator: Thank you. Our next question comes from (Aurianna Hawkins). Your line is now open.

(Aurianna Hawkins): Hi. Thank you. We appreciate the FDA holding this virtual town hall. My question is related to surge logical test validation. And I'm wondering is the Frederick National Laboratory still participating in independent validations? And if so, is that still restricted to serum and plasma or are they looking to expand to whole blood or even finger stick blood?

Dr. Timothy Stenzel: Yes. NCI is still performing testing to support serology technologies that are able to be assessed at NCI. It is primarily - it is only serum and plasma right now. Getting a hold of sufficient whole blood and storing it properly, obviously is a huge challenge. And finger sticks obviously is a huge challenge.

(Aurianna Hawkins): Even more so. Yes.

Dr. Timothy Stenzel: Yes. So the, you know, it's going to be easiest for us to assess the quality of the devices on serum and plasma. There are some devices that may not work so well on one or the other of the sample types. In those situations we typically have enough serum or plasma samples in the panels, to independently assess performance. And we'll be as flexible as possible.

But I'll just speak relatively frankly, we have denied and otherwise declined to issue so many serology tests that have failed at the NCI, that we are

challenged to make the best decisions on these serology devices. So to the extent that we can assess them at NCI, for those that are amenable there, that's been at NCI that, and they passed, and obviously we've seen many of those, it makes our job more straightforward and easy to make decisions.

(Aurianna Hawkins): Okay. Thank you.

Coordinator: Thank you. And our next question comes from (Franklin). Your line is now open.

(Franklin): Hi. Thanks for taking my call. We've determined that antigen tests work with NP swabs, OP swabs and nasal swabs, okay, and our goal is to make this an OTC product. We've done enough exercises already with very laypeople giving them the kits and guiding them through the process to perform the nasal swab and then put it into the reagent and then removing the swab from the reagent and then sticking the paper strip into the reagent and then pulling it out and reading the results.

And we have been very surprised, gladly surprised by the results that we have been obtaining both on the positive and negative concordance. Now the comparator tests that we have been using are the Abbott ID NOW. So my question is regarding the comparator, okay?

Do we have to have a comparator that provides CT values for if our claim is going to be OTC use for this antigen test? And then number two, I'm engaged with an academic institution in this exercise and we're trying to develop a very simple process.

Given that to date FDA only has approved one antigen test for at home use, the Lucira one, there aren't really that many resources that we can go and

follow in terms of, you know, this would be the protocol, you know, to follow. What would be, you know, a very simple protocol to submit if we're going to only claim that for ease of use and for, you know, issues regarding replication? We're going to stay with the nasal swab because people don't seem to have issues with it. They seem to follow the steps, you know, quite easily. And again, the results that we are obtaining compared to the confirmatory tests, are positive.

So I'm wondering if you guys could provide, you know, maybe some guidance as to that, what do you want to call it, protocol I guess, at home use protocol, given that there isn't specific guidelines to follow, so it's sort of uncharted territory I guess.

Dr. Timothy Stenzel: Okay. A lot of questions there. I'll try to address all of them. First off, we do have a home template for antigen testing and it includes information on both RX and OTC. So look to the template. Any questions that you don't have answered firmly from the template, you can ask in a pre-EUA format of the agency.

If it's right out of the template that's going to be our recommendation. Comparator assays are extremely important. I encourage every developer to check in with us about our current thinking for a molecular comparator. What we're asking is a molecular comparator to be, is a high sensitivity molecular assay with an external or a separate can be all integrated extraction, concentrating extraction procedure.

So anything that's direct like the Abbott ID NOW, is not an ideal comparator. And you will have challenges when you come in to the FDA with such a comparator. Now of course, I have released - I am quoted in the press release from the agency, about the Abbott ID NOW and it's - anybody who has come

in with an Abbott ID NOW comparator, realizes the challenges that they face in using the Abbott ID NOW as a comparator.

So I would strongly recommend the developers do not use the Abbott ID NOW as a comparator, and that they don't use any other direct test, molecular test as a comparator. For those molecular tests that don't necessarily have a CT readout and there are excellent molecular assays out there that would otherwise, and do otherwise function as a comparator.

However, when we make authorization decisions for - particularly for antigen and for molecular assays, we want to know that a full range of viral levels have been tested. And we have a target of, you know, these sort of in the range of about 20% low positive samples to be assessed. Because if someone comes in only with very high positive samples obviously that kind of rigs the system to say oh, you have a great assay. It doesn't really test the system.

And we know that there - even in the first few days of symptomatology for those who have symptoms, that some of them measured in the sample at least, that's acquired, viral levels can be very low. CTs can be very high. So in order to have adequate performance in let's say the first five days even, of symptoms, we want to see a good representation of viral levels in those five days, if you have an antigen device.

Also, the sample type for antigen devices are important to consider. We certainly do have interest in seeing interest in oral fluid saliva. We haven't authorized any yet. There should be a reason for that. You know, I would proceed with caution. Make sure that it's the sample type that's working for you, when you do your clinical studies.

Or if you do multiple sample types that mitigate your risk, you just go with the sample types that have good performance. Nasal swab is obviously very easy to obtain by patients and we've authorized quite a few self-collection, home collection kits and devices for nasal swab.

I would say that a mid-turbinate swab is also well received by patients in self-collection in home collection situations generally. Consideration should be made for pediatric patients. We want to have something that protects harm to them. Obviously the pediatric patients won't be swabbing themselves. They'll want some more senior person, a parent or guardian, or other adult capable of performing the test on kids.

We also want to see if you're going to include claims for kits that you demonstrate in the home environment, whether by RX, prescription that is, and OTC, that those in the home can adequately obtain a sample from the kids in your study and then get accurate results. Let's see. What else that I didn't cover? Yes.

So I think I pretty much - oh, there was one correction. And to my knowledge, the only home test that is performed in the home that we've authorized, has been a molecular test, not an antigen test. We're very eager to authorize the first home antigen test. There are a number of sponsors that are in the process of developing such tests.

I think that there will be at least some that will be successful and we look forward to that. Thank you.

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

(Josh Proveto): Hey. Thanks for taking my call. My question is about saliva collection devices in a healthcare setting. You know, we've been hearing from some providers that they're having difficulty obtaining approved saliva collection devices. And, you know, we have a test kit that just uses saliva. It doesn't require any guanidine or preservatives.

So really technically, any kind of like sterile polypropylene container would work for this sort of task. And I guess I'm just wondering like what - if there's any pathways or routes that the provider can use other non-approved saliva devices or like a urine collection cup which is approved for a different purpose. Or what we could advise people facing these challenges.

Dr. Timothy Stenzel: So if a lab wants to validate a saliva collection with a sterile container, say for their purposes of self-collection within the confines of a healthcare environment, I say go ahead, validate it. Make sure it works and go forward. We do not require a submission for that.

If you can use an authorized saliva collection device, we encourage that even in that situation. And we are very eager to authorize additional self-collection kits both for use obviously in healthcare environments, but also in the home either by prescription and going forward, totally open to OTC situation.

So that's kind of our high level recommendations. I know that Toby has spent a good deal of time thinking about this and examining this issue so I do want to give her a chance to add any color or correction to me. She needs to sometimes.

Toby Lowe: Okay, thanks.

Dr. Timothy Stenzel: She sometimes corrects me.

Toby Lowe: Thanks, Tim. No, I think what you said is correct. You know, it would be important that a collection device not be marketed as a saliva collection device for COVID testing, without being authorized for that use. But if, you know, if your test is validated for use with a, you know, sort of generic, sterile container, excuse me, and you're not labeling that generic sterile container as a COVID-19 saliva collection device, then that's not an issue.

We just would - if you are looking to market a collection device that is labeled for COVID testing and you're, you know, sending that out for testing, then that's something that we would want to see as a collection device. But there are some tests that are currently authorized that do use, you know, just a sterile - available sterile container commercially available.

And that's definitely something that is useful because they are more readily available.

(Josh Proveto): Great. Thank you.

Coordinator: Thank you. Our next question comes from (Wendy Jones). Your line is now open.

(Wendy Jones): I thank you for taking my call. And actually this is very interesting. I'm just follow up the previous caller's question about the home collection kit. So basically, what I heard is if we use those sterile collection tube to collect saliva without marking as COVID, for COVID testing, it is okay. So am I understanding correct?

Dr. Timothy Stenzel: No.

Toby Lowe: No.

Dr. Timothy Stenzel: I'll let Toby be more explanative there.

Toby Lowe: Yes. So if you're - if you're using a test - if you have validated a test for use with saliva and you have validated it for use with saliva collected in, you know, any sterile commercially available container then you would be able to market your test for use with saliva collected in any commercially available sterile container.

We would expect that you would validate your test with saliva collected in a variety of commercially available sterile containers or in, you know, or including your instructions the specific containers that you have validated the test for use with.

Where we would expect to see a submission for a collection device is if you are labeling the collection device for COVID-19 testing.

Dr. Timothy Stenzel: Well and...

Toby Lowe: So if you're...

((Crosstalk))

Dr. Timothy Stenzel: Yes. More me expansion on that. If you're just using - if a lab or a hospital - a clinic that has a lab, if you're providing a sterile container within the confines of your healthcare facility to self-collection and non-self, you know, it's always self -collection. But to collect either observed or unobserved in the healthcare environment, that does not require submission unless you make the claims that Toby just described.

But if you're doing home collection or home testing, that always needs - if it's not already authorized for that it does need a submission and FDA authorization, prior to marketing. Toby, you can add anything else.

Toby Lowe: Yes. Absolutely. That is absolutely correct. Anything for home collection would need authorization prior to use.

Coordinator: Thank you. And that was the final question. Now I would like to turn the meeting back over to Irene.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Today's presentation and transcript will be made available on the CDRH Learn Web page at www.FDA.gov/Training/CDRHLearn, by Tuesday, December 8th. If you have additional questions about today's presentation please email CDRH-EUA-Templates@FDA.HHS.gov.

As always, we appreciate your feedback. Following the conclusion of today's presentation, please complete a short 13 question survey about your FDA CDRH virtual town hall experience. The survey can be found at www.FDA.gov/CDRHWebinar immediately following the conclusion of today's live discussion. Again, thank you for participating and this concludes today's discussion.

Coordinator: Thank you for your participation.

END