

**FDA Virtual Town Hall Series –
Immediately in Effect Guidance on
Coronavirus (COVID-19) Diagnostic Tests Moderator: Irene Aihie
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OPERATOR: 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 one. 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 of CDRH's Office of Communication and Education. Welcome to the FDA's 25th in a series of virtual townhall 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 if we are not able to respond to questions about specific submission that might be under review.

Now, I give you Toby.

Toby Lowe: Thanks, Irene. Hi, everyone. Thanks for joining us again this week. I just have a couple updates this morning. We added a new question-and-answer to our FAQ page and updated a few of the existing questions.

The new question is regarding leveraging validation data that has already been reviewed by the FDA for another test. We've had a lot of questions about the proper way to do that and proper way to use or right of reference. So we added some additional information about that to the question. And we also updated a couple of the questions to add information about the CDC multiplex tests because CDC has the right of reference to the performance data in their EUA for their Multi-Analyte Respiratory Panel. So we've also had questions about that and added information there.

And we updated a couple of the questions in the testing supply FAQ section, specifically the questions related to extraction platforms and instruments for use with the CDC singleplex test.

And that's all that I have today. So I'll turn it over to Tim for his update.

Timothy Stenzel: Thank you, Toby. And welcome again, everyone, to this weekly call. We hold this call weekly to assist all developers of COVID-related tests to assist them in explaining any of our recommendations, to listen to concerns that we can sometimes address immediately or take back for consideration. It is an ongoing effort and extension of what we do day-in and day-out, every day of the week, and nearly every hour of the day in working with developers.

So again, welcome. We are committed to being transparent and to giving us a direct response as we can on the effort to help. I don't usually note up-to-date the number of authorizations we've made, and I make this as long as these calls go on at least a monthly update. To date, we have authorized 243 tests, and it includes 195 on molecular diagnostic tests, 44 antibody or serology tests, and four antigen or direct antigen rapid tests.

We definitely are interested in seeing more submissions for the direct rapid antigen tests. We just haven't seen as many of those as we have seen in the others, and that's reflected in the relative number of authorizations. However, we also in addition to these authorizations, offer very flexible policies that

have allowed more than a hundred other tests, frankly hundreds of tests to be on the market while their EUAs are under review and consideration. So in total, the amount of tests that are in the market undergoing review or already authorized are in the many hundreds.

I did want to also open up that we are eager to authorize as many antigen tests and molecular diagnostic point of care and home tests as possible. We have provided templates with our recommendations for both point of care antigen and molecular assays as well as in the non-lab or home situation. Our templates provide recommendations for validations. If you have alternate approaches, please engage with us through the cdhrh-eua-templates@fda.hhs.gov email address and/or provide us with something to assess through pre-EUA submission.

With regard to point of care tests, we would like to further assist developers in the pre-market validation period by opening, further opening up the chance for developers to use banked samples for their point of care studies. If the technology is amenable to that where they can use banked samples, then that may be a very good approach pre-market.

We do ask that and work with the member of our team to define your study plan because we would like to mimic as near as possible those samples being handed off to a point of care tester in a manner similar to which they would normally see patients in the clinic and do an actual prospective collection and test so that we can mimic a busy clinical workplace and assess the performance of the test.

So that is the loosening, further loosening under an EUA situation pre-market. There may, of course, be some post-market studies that are likely to be part of such an authorization.

Similarly, we have heard from a lot of developers that accumulating asymptomatic samples for asymptomatic claims or over-the-counter tests has been a little bit more challenging than expected. So there are two ways that we suggest that can aid in the accumulation of asymptomatic patients. One is to team up with any of the large screening and/or surveillance programs, I'm

looking at large populations. Of course, this is being done on many college campuses across the country.

And if they identify a patient in their screening or surveillance, that's potentially a perfect opportunity to enroll that patient or that residual sample into the clinical study for asymptomatic claims. So that can be accomplished in a number of different ways. One is that it's banked samples can be used for your device from those testing efforts. And you can simply of all your local authorizations are achieved to use that sample for development of a commercial product allowed then you can use that banked sample.

The other thing you can do is potentially call back any positives for re-collection. So we have been working with recently, very recently, with some who have tried to utilize this approach. And there has been some success in this. So we wanted to make that further awareness available to all developers.

We also would like to start something new. Again, this is a pre-market validation assistance. We're open to, in addition to having a minimum number of asymptomatic patients pre-market, sometimes it's only as few as 10 or 20. We ask there be a minimum of 10 asymptomatic patients enrolled and tested. If in the case that 20 maybe required which is the most common number of samples that are asymptomatic to be required, we'll allow a minimum of 10 pre-market and the other 10 could be matched symptomatic samples and the matching process should be worked out with a member of our team but in general we'll be trying to find samples that reflect the viral loads, or CTs, or viral levels of those 10 asymptomatic patients who have been enrolled.

If the requirement is for more than 20 asymptomatic which is in some cases where developers only want to seek an asymptomatic claim, there may be requirements for 30 asymptomatic samples and we are going to allow 15 of those 30 to be supplemented by symptomatic in the pre-market.

Again, with the point of care studies there maybe requirements post-market to bring the total up to the recommended amounts. In both cases, we will obviously allow enough time for those studies to be completed post-market.

The other thing I wanted to mention is that this morning the center director and I have published an opinion piece in The Hill. We hope you find our comments welcome. They are on all along the lines of what I just mentioned, our flexibility to adapt to the changing situation, adapt to the needs of developers and to speed access to technologies that will help. A lot of it has to do with point of care and or home type testing. We are very open to all developers who come to us with these ideas, and their tests.

As I said earlier and from an opinion piece, our recommendations are just that, recommendations. The FDA is always open to alternative proposals from developers and we'll continue to consider those. There could be significant trade-offs and test accuracy that maybe appropriate where the need for availability and fast results is not being met.

So for one example where our recommended levels of sensitivity may not be achieved with a single test result in a home situation, maybe with the paper strip test. Strategies utilizing serial testing, for less sensitive tests, could be deployed. Regarding serial testing, I mentioned this last week I believe.

For example, what if the test had a 70 percent sensitivity? I also want to go into further detail about what we mean by 70 percent sensitivity. Let's just say that 70 percent sensitivity is what can be achieved with one test result. Well perhaps with a two-pack, two test results you can achieve a greater sensitivity together and maybe on a day one, day two, or day one, day three strategy.

So the sensitivities can be such that one or the other being positive gives you a positive result. We are open to that kind of testing format to see that we're capturing, and this is where I'll go in to what we mean by sensitivity. In some senses, the absolute LOD of an assay doesn't matter as much especially in this home situation where you're trying to find folks who are carrying a level of virus that can infect others.

So we typically think for symptomatic patients that the first five to seven days are some of the peak days for potential for infecting others with the virus. There's in all likelihood a very similar window for those who are without

symptoms who are infected to start shedding virus and then eventually tail-off and are no longer shedding significant or any virus.

We are really looking and as we've authorized our direct antigen tests, some of them have been authorized for five days post-symptoms because those are either the days that were studied in a clinical trial or those are the days at which performance was high enough to authorize.

So some less sensitive tests may fall off more quickly after that five day period. That can be OK. We do want to see adequate sensitivity during those peak periods of virus shedding when patients are at most risk of being able to infect others. We think that by identification, of course, those individuals and isolating them, and treating them as needed we can do great good in reducing the incidence of new cases in the U.S.

So with that, we will now turn it over to questions and answers.

Operator: Thank you. As a reminder, if you would like to ask a question please press star, then one and record your name clearly when prompted.

If you need to withdraw your question, you may do so by pressing star, then two.

Our first question comes from (Cory Yekel). Your line is now open.

(Cory Yekel): Hi. Thank you for taking my question. We are currently authorized for molecular SARS-CoV-2 test with use of our at-home collection kit. We are also interested in pursuing a new EUA for a COVID-Flu multiplex test. Can FDA comment on authorization of at-home collection kits for COVID-Flu multiple tests, and what is FDA's expectation for data needed to support at-home collection with COVID-flu?

Timothy Stenzel: Yes, I'm not sure that our home collection template covers the multi-analyte. Toby maybe able to fill on this. However, we have provided some helpful hints and suggestions for, and recommendations for validation in the molecular template for kit manufacturers.

So I would refer to that and if you want to put together some proposals that we can consider and then send it in to our email address or as a pre-EUA as an amendment to your current authorization. We will welcome that dialogue with you. It is something that as we head into the flu season we've already authorized some panel tests and obviously we want to authorize many more in addition to that.

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

(Oriana Hawkins): Thank you. So my question is, what is the FDA's stance on using multiple high-sensitivity RTP-CR assay systems for comparators rapid antigen tests, clinical performance validation? So for example if you have four sites participating in a study and just due to logistics half of the specimens go to a lab that's using say a Roche covox system or half go to a lab using say Expert Express or Luminex, is there any challenges associated with that that you expect or do you think that FDA is flexible enough to accommodate that situation?

Timothy Stenzel: Yes, we're absolutely flexible to accommodate that situation. Really only our recommendation is that you use EUA authorized high-sensitivity molecular tests. Though we understand that different centers would have different local tests that you can use as the comparator.

You can also use multiple tests to annotate your tables so there might not be an ideal comparator but you can do discordant resolution with another test. Do discuss resolution with your contact at the FDA so that it's done in the appropriate way. And then at the very least the tables in the extractions for us can be updated with that annotated data.

Depending on how you do the comparator and what you use for your reference method, it may or may not be able to have corrected results. There are opportunities to use corrected results, but then it does require multiple upfront comparator assays and a pre-specify reference algorithm in order to do that and use combination of tests as a reference method.

(Oriana Hawkins):OK. Thank you.

Timothy Stenzel: You're welcome.

Operator: Thank you. And our next question comes from (Daniel Marcus).

(Daniel Marcus): Hey, guys. How are you? So very quickly, I know that on certain templates there's recommendation as to the sufficiency of in terms of the amount of samples. That one is a test for EUA, I know the recommended number is 30. I don't know if that varies depending upon the fact of the circumstances or if that's an absolute floors so it wouldn't necessarily be higher. So that's one.

And then the second question is, assuming a developer has custom kit components specifically a custom swab. I'm wondering what level of validation would be required for that to be approved or if that is something that can be done under design controls? Assuming you got the EUA on that first go.

Timothy Stenzel: Is the kit collection going to be something that's going to be sent to a home user?

(Daniel Marcus): Over time yes, but at least in the initial EUA filing likely no. So likely yes, a healthcare worker, at the point of care absolutely, yes.

Timothy Stenzel: In a healthcare setting, there are things that they will be required if it was a home collection setting and after I respond to both questions, Toby, you may want to add something. Typically, test developers can and frequently do kits, a swab, and/ or on a transport media with their tests. A number of developers do that so that users don't have to go out and find these supplies. They also provide these so that they know that it works with their tests.

So there are certain advantages when you can provide those swabs and any other collection reagents with the kits. It's not required but sometimes a nice to have. It depends on your assay.

As far as the minimum recommended number of positives and negatives, we're pretty firm on that but we're flexible on as I mentioned earlier on how we actually approach that.

Early on, we allowed contrived samples and then we shifted to using actual patient samples when the numbers of samples were sufficient out there in the marketplace and in the community to be able to specimen, the recommended amount of 30 positives. Negatives are obviously very easy to get, 30 positives, can sometimes be challenging for some new developers who don't have the connections in the community.

A number of developers have found that using certain commercial organizations, and CROs, to be able to provide those samples has been helpful to them. There's also a number of ways to collaborate with clinics and hospitals, and academic centers but we can flexible to some degree on the sample type.

So one of the first direct antigen tests really wanted to have a direct swab claim but they had adequate performance on VTM. So we are able to authorize the test on VTM and then later on they were able to collect enough of the direct swab to update their label for use of just the direct swab.

So we want to approach things in as flexible manner as we can. So there may be some details or specifics about a specific sample type that be more challenging to acquire. So in some cases, we have allowed a minimum number of samples to be tested for an additional sample type in addition to something else that had the 30 positives to go into the intended use with the post-market commitment. So again we try to take as flexible approach as we can even given that the bars are really, the recommended bars are really quite low.

(Daniel Marcus): OK. Yes. I'm not even suggesting to go lower, I'm suggesting, I'm asking if there's a scenario where the bar would be higher depending upon sample size on one hand and then the other question that I would want to fit in very quickly is, is there an expectation that there's an, there should be an IRB in

place for all studies or there's no need to necessarily demonstrate it, it's just part of good clinical, good practice.

Timothy Stenzel: The IRB assessment is not a part of our standard EUA assessment. We do expect folks to adhere to all federal, state and local laws and regulations. So really that's for you to determine to do the appropriate one.

(Daniel Marcus): OK. Thank you.

Toby Lowe: And just to add to that, generally the studies do fall under IRBs oversight and so we would encourage you to talk with your IRB about what they would expect for your specific plans.

Just to add a little bit on your swab question as well. Most swab or many swabs are exempt from 510(k) review. So they just would need to be registered unless did and follow the other regulatory requirement depending on your particular situation. If there is something particularly unique about your tester, about your swab, then you may want to have further discussions about that. So you may want to send that question and with any relevant details so that we can make sure that we get you the right answer there.

(Daniel Marcus): OK. Thank you.

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

(Josh Presados): Hi. Thank you for taking my call. We are a molecular test kit developer and we have nearly completed validation of a saliva test including the peer study and also that background interference study because we have been using an extractions system.

My question is about the collection devices. Our system is based on unique saliva meaning it doesn't need any sort of preservatives or guanidine or anything like that in it. So it can be collected just in like a empty plastic tube. So we would ideally like to have an authorized test where it doesn't require a specific collection device so that somebody who doesn't have it could use any

tube. We would also like to make it easier for customers to be able to source, be able to provide a specific collection device that they would have.

So what is the best pathway for us to accomplish both of those things? How best can we do that?

Timothy Stenzel: So I would say the short answer is it depends. I don't know if you're doing any offsite collection, home collection, shipping or if it's all going to be within a healthcare center. If it's all within a healthcare center or a healthcare facility, I would -- there may be more openness to not specifying a particular collection receptacle and not providing it. That would -- I think that's best entailed with working with one of our contacts in our office to assess how you might determine appropriate collection receptacles.

So there are common receptacles used across all healthcare systems very common probably. So it could be as simple as providing a part and part number, and a manufacturer for that collection receptacle that is required say but not provided.

The specifics of this is best worked out between somebody on our staff and you the developer.

(Josh Presados): All right. I will write in to you. Thank you.

Operator: Thank you. Our next question, I believe the name is (Winnie Joe). Your line is now open.

(Winnie Joe): Yes. Thank you for taking my question. I have a question regarding the asymptomatic and symptomatic tests. So basically, we are doing some screening under the order of medical director or clinician. So we do find some people there asymptomatic but have very high viral load especially in the young people. So I think what is the essential requirement for the EUA authorized to test the asymptomatic people? So we do have enough asymptomatic people we test them positive, is that all we need to present to see our assay can be used for asymptomatic or I'm just a little bit confused here? What other things we need to do?

Timothy Stenzel: So you have molecular kits.

(Winnie Joe): Yes.

Timothy Stenzel: It's already authorized and you want to add asymptomatic to your intended use. I believe we ask for 20 positive asymptomatics. We want those to be collected in an un-biased way and not cherry-picking way. They just require those 20 and that you show that that's comparative performance to the accepted recommendations. That's all you need.

There are some alternative pathways you can pursue and compare CTs between symptomatic and asymptomatic historically. So if you already have the samples and you have the 20 minimum samples and they were collected in a manner in which is unbiased that may be all that you need.

So I would just submit a question to probably the reviewer you worked with before and find out if that's sufficient to update your intended use.

(Winnie Joe): That's wonderful. OK. Great. Thank you.

Operator: Thank you. Our next question comes from (Roxanne Cheng). Your line is now open.

(Roxanne Cheng): Thank you. Yes, we have EUA authorized COVID-19 kits and we're working on the saliva claims. So my question is that we're able to find the commercial company that will collect the paired NP and saliva samples but there seems to be a challenge getting VTM or UTM. So does FDA approve use of CIVD certified VTM in such study or collection of samples for research like for our company?

Then the second question I have is that for negative saliva samples, are we allowed to use saliva from subjects that have been tested NP negative by a public laboratory on the same day?

Timothy Stenzel: Can you ask the second question again? Do you want to source negative saliva samples from another lab?

(Roxanne Cheng): No, it's actually a subject, a person has already done their NP, their COVID test with NP in another lab, and we want to use their saliva.

Timothy Stenzel: Yes. I see. So they've had a test of record with NP and then you want to as quickly as possible collect the saliva sample from that patient for use. Yes, again our recommendation is that the test of record or the comparative test, the one used with NP be an EUA authorized high-sensitivity molecular test as the comparator.

Then, yes, we're open to that recollection of a sample. There's a couple of things that I just want to clear with one of our staff. One is when you recollect a sample you obviously know whether that patient is positive or negative. So whoever is performing the test should be blinded to that result which means you should be, considering you want to be considering providing that tester with also negative samples so that they know that if they don't know that all the samples that are coming to them are positive. So that tester remains blinded and unbiased in their approach.

(Roxanne Cheng): OK.

Timothy Stenzel: Then on the first question where VTM. Of course, there are -- we have provided a guidance on VTM where it matches the CDC recipe. So anything that falls under that immediately in effect guidance should qualify even if it's not manufactured in the United States.

Then, so you can look at that guidance to see if that, the other VTM providers would be that. Also PBS and phosphate buffered saline, we found to be a very acceptable media.

(Roxanne Cheng): Indeed, yes.

Timothy Stenzel: So that can be easily purchased for your use in your study. So those are the options. Toby, you may want to add something on either those but maybe on the VTM too, so I'll pause.

Toby Lowe: I think it's mostly covered. I just want to emphasize that how you are testing should be reflective, how you're testing for your validation should be

reflective of how you intend to indicate your test for use. So that's something to keep in mind when you're selecting a media.

(Roxanne Cheng): Sure. Yes. OK. Thank you very much. Perfect.

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

(Wendy Strong): Can you comment on the use of saliva for rapid antigen tests? Would you want to -- would you allow storage of saliva samples compared to matched PCR results? Would you consider that sufficient? Specifically, can you comment on the use of saliva for a rapid home antigen test?

Timothy Stenzel: Yes. So certainly open to saliva use in any test situation whether at the home, non-lab, point of care or other as long as it works. So we have heard from the numerous developers who have not been able to make saliva work for the direct antigen test. So if you can do it, more power to you. We make our decisions based on data and not on pre-ordained facts.

So it still fascinates me that it's oral fluid and saliva can work as well as they can in some cases for the detection of SARS-CoV-2 infections. So then you said what about banked frozen samples.

(Wendy Strong): Correct.

Timothy Stenzel: So in a point of care setting, I did mention earlier in this session that we're open to using banked samples and that could include frozen. Typically when frozen samples are used, we want to know how the frozen samples compare to fresh samples because the fresh samples are what would be used in a natural point of care setting or home setting.

There could be situations where samples either degraded or viruses made more accessible by freezing. We have actually interestingly enough seen situations where we think freezing of a sample actually improved sensitivity but it's obviously not in a standard workflow situation for any sort of routine testing to first freeze the sample before you test it.

So we do want to understand those parameters. We would probably want to see some minimal number of fresh samples in addition to banked samples. So I think some of the details should be discussed with a member of our team to give you a very specific feedback.

(Wendy Strong): When you say that it would have to work, I certainly agree with that but what is your, what are you considering work and that kind of gets back to the question you touched on earlier, what sensitivity or what measure, what LoD would you need to see to consider saliva is acceptable? Tying that into what you said about a multi-pack if the claim is for doing the test several times over several days, how does that affect whether you consider that acceptable?

Timothy Stenzel: Yes. As we have mentioned in our templates and as we mentioned and I have mentioned in the opinion contribution to The Hill this morning, we are open to single tests that are less sensitive if in combination They provide adequate sensitivity.

I mean the most important thing is if someone has viral levels that could be contagious, could infect somebody else. We're not talking about rare occurrence weeks after infection with very, very low potential viral level. We're talking about peak period of viral transmissibility. We want to see good performance in that window because otherwise people would get a false sense of security from a negative result.

So if combination of two tests, three tests over one to three or so days improves your sensitivity so that we're making sure that we capture a significantly number of who can transmit virus, then we're open to that.

(Wendy Strong): What viral load do you think would be important to detect? Do you have a number on that?

Timothy Stenzel: Well, we're starting to look at the available information we have for say CT results. CT results and the CAP has come out with an article saying it's really hard to make these tests truly quantitative. There's all sorts of factors that go into there. Probably the most important factor is adequate sample, and then there's biology. So but we have seen very high CT, for some of the

submission in the first few days of post-symptoms. That was a little bit surprising to us.

So a simple cut off for CT may not be sufficient for performance evaluation in that situation. So again we're data driven. We understand the typical course of infection and the infectivity, and it usually means that in the prescribed seven days after symptoms have initiated in a patient they can be considered potentially infectious obviously.

(Wendy Strong): So would you consider-I mean in terms of say 10 to the 3, 10 to the 4, 10 to the 5 viral particles per ml, do you have a range that you believe should be detectable in order to detect that early infectious stage?

Timothy Stenzel: Yes. So LoD is really, really, really tough to get at and there is not an international standard. There's not a really good way to assess that. There's not a really good way to get a great sample every time. I was involved in the early days of real-time quantitative PCR development and FDA authorization for an HIV quant, HCV, HPV quant assays. When you have a blood sample which is pretty uniform, and you have a highly sensitive and linear molecular test which is real-time test that's more well-developed, well-validated, You can start to really specify what levels matter.

It's very challenging with the respiratory specimen to do that. So we remain open and flexible. LoD is not primarily the determining factor in whether we authorize a test for the detection of virus or viral RNA. It's largely the clinical study where in comparison to, for the period that you're looking at, compared to a high sensitivity molecular test which provides the reference result for those say early days of post-infection to know whether a patient is infected or not with a SARS-CoV-2 or they have something else. So that more establishes the truth of the infection rather than the level of the infection.

(Wendy Strong): OK. Thank you.

Timothy Stenzel: I wish it were easier than this.

(Wendy Strong): Me too.

Timothy Stenzel: We are trying to deal with very complicated situation. Typically an assay that performs very well in the first five days post-symptoms then we just want to see if you want to go after an asymptomatic situation and we just want to see how it really does perform in an asymptomatic population.

As I said before, we're willing to go as low as 10 asymptomatic samples pre-market with the post-market commitment to fill in the rest. Go ahead.

(Wendy Strong): Yes, and my last question was, at what point would you recommend trying to set up a pre-EUA contact with FDA?

Timothy Stenzel: So we have provided a lot of recommendations in our templates and to say save precious time we urge those recommendations to be reviewed. It would really be those questions that aren't directly addressed in those templates where there's the most value that we can add.

So I think the authorization has been made with direct antigen tests already in the first five days of symptoms, they're the first two that were authorized, I think we're authorized for five days. Those were sufficient performance in the symptomatic population. If you can show the rough equivalent to that kind of detection in those acquired asymptomatic infection then I think you're a long way, you're all the way there but do engage with us on the specifics.

(Wendy Strong): Thank you. Thank you very much.

Operator: Thank you. Our next question comes from (Grace Cardin). Your line is now open.

(Grace Cardin): Hi. Yes, my question is from an investor viewpoint. I realize you can't mention specific companies but I've read from previous townhall transcripts that you operate on generally a 90-day window for EUAs. My question is, actually it's two questions, first question, if we're outside of a 90-day period, is it safe to assume that possibly that test was problematic or rejected?

My second question is regarding the home saliva test kits. I've read something recently or heard something from the FDA that you've changed or

amended your requirements regarding reporting of those tests to authorities like the CDC. Could you comment on that also?

Timothy Stenzel: Yes. So I'll take the home saliva and or any other home tests that isn't performed in a healthcare facility or any facility that doesn't have a CLIA certificate. Any entity that has a CLIA laboratory certificate is obviously required to report at least positive and negative results for COVID-19. In the home testing situation or non-lab testing situation where the testing is performed and allowed in a non-CLIA certificate setting, home would be perfect for this example.

There is not a requirement under law that I'm aware of to report that result for public health purposes. However, there's great advantage from there being a way to facilitate the reporting of that result. So we do have in our template not as an EUA authorization requirement.

We do have questions around what thought the developers have given to how home test users for example could report results. Some are way ahead of the curve here and they want to help out as best as they can, and they actually have apps or they have a device that's connected that could actually easily report these results. So but there are those who have very simple, paper strip tests where it may not be as easy.

I know there are those in the U.S. government that are looking at ways to facilitate reporting in those situations. So again this is not something that we are asking as a review criteria to make a decision on an authorization for developers but we do welcome the ideas that developers have about how they can facilitate the reporting of the important results for public health purposes.

So I think your other question has to do with what does it mean if some of -- in the EUA submission has been made and it is taken longer than we had hoped to make a decision. We are absolutely inundated in submissions. It's why early on back in March, we basically really opened up so that developers could within a certain timeframe after notification for many purposes, not all purposes could -- once they notify begin marketing their test in the U.S. while we do our review.

Because there are so many we have had to determine a triage process and that triage process does move high priority tests ahead of others because either they require an EUA to be marketed for their intended use or they are going to have a bigger impact on public health. All the while for those that are allowed to notify, they can market.

We do -- we attempt to do a really quick check on all submission, EUA submissions to make sure there are no issues of public health concern and if they are, we tend to try to deal with those as quickly as possible obviously.

So I would not read into anything at all on the specific case based on the time it's been with us.

(Grace Cardin): All right. Thank you very much.

Operator: Thank you. Our next question comes from (Katie Ertley). Your line is now open.

(Katie Ertley): Hi, yes. This is (Katie) from (InBio Diagnostics). Can you hear me?

Timothy Stenzel: Yes.

(Katie Ertley): OK. Thanks a lot for hosting these sessions. They've been very helpful. My question is, what is the current expected timeline for notification acknowledgment?

Timothy Stenzel: So that typically should happen in 24 to 48 hours. If it's going longer than that, then I would email the team and find out what's taking more time than that.

(Katie Ertley): When you say email the team, would that be the original mailbox or a different contact?

Timothy Stenzel: Yes. You would get an automated reply to your email. That's not the notification response email. A member of our team takes a look at things and assesses the suitability for notification, and then once they determine that as suitable then they provide you with the specific notification email.

Then as soon as possible after an EUA submission and my direction is within two weeks for that submission, you will have some contact with in the office depending on as priority. Either reviewer, if there's room on a reviewer plate and the submission is high priority or somebody, one of our administrative folks who oftentimes knows a lot about test development, and I've directed them to give at least weekly updates on your status.

So but again it's been one or two days, more than one or two days, work days, business days, since your notification submission then do check in back with the same email. Somebody should respond quickly with at least acknowledging your request for information and trying to find out what's going on.

(Katie Ertley): Perfect. Thanks so much.

Operator: Thank you. Our final question comes from (Jessica Russell). Your line is now open.

(Jessica Russell): Hello?

Timothy Stenzel: Howdy?

(Jessica Russell): Can you just say a little bit more about post-market validation that you referenced at the beginning? And just now again. Is that just for POC or another context?

Timothy Stenzel: There are several situations where there can be post-market commitments. One is for any pooling claims. A pooling sensitivities can vary over time if the patient viral load shifts one way or the other. So in all pooling authorizations, we do have a monitoring plan that is a post-market commitment, that's not necessarily a completion of validation.

And others, such as I mentioned in early antigen tests where to add a direct swab we only require pre-market a five swab study. They can have 30 VTM samples for that. This is just some example there are other similar or dissimilar types of post-market commitments.

But then the company agreed under the authorization to complete 30 direct swabs which they then did and they updated their intended use with the full 30 plus, and if they had more than 30 in the end, they updated the IFU with the performance data on those direct swab samples. I think in that case, they actually removed their VTM from the label.

So we try to be maximally flexible in what we require pre-market. So sometimes in offering that flexibility, we do ask for completion of the intended recommended studies post-market. They weren't able to be completed as usually recommended in the pre-market setting.

Those studies are usually, there are some negotiation on what that study design is and what the time period is. Those should be very relevant to the question at hand and to the estimated amount of time that it would take to complete those things. Hopefully, that answers your question.

Irene Aihie: Operator:

Operator: Thank you. No additional questions.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the CDRH Learn webpage at www.fda.gov/training/cdrhlearn by Tuesday September 15th. 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 townhall 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.

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