

## **FDA Virtual Townhall**

**Moderator: Kemba Ford**  
**March 3, 2021**  
**12:15 pm ET**

Coordinator: At this time all participants are on listen-only mode. 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. Kemba Ford. You may begin.

Kemba Ford: Thank you. This is Kemba Ford of CDRH's Office of Communication Education. We apologize for a delay in starting today's call. We do want to welcome you to the FDA's 45th 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, the Director of the Office of In Vitro Diagnostics and Radiological Health and the Office of Product Evaluation and Quality and Toby Lowe, the 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 the development and validation of tests for SARS-CoV-2. Please remember that during today's town hall we are not able to respond to questions about

specific submissions that may be under review. Now I will turn the call over to Timothy.

Dr. Tim Stenzel: Yes apologies for the delays. We had multiple technical issues. And I'm not sure that everybody who wants to be is on the call quite yet. We did have a formal remarks that we are ready to present but I think we're going to delay on that until we have a, you know, as many people call in as possible. People should look to their emails if they're - if you know of folks who are having trouble connecting with the connection information.

And with that I think we'll get into - right into questions. We'll take questions for a little bit then we'll pause and do the usual announcements. And so operator if you are able to set up the questions that would be great.

Coordinator: And if you would like to ask a question over the phone please press Star 1. One moment. Thank you for your patience. Our first question comes from Shannon Clark. Your line is now open.

Shannon Clark: Hello. This is Shannon Clark with UserWise Consulting. I have a question about point of care molecular or antigen tests. For those using a mid-turbinate swab after the clinical evaluation testing is complete can we add an additional swab with perhaps the same fit, form and function as originally used swabs to the test kit?

So imagine that the point of care testing and clinical evaluations have now are completely done, it's been like a month, can we add another swab with the same fit, form and function as originally swab and include both swabs in the emergency use authorization just to ensure continuity of the supply chain due to concerns about well what does this one swab that's authorized is no longer available?

And then also like what are the aspect of fit form and function that would be concerning to the FDA in this context. Does that make sense?

Dr. Tim Stenzel: Yes, no I think I understand and we absolutely want to ensure adequacy of supply chain my - our prepared remarks was going to speak to some supply chain, potential supply chain issues in our focus on making sure that that's not an issue.

So if it's also a mid-turbinate swab and it is just a different provider but different swab manufacturer, you know, it's unlikely to cause a review issue. But that's the sort of question to ask the review team.

We're going to be very supportive of adding additional alternatives especially if it's just the same body site. So if it's mid-turbinate to mid-turbinate with antigen tests that is - that's going to be easier than if you moved to a different site or location. And that might need additional validation but hopefully minimal and perhaps only analytical validation at most of additional swab that is the same as the study swab.

Shannon Clark: Thank you so much.

Coordinator: Thank you. Our next question, I believe the name is (Seth), your line is now open. Okay moving on to the next question. It comes from (Richard). Your line is now open.

(Richard Montegna): Thank you. This is (Richard Montegna). We received a EUA authorization back in April for a PCR-based test that use respiratory samples. And then we subsequently amended that to include saliva that was collected with a healthcare worker.

We are now working to have a self-collection kit developed and we put together a usability study which we actually sent a draft off to one of the lead reviewers the other day. And it got back to us yesterday and suggested that we send it in as a pre-EUA. My question is, is a permissible to restrict that pre-EUA to just the usability study or will you require that we fill out the whole template? Thank you.

Dr. Tim Stenzel: I think you can just fill out the new items and refer to your previous submission...

(Richard Montegna): Okay.

Dr. Tim Stenzel: ...for all other details.

(Richard Montegna): Okay.

Dr. Tim Stenzel: The reason that they're asking for that is so that we - with all the thousands of applications we receive, we want to make sure that we track things in our electronic system. And by sending it in rather than just an email that is a pre-EUA, that gets logged in and tracked and everything gets connected and we don't lose - we don't risk...

(Richard Montegna): Okay.

Dr. Tim Stenzel: ...losing it.

((Crosstalk))

(Richard Montegna): All right thank you very much, appreciate that.

Coordinator: Thank you. Enter next question comes from (Kumin Mudi). Your line is now open.

(Kumin Mudi Enconteserin): Good afternoon and thanks for taking the question. I am (Kumin Mudi Enconteserin) from Tetracore. Actually I have seen your article Dr. Stenzel, in the New England Journal of Medicine recently about the COVID-19 antibody test today with your experience. What I would like to ask you is at least for molecular tests there are some reference standards that are made available by FDA and the other - the government agencies. Has anything been done for serology tests done with (x air spaces) or can you kind of throw some light on what are the steps that are given by the agency or the other government partners to provide reference material for serology assay developers? Thank you.

Dr. Tim Stenzel: Yes that's an important question. We still are evaluating tests at NCI as an inter-government agency, interagency government effort obviously NCI and CDC, BARDA, FDA and that program's still active and we are sourcing samples for that. Toby may know more details.

I know we are still looking for the ability to send out samples and I haven't gotten an update recently from them that says that they're ready to send those so I expect that they're still working on it.

It has been a bit of a challenge to source of these samples and so, you know, in enough quantity to provide to all developers, have noted that WHO has recognized an international standard. I don't - I know it's available for molecular. I don't know if it's available for serology yet so that certainly could play - could be helpful to you.

I will take a note. We'll specifically query the interagency group and provide an update next week on a serology, a sample panel or anything like that.

(Kumin Mudi Enconteserin): So you've got any priority for this or it is low priority?

Dr. Tim Stenzel: Well we've been working on that for a long time but if we have challenges just keeping samples going through the NCI effort. And we don't have any extra. We haven't probably been able to move that. So the NCI evaluation program would take priority over sending out panel material.

(Kumin Mudi Enconteserin): Thank you.

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

(Ellen Allen): Oh hi. Thank you. We recognize FDA's efforts to prioritize the EUAs and terminate or decline acceptance of new EUAs based this prioritization scheme. Are there any guidelines FDA can provide for us who have EUAs that have been accepted and are pending review and how long those authorizations can be expected if they're not a priority EUA?

Dr. Tim Stenzel: Yes I think this is now a good time to do our introductory announcements Toby. I'll just address the specifics of this question and then I do have...

(Ellen Allen): Hello?

Toby Lowe: Tim, if you're still talking, we can't hear you.

Coordinator: One moment. It looks like we are experiencing a little technical difficulty. Please stand by.

Toby Lowe: Okay so it looks like Tim may have gotten disconnected. Are folks able to hear me?

(Ellen Allen): Yes I can hear you.

Toby Lowe: Okay great. So to address your question about, you know, review timeline and prioritization we are, you know, continuing as we talked about before to have large volumes of submissions. And we are having to prioritize those submissions.

We, you know, discussed previously that we prioritize based on the public health need and we consider, you know, factors such as whether the product would serve a significant unmet need particularly in terms of access such as at home specimen collection or at-home testing or the ability to expand the availability significantly such as the quantity and manufacturing capacity. So those are some of the considerations that go into our prioritizations.

And additionally we, you know, we are trying to review it as quickly as possible but we do use those prioritization factors to determine, you know, the order in which we review and where we spend our resources. And we also consider, you know, how complete a submission is in terms of whether we can move that forward.

So Tim it looks like you might be back on. We just went through a little bit on prioritization but if you want to go into more detail please do.

Dr. Tim Stenzel: Yes I - sorry. Hopefully I'm not crackly. I think I might not have a good line but I don't want to risk disconnecting. Well, I got disconnected.

Toby Lowe: Yes, you sound good now.

Dr. Tim Stenzel: So okay. The priorities - so if somebody has come in, and there's two different kinds of lower priority. So if someone's in and you have not have an active reviewer but we haven't made a determination, we will get to your applications as soon as possible.

And this is especially true for those who have notified the FDA and are allowed to sell their tests in the United States prior to an FDA authorization. We are making some other decisions and sending out de-prioritization letters. And I did want to go over that now in more detail.

And so we do continue to receive a high volume of EUA requests and want to again share our priorities. As we've stated before, we believe we're at a different stage in the pandemic now than we're even a half year ago or several months ago in terms of tests available and testing needs. And so accordingly we have prioritized reviews and authorizations of EUA requests that take into account a variety of the factors as discussed in the guidance emergency use authorization and medical products and related authorities.

And, you know, important to this is the public health need for the product and the availability of the product, you know, how much product could be brought into the US over time and certain things like - I'll go into some of those other details but, you know, product availability is also important.

We have for example prioritized review of EUA requests that have to do with increasing test accessibility, for example point of care tests, home collection kits, home tests and those tests that would significantly increase testing capacity, for example tests that significantly reduce reliance on test supplies that may limit access as well as those tests that are extremely high throughput

and widely distributed and can run on platforms that are widely distributed in order to best address public health needs.

But if you're a notified test and you're allowed to be on the market you may be in a lower priority than this but you can stay on the market. But we are on new test submissions, we are occasionally making determinations that we're not likely to get to those EUAs and so there's a different kind of response from the FDA.

It's important to ensure and it's critical to ensure adequate supply chains for authorized tests and avoid spot shortages and widespread shortages of testing supplies. So especially for priority tests we would like to avoid those shortages that could happen with diversion of supplies away from nonpriority tests.

Also, you know, diverting as way of an explanation for these priorities in more detail, diverting reviewer time to reviewing EUAs that would minimally contribute to expanding US testing capacity or patient access to testing would delay the review of EUAs for tests that would better serve the public. That's the reason for some of the shuffling and the priority, prioritization that's going on now with tests that have been submitted.

Additionally even for priority tests if the data in that EUA request is not supported to use, the data isn't good enough, we have an obligation at the FDA to decline an EUA authorization to protect the American public.

When we do receive a complete submission -- this is important -- with good data for a priority test we move quickly to authorize it as we have done this week with the authorization of another home test, Quidel QuickVue test. It is

by prescription right now but the developer has publicly stated that they intend to come in with an over the counter submission.

And we look forward to that submission as we do for any home test, home collection whether it be by our point of care test, whether it be by prescription or for the home test over-the-counter.

And so we do not sit on good priority tests that have complete submissions. We are committed to ensuring the public has access to a wide variety of test options and those most - in those reviews that we're doing now we believe do to this prioritization are the most critical ones needed to address the pandemic at this stage.

So at the start of the pandemic we have since the start of the pandemic we have authorized over 300 tests and almost 250 molecular tests, five home tests now, over 40 collection home kits. So this access has been very important.

Initially there's a concerted effort by the US government to invest in increasing production of select tests and supporting development of certain tests through the RADx program. I'd refer you to the RADx and other elements of the US government talk about their prioritizations.

We do believe this may in fact be a more effective strategy at this point in increasing testing capacity and access over a more broad approach to, you know, making all tests of equal priority shall we say.

If you have a question about determining whether a test that you have in development would be considered high priority review, we recommend that you submit either a pre-EUA or even just an EUA or just an email, either a pre-EUA or an email to our EUA template email box which is cdrh-eua-

templates@fda.hhs.gov with information about the features of your test in either a pre-EUA or an email as I've said.

It's helpful to have information about your intended patient population, the patient setting whether it's central lab, point of care, home collection or home testing, what it's throughput is, you know, on an instrument for a given shift with a single staff member in the lab and what your manufacturing capacity is. This will help us to assess how we would prioritize such a EUA request.

So that was in great detail. I hope that is all helpful for folks to understand our current priorities and why we're making those priorities and why we're making this clear now. Toby anything to add on that?

Toby Lowe: No, I think that was - that covered all of that, right?

Dr. Tim Stenzel: I do also want to make a couple of other brief announcements and then turn it back over to Toby for the rest of the call as I'm going to have to drop off again today.

The Abbott has now authorized - has now been authorized for a nine month dating on their Abbott BinaxNOW. There was some reports product in the field that may go out of date. Abbott has addressed this through a letter to customers on which you can reach out to Abbott about. Many customers have now received that I'm aware.

So all products that they've produced for the Abbott BinaxNOW from the beginning can now have nine month dating. Hold onto that letter if you're a lab. And should CLIA come in to inspect, show them that letter as far as whether or not it was okay to run a test kit that has an expiration date on it.

This letter supersedes the expiration date on those kit lots that are provided in the letter provided by Abbott, and CMS has signaled that they will review those letters, and if the kit lot that you're using is on that list and you're using it up until the new expiration date you should be fine.

I also wanted to say that there is now an Ebola outbreak in Africa, that there is testing going on upon entry to the US from certain locations outside the US. We do have still, the emergency still is declared for Ebola and we do have ten EUA tests listed on the FDA Web site.

We also granted one De Novo test for Ebola and so just want to make that aware for all. And Tony I'm going - to I mean Toby I'm going to turn this over to you for continuing to answer questions on this call. Thank you.

Toby Lowe: Great. And I had a couple of updates as well that I can give now while we're on a break from questions and then we can jump back to the questions.

So Tim did already mentioned that this week we authorized the Quidel QuickVue At-Home home test. And that was an additional home test to add to the availability there. We've also recently authorized several home collection tests for direct to consumer nonprescription use. So those can be found on our Web site as well.

If you - if you're looking at that EUA table and you search for DTC, Direct to Consumer, those will all come up if you're interested in taking a look at those.

I also wanted to give a clarification to a point that was discussed on last week's call. There was a question regarding a comparative test for flu for use with or for validating multi-analyte SARS-CoV-2 tests. And so we just wanted to clarify that we do have recommendations regarding which flu test

should be used as a comparator. And we prefer molecular free tests that have been cleared in the last five years or at least that have clinical data from the last five years to ensure that those comparators are still testing currently circulating strains.

And if you have a question about an appropriate comparator you can reach out to the EUA mailbox and we would recommend doing this before performing your study to ensure that you confirm that you're using an appropriate comparator before collecting data. And with that I think we can turn it back to questions.

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

(Franco): Thank you Toby. So first I'd like to point out that her - our test probably at least in our opinion qualifies as a priority test because it's designed to be self-used at home and it's the pure naked paper strip. The closest one to it would be the one that you just approved by Quidel except Quidel's is by prescription. And our plan is to make it over-the-counter or DTC. And I wanted to ask you if you could tell if there is a difference between OTC and DTC? That's one thing.

The other point I wanted to make was that in - during all this time that we have been trying to get the validation taken care of we have had to identify new suppliers, new OEMs because we have some issues with the previous ones. And so we now have the ability to work with multiple suppliers, probably four or five at least which in terms of the production, you know, we're talking now tens of millions of tests that could be potentially made available, you know, should we be able to complete the validation.

And my next point is regarding the analytical validation which we actually started going through with one service provider, but then we've run into some issues. So then we had to go back to the drawing board working with a different OEM.

And it turns out that this OEM that we are working with says that they can provide the analytical information required by FDA. I'm referring to the molecular interference, I'm referring to the endogenous effects, you know, the hook effect and all that, all those requirements.

The OEM is based in China okay. And the question related to that is would FDA be amenable to looking and not only that but actually accepting the analytical information that is provided by the OEM related to that?

The other question I have is regarding the reporting component. When we go through the usability studies does FDA want us to go through the complete reporting process or do we stop it at a simulation level? Do we actually have to - I hope my question makes sense.

So what I'm asking is if we actually have to report the results of the usability study in the way that a person would do if they actually got a test once we got EUA?

And the final one -- and I am sorry -- this is a lot. I know that there has been a design-a-thon going on which was I believe funded by HHS. I wonder if you have any resources for the companies that have been chosen in that design-a-thon so that maybe we can contact them about the reporting component? Sorry if I asked you too many questions there.

Toby Lowe: That was quite a few questions. I will try to address each of those points as best as I can. First regarding DTC and OTC that's - we've tried to use that terminology to make a distinction between home test and a home collection test. So over-the-counter or OTC and direct to consumer or DTC are both nonprescription. They are, you know, by regulation really are - these are, you know, EUAs but OTC is the official term for what we...

(Franco): Okay.

Toby Lowe: ...use for nonprescription. But most people think about OTC as something that you, you know, can purchase, bring home and use completely at home. So we've mostly been using OTC to refer to those at home tests...

(Franco): Okay.

Toby Lowe: ...whereas direct to consumer or DTC we usually use when we're referring to a home collection test where the collection is done at home but you need to send your sample to a lab for processing. So it's not performed fully in the home the way that, you know, a strip like it sounds like yours might be.

(Franco): Okay. Right, okay.

Toby Lowe: You had a - I didn't fully understand your question about multiple suppliers and but I know you've mentioned analytical validation from China. As long as it's properly validated or sorry, it's properly documented, you know, there's - and the data looks appropriate we can accept that. We do prefer that the clinical data, especially usability data is done here in the US.

(Franco): Of course.

Toby Lowe: And in terms of usability we do expect to see for an over-the-counter test we would expect both usability and user comprehension to be provided.

(Franco): Right.

Toby Lowe: And I don't have information about the HHS design-a-thon that you - I would suggest reaching out to them directly.

(Franco): Okay so just one further question regarding the reporting part of the test. So again this, you know, our test is for self-use at home. So if we're talking about the reporting component I don't want to get into technical but do we, when we do the usability do we actually have to go through the entire process? We have to complete the reporting meaning that the reporting does go all the way to wherever it needs to go just as if a user was actually purchasing an EUA approved test or how far do we take the reporting in the usability exercise?

Toby Lowe: Are you talking about reporting that the...

(Franco): The result.

Toby Lowe: ...results to the individual or...

(Franco): Yes.

Toby Lowe: ...report it to public health?

(Franco): Well the reports of the individual test, because my understanding from previous calls is that FDA recommends tests that do have some reporting capability.

And I also understand that it's not a must but I take the recommendation is that if the application has a reporting component that FDA would be more amenable to that application versus one that does not have a reporting component. So again do we have to take the reporting all the way to the finish line? Does that make sense?

Toby Lowe: You're referring to reporting it to public health authorities, not reporting...

(Franco): Correct. Correct.

Toby Lowe: That's something that we could work with you during your submission. It's not something that we have that we would hold off an authorization for. So that's something that we would work with you on.

(Franco): Okay.

Toby Lowe: We do want to see usability and user comprehension to the - at least to the point where the individual is getting their own result and understanding their own result.

(Franco): Okay very good. Sorry for taking so much of your time. Thank you.

Toby Lowe: Thanks.

Coordinator: Thank you. As a reminder to ask a question please press Star 1 and record your name clearly when prompted. Our next question comes from (Kathleen Copeland). Your line is now open.

(Kathleen Copeland): Hello. We're developing a point of care antigen test using saliva collection. And we're - and the test is very quick and is expected to be high throughput. So my question is around the saliva collection device.

So if we do this test, you know, with under CLIA waiver at sites like airports or offices or something like that where maybe there's a line of people waiting to submit their sample, what is the level of supervised - supervision required for sample collection?

So in other words can we give the collection device to somebody standing in the line waiting to deposit their sample and then as long as the healthcare worker tests the sample, looks at the sample to make sure that there's enough to do the testing, is that sufficient or is part of the EUA do we have to do additional testing in the clinical study?

Toby Lowe: So we would want to see your test validated the way that you intend it to be used. So if you intend it to be used for unobserved self-collections then we would expect your validation to be done in that same circumstance. And so then...

(Kathleen Copeland): Okay.

Toby Lowe: ...that would be, you know, that would be sort of up to you and up to the performance of the test of, you know, whether it's impacted by those conditions and whether or not anything needs to be adjusted to get appropriate performance.

(Kathleen Copeland): But would we have to do more than 30 people net positives and 30 negatives? Would we have to do different age groups or can we just do all comers?

Toby Lowe: You know, I don't have the template up in front of me so I don't want to misspeak on that. But I believe that the template does outline what we would want to see in those studies. And if you have questions beyond what the, you know, for your particular circumstances beyond what the template says, I would suggest sending that into the mailbox or submitting a pre-EUA rather if you want to discuss your study design. But generally the recommendations for study designs that are in the template should be applicable.

(Kathleen Copeland): I guess then my question is which template because for POC we just need to follow the antigen test blood for test developers right, not the one for non-laboratory use?

Toby Lowe: That's correct. We would want to see, you know, the additional point of care consideration for in terms of usability. But you would not need to do the non-lab additions if you're planning for it to be used at the point of care.

(Kathleen Copeland): Okay thank you.

Toby Lowe: Sure.

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

(Andrew Louia): Hi Toby, good to talk to you again. We have a number of people who we're talking to who are interested in submitting some point of care tests. And we have just kind of a general question in terms of prioritization for you here which is that they're interested in doing something I know a number of people have done where they put in a more simple EUA submission first that's just

for high complexity lab use. And then they want to update the EUA later with the point of care or home use or whatever the claim may be.

So in terms of how prioritization might impact that if they notify and it's kind of not a high priority and they're not assigned a reviewer right away, when they then get everything together for point of care or home use or anything like that and submit that update does that automatically bump it up the priority list or might it get stuck in limbo?

Toby Lowe: That is an interesting question. I would suggest that - so I mean yes, it would bump them up in priority. It may not be picked up right away, you know, that it's - it may not be obvious to our process right away that that is the case and so you may need to, you know, particularly flag that you'd like it to be reconsidered for prioritization.

You know, generally if a test is designed to be used at the point of care it's not going - it's not likely to have as much usefulness in high complexity setting because it's usually not designed to be, you know, high throughput tests that are high complexity lab might find use for.

So it's, you know, we have found in working with developers that it's usually more beneficial to focus on getting all of the point of care testing, you know, fully flushed out and ready and then submitting a, you know, fully completed submission for the actual purpose that you are intending. It does, you know, sort of confuses things to submit it for one use when you don't really intend it to be used there and then update it later.

Coordinator: Thank you. And our next question comes from Shannon Clark. Your line is now open.

Shannon Clark: Oh hello, Shannon Clark with UserWise Consulting. so we do a bunch of home use for OTC or prescription only testing with intended users. And there's a requirement in the nonlaboratory template to use users with no experience with self-collection.

We're sensing a problem here in the Bay Area California because now all the adolescents are going back to school and they're required to self-swab twice a week in order to go back to school. So recruitment of adolescents is getting more and more difficult as the days go by.

And now the intended users basically all have experience with self-collection so it would be a little odd to just try to self, just select and cherry pick the homeschooled adolescents who have no experience. So do you think the FDA might change their position on this requirement to have individuals with no self-collection or can we at least reduce this - the requirement to individuals with no experience with anterior nares in the case that we're pursuing that swab?

Toby Lowe: That's an interesting situation that I think we may need to have some further discussion about. If you could send that question in and flag it for me, I - we can have some further dialogue on that.

Shannon Clark: Thanks so much.

Coordinator: Thank you. And I believe our next name was (Zach). Your line is now open. Sorry I did not get your name completely. I believe it was (Zach O'Keefe), but your line is now open.

We'll move on to our next caller. The next question comes from (Seth). Your line is now open.

And check your mute feature. (Seth) your line is now open. You may ask your question.

Not hearing a response we'll move on to the next question. It comes from (Nancy Rector). Your line is now open.

(Nancy Rector): Hi. Can you hear me okay?

Toby Lowe: Yes we can.

((Crosstalk))

(Nancy Rector): Okay great. I do not have a question. I have an answer for the individual that asked about the design-a-thon. My company U Do Test is part of - is one of the 16 companies in the design-a-thon and we do definitely have a software - our aspect is a software that connects the patient demographics and information to HHS and to state authorities. So is it okay if I provide an email address for that individual that was looking for some entry into that - the group, the HHS group?

Toby Lowe: Sure.

(Nancy Rector): Okay so they can email us at partners PA-R-T-N-E-R-S@udotest, U-D-O-T-E-S-T, udotest.com and we'll get back with you as far as assisting you with developing that software and getting you introduced to each of the companies.

It's a great network and I am very impressed with what they're doing what HHS has done and I'm very impressed with what you all have done. I've been

in the industry for a couple of decades and you all are doing a great job so thank you.

Toby Lowe: Thank you. I appreciate that.

(Nancy Rector): No problem, that's it. Thanks.

Coordinator: As a reminder to ask a question please press Star 1 and record your name clearly when prompted. Please ensure your line is not muted. Our next question comes from (Komudi). Your line is now open.

(Komudi): Thank you for taking my question. Toby I have a request. This call initially also there was some technical difficulty and in-between I got disconnected. Is there any way that Timothy's and your statement that was read that can be posted instead of us waiting two weeks for the transcript to come?

Toby Lowe: I don't know that we can get anything up separately from the transcript, but the transcript will be posted as soon as it's available and we'll try and get that up quickly.

(Komudi): But it is not recorded, I would like, you know, document that he read that we will just - because I just when he was talking about the priority of something like that, I got disconnected and I did not get a chance to hear the - what is that statement that he read, is there a possibility of making that statement available?

Toby Lowe: Oh no, it was not a written statement. But we did, you know, provide some information and it, you know, basically it will be in the transcript, but information about the prioritization as we've discussed before in some of the factors that we consider.

(Komudi): Okay thank you.

Toby Lowe: Sure.

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

(Scott Turke): Hey thanks for your time and appreciate you doing this. My group has licensed a couple new technologies which is rapid testing for COVID. And it is based on protein synthesis that we have patented out of two universities that were funded by an NIH and the RADx grant that result less than five minutes and I can produce it less than one minute.

The thing that I'm wondering is we've also developed technology that where we can put a QR code on it so if they're buying an off-the-shelf at Walgreens, Walmart -- wherever else it is -- it will actually tell the patient as to whether they're positive or negative and report to the appropriate authorities.

The thing that we're doing right now is working with Indian Health Services but my challenge is getting this thing to market right now. And I'm wondering what is the priority as far as looking at tests that I've licensed that are NIH and RADx funded versus other tests by other groups because I think the vaccines are going to come out and everything else but we're still going to need testing and especially in indigent populations.

Toby Lowe: Sure so it sounds like this is a test that you would be indicating or seeking out claims for over-the-counter, you know, rapid home use -- something along those lines. And so that as we said would be a priority. It sounds like this may be, you know, a newer technology so I would suggest that you submit a pre-

EUA so that we can discuss that with you and make sure that when you submit an EUA request it includes all of the information and all of the validation data that we would want to see.

You mentioned licensing this and so, you know, one thing to look at there is whether this is also something that another entity is seeking to get authorization for if the manufacturer themselves is coming in.

It's much easier for us if there's a single entity that is coming in for authorization for specific technology. And then when authorized they can request, you know, additional labeling to be included in the authorization for different distributors with different brand names if that's something that the manufacturer is looking to do to license it out. But it is...

(Scott Turke): Yes. And we're...

Toby Lowe: ...much simpler...

((Crosstalk))

Toby Lowe: ... with a single submission.

(Scott Turke): Well and that's what we're doing from the whole stream of flow is when licensing the technology which results in I can manufacture for less than a buck and probably get to the retail market for five bucks for airports, mass transit, schools and everything else.

But we've also built in software to where when you buy it off the shelf at Walgreens, Walmart or anything else is that you take a picture of the result and it tells you coming back with 99% validity as to whether the result is

correct or not. But two is it automatically sends results to the reporting agencies. Do I need to...

Toby Lowe: Yes...

((Crosstalk))

(Scott Turke): ...sit there and do an EUA...

Toby Lowe: ...so we would want to see...

(Scott Turke): ...on the software as well?

Toby Lowe: ...validation. Yes, we would want...

(Scott Turke): What?

Toby Lowe: ...to see validation of that software for the reader if it's interpreting the result for the patient. We would want to see...

(Scott Turke): Yes.

Toby Lowe: ...validation for that.

(Scott Turke): Okay so I'm fine...

Toby Lowe: But we would want...

(Scott Turke): ...with because I've been in the FDA for a long time as far as the validation on the studies as far as the validity of the test. But that's what I'm wondering is

because my vision is you buy this thing off of a shelf in a pharmacy and for less than five bucks you also get the software that comes to it that does the reporting and gives you a validation and an authentication letter that like if you want to travel or anything else because it's 92% to 95% sensitive.

So do I have to sit there and do in EUA on the software and the test or how do I combine those two together because we brought the technology to the test, you know what I'm saying?

Toby Lowe: So you - we would, you know, as I said I would suggest that you submit a pre-EUA because it does sound like we would want to discuss the approach with you. And then we could figure out the best pathway there. But yes we would need to see an EUA for this - the software with the test.

Coordinator: Thank you. As a reminder to ask a question please press Star 1. Our next question comes from (Franco). Your line is now open.

(Franco): Hi Toby. Thank you again. So I actually had a related question to the reporting again. So regarding the data how long do we need to maintain that data? As a, you know, as a test developer how long do we have to keep that and where do we submit it?

Do we have to submit it to some authority from time to time? Do you have anything on that because as of now there's only one test right? it's the Ellume test that is 100% home use, not prescription. So it's really hard to go and look at what others and are doing, you know, to kind of, you know, follow the same path if you will.

Toby Lowe: Are you talking about reporting out to public health authorities or...

(Franco): Yes, yes, yes, yes correct, sorry yes.

Toby Lowe: Okay. I'm not going to unfortunately be able to answer your question about how long to store data. I'm not sure that we would expect the individual data to be going back to the manufacturer so that's something we would have to discuss with the reporting experts. If you send in your question to the mailbox we could connect you with the folks there.

(Franco): Okay thank you.

Kemba Ford: Hi. Thank you.

Coordinator: As a reminder...

Kemba Ford: This is Kemba Ford and we appreciate your thoughtful questions during today's town hall. Today's presentation and transcript will be available on the CDRH Learn Web page at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Friday the 12th. If you have additional questions about today's presentation please email [cdrh-eua-templates@fda.hhs.gov](mailto:cdrh-eua-templates@fda.hhs.gov).

As we continue to hold these virtual town halls we definitely 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](http://www.fda.gov/cdrhwebinar).

Again we apologize for the technical difficulties during today's Webinar. We will work behind the scenes to make sure that next week's town hall will start on time as scheduled. This concludes today's virtual town hall.

END