

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

**Moderator: Kemba Ford  
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12:15 pm CT**

Coordinator: Welcome and thank you for standing by. Today's call is being recorded. If you have any objections you may disconnect at this time. All participants are in a listen-only mode until the question-and-answer session of today's agenda. To ask a question at that time you may press star 1 and clearly record your name for question introduction. I would now like to turn the call over to your host Kemba Ford, thank you.

Kemba Ford: Thank you. Hello. I am Kemba Ford of CRH's Office of Communication and Education. I'd like to welcome you to the FDA's 38th in a series of virtual townhall meetings to help answer technical questions about the development and validation of tests for SARS CoV-2 during this public health emergency.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health and the Office of Product Evaluation and Quality and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, both from CVRH will provide a brief update. Following opening remarks we will open the line for your questions related to the

development and validation of tests for SARS CoV-2. Please remember that during this townhall we are not able to respond to questions about specific submissions that might be under review. Thank you and I'll now turn the call over to Tim.

Dr. Timothy Stenzel: Hello everyone and welcome again to this continuing dialogue. It's a new year. I certainly hope that this is a much better year for us due to our combined efforts than the last year. So we look forward to assisting the development of new products that can play a key role in the pandemic.

We were busy over the holidays. If you remained aware we had a number of authorizations that happened and that has carried into this week. One authorization that's a little bit unique is we did authorize the first antigen dipstick assay. So this is a simple strip that goes down into a test tube. It's authorized for point of care. There's been a lot of interest in the, you know, very inexpensive tests. And this antigen test doesn't even have a test cartridge around it.

So hopefully this adds to our arsenal. That is the Quidel QuickVue SARS test and, you know, joins the Abbott BinaxNow as a very, very simple, non-instrumented antigen test. And it's just one example of the many awesome products that have been developed during the pandemic to meet our needs. And it's I think a little bit unique in that it can really drive down the cost of the results and because it's a rapid antigen test it can be produced in high volumes as you might expect just like the Abbott BinaxNOW.

And there are great other antigen tests. I just know that there's huge public interest in driving s down that's why I highlight that one. We of course want to continue just to make clear what our priorities are. They're focused on those things that can have the greatest public health impact. So home tests,

home collections, point of care tests and super high volume central lab tests. All, you know, primarily the diagnostic tests but obviously we look at serology tests as well.

So, you know, these are our priorities. And if an application comes in and it's complete and picks one of these boxes, we will make it a priority to give you feedback as soon as possible and try to authorize these tests as soon as possible.

We do continue to ask that the submissions are complete. That they're well written and clear so that our folks can rapidly assess the submission. We also need Why Missing data submitted in a common spreadsheet so that we can look at the data very quickly. We don't have to ask for this because we will ask for this. And really it's considered incomplete unless we have that Why Missing data which should have the results plus any demographics of the candidate test plus the comparative tests in enough detail.

We also want to see your protocols for your clinical examination study - important and a detailed one. It's important to know how you selected samples, how you collected samples, how you tested samples, how you did the comparator assay. These are all really important questions. And we really can't make our assessment without them. So it only slows us down if we don't have complete information about these things.

I did want to also talk about another hot topic and that is mutation. So we're all aware now of the UK variant mutation and it's a concern in the U.S. and we've seen a handful already confirmed. And then also the South African variant which has some overlapping mutations but also some clear differences between the South African variant and the UK variant.

Both of these variants appear to be of higher infectivity due to the viral mutation with enhanced binding to the receptor and that's the theory at least. There's some pretty good evidence for that. Some of them may also have increased amounts of virus and then also greater binding to the receptor obviously can lead into a greater impact.

So it's important to understand the variants that are circulating. We do have an interest in sequencing-based tests that can provide a whole genome sequence. Of course we've already authorized at least one such kit. That's the Illumina Kit. It is authorized and has within it reagents to sequence the entire genome. And that's been a great step forward that we authorized quite a long time ago before we really knew how important the mutations would be.

The other thing that the FDA has been doing is on a regular basis of course with all applicants especially for the molecular assays we've been asking them at least twice during the authorization process to check the known sequences of variants and explain any challenges with their primer and probe sets that we have with those variants that are in the database.

In addition the FDA has bioinformatics capability. We have the list of all EUA authorized primers and probes for molecular assays. And we have been interrogating the sequence databases to see if there are any mutations that could impact test performance. We have done this for the UK variant. We have done this for the South African variant. And we have done this prior to these variants for any variant that's seen in the database that was at 5% of the sequences in the database or above.

In all cases we reach out to the test developers. We ask for their assessment of the impact of these mutations on the performance of the test. We do our own evaluation of what we anticipate might be a significant potential

performance alteration. And work with the developers to assess the potential impact. As soon as all that work has reached a point where we feel like it's important to share any information with the community we will. And what I can talk about today of course is publicly known that the UK variant there's at least one test out there that has been publicly mentioned that's the Thermofisher Attack Path Assay that has S gene dropout.

So with S gene dropout we have looked at a number of variants in the U.S. database and a number of sequences. And the majority to date do not have all of the UK variant mutations. What that means exactly we're not sure yet. But only a subset right now in the U.S. have - of the S gene dropout by Thermofisher have that. We believe that around 5% of the Thermofisher positives have an S gene dropout. But again as I said we think the great majority of those to date have not carried the UK variant mutation.

So for the time being at least sequence verification of S gene dropout samples is something that we would recommend. Hopefully you have access to sequencing. As I mentioned there is an EUA authorized sequencing assay from Illumina that can suit this purpose.

Also you can reach out to your state and local public health labs and they may or may not have a sequence capability. Some of them do and/or they can guide you in what is the best process to assess this. If you're a public health lab the CDC has asked that those isolates, those samples be sent to the CDC for sequencing. And so follow the CDC procedures and, you know, I would refer the public health labs to the CDC for any further questions on that.

Obviously there are assay design issues that could be impacted by mutations particularly if an assay is a single gene target assay. And there are a number of single gene target assays that we have authorized. So it goes without

saying that multi-gene assays are going to be less impacted by mutations as they continue to propagate in this pandemic. And will have an advantage over single gene target assays. Some technologies don't lend themselves well to multi-gene targets. We understand that completely. There's nothing wrong with the single gene assay. However there is a little bit more pressing need to understand, you know, how variants might impact performance with single gene assays.

With the Thermofisher assay it is a 3-gene target assay and with S gene target dropout you can still detect positives by the other two targets. So we don't know as of now that there's any significant decrease in test performance of the Thermofisher assay. And for the moment at least it's a very helpful assay to identify potential S gene dropouts that could be the UK variant as we try to assess whether spread is continuing within the U.S. of the UK on variant.

Moving onto antigen tests. Obviously there are mutations in the targets for antigen tests as well. It's a bit more difficult to assess the impact on antigen tests because we can't just simply look up sequences and primers and probes and identify whether there could be an impact on antigen tests. So the CDC has graciously agreed at least for the UK variants which they are now culturing to test the EUA authorized antigen tests at the CDC for their ability to detect the UK variant.

So we will be reaching out to all of the EUA authorized antigen tests and asking them to send their kits. I think we need to be looking at 75 to 100 test's worth to send to the CDC because they do multiple levels and multiple replicates even for just a single variant such as the UK variant. So stay tuned with your EUA authorized antigen test and we will be reaching out to you with more information shortly.

And finally I did want not mention serology tests. Obviously they can be impacted as well. And we will need to await the availability of immune serum or plasma from certain variant patients in order to assess the impact on serology. We have put requests out already for such samples. Obviously and thankfully at the moment there aren't that many in the U.S. of the UK variant and the South African variant. But if they do become more prevalent we expect to be able to access immune plasma or serum to assess performance in serology tests.

And again antigen and serology tests are a little bit more difficult beasts to handle when it comes to assessing their performance with variants but we'll do our best here given the limitations of biology and science.

I don't believe I have any other preliminary remarks. So let's go ahead and open this up to questions and we look forward to that, thank you.

Coordinator: If you'd like to ask a question at this time you may press Star 1 and record your name clearly. Our first question will come from (Wendy Strongen) your line is now open.

(Wendy Strongen): I had a question about what the template says for point of care studies. And it says that in addition to studies with 30 positive and 30 negative samples there should be a study with 5 to 6 untrained users with 3 positive and 3 negative samples showing that they can perform the test just following the test instructions. My understanding is that those three positive and negative samples could be contrived swab samples. Is that correct?

Dr. Timothy Stenzel: Toby do you know the answer to that about contrived? I know we probably prefer pressure frozen samples for that.

Toby Lowe: Yes I'd have to look at the template to be sure.

(Wendy Strongen): Yes I don't believe...

Dr. Timothy Stenzel: I would ask that you send that question into our template email address box and we'll give you a fast turnaround on that...

(Wendy Strongen): I actually did send it in...

Dr. Timothy Stenzel: ...as accessible as possible to get more and more point of care tests authorized. And...

(Wendy Strongen): I actually did send that in already and I got an email back saying that was beyond the scope of things that could be sent in for questions. But I will send it in again.

Dr. Timothy Stenzel: Ask for - ask that Dr. Stenzel and Toby Lowe get copies. At least send it in. I apologize.

(Wendy Strongen): Okay thank you very much.

Coordinator: Our next question will come from (Isha Varilee) your line is now open. (Isha) please check your mute button. Again please check your mute button. Okay our next question will come from (Christine Shun) your line is now open.

(Christine Shun): For reporting purposes what CT cutoff would be appropriate and would it correlate with infectivity?

Dr. Timothy Stenzel: Can you explain your question a little bit more? Are you developing a molecular assay or using a molecular assay as the comparator?



(Christine Shun): Using a molecular assay as a comparator for a rapid antigen test.

Dr. Timothy Stenzel: Okay. So what we ask is that you use the EUA authorized comparator test as its developed and that you report all results to us in alignment. We are not using a CT cutoff or some sort of infectivity cutoff because in fact CTs vary widely. For rapid antigen tests we have seen CTs as high as 40, four zero, in the first five days of symptoms. And exactly why that happens, don't know yet. But we very clearly see a healthy or an unhealthy number of high CT results in the first five to seven days of symptoms. And so we feel it's important that when someone has symptoms that we know the true performance of the antigen test.

Now we do recommend that direct antigen tests - that their inclusion and exclusion criteria for their clinical study appropriately. We don't really expect the antigen tests are going to perform well after five to seven days depending on the test. Some tests do a little bit better than that. The bulk of tests have been authorized in the five to seven-day symptomatic period. And we want to understand symptomatic people who are confirmed positive to be SARS positive, you know, what is the detection rate of those people with the antigen test.

(Christine Shun): Okay. And for clinical validation as a screening test, what is the recommended minimum number of positive and negative PCR cases?

Dr. Timothy Stenzel: If you're going for a screening claim -- an asymptomatic screening claim - and if you're doing it as your first and only study, then I believe you need 30 positives. If you're adding it there are a couple of different options for you whether you're adding it to an already authorized test or you are doing it in line with seeking your first EUA authorization. We have a minimum I believe

depending on the pathway at 10 positive asymptomatic patients premarket or preauthorization.

If you're doing this with an antigen test I would recommend that you perform a study that will maximize our understanding of your true performance in the asymptomatic population that makes sense. So as I said antigen tests are at their peak performance in the first five to seven days of symptoms. Virus peaks - virus levels and shedding peak in that - typically peak in that window. And it may be, you know, earlier on in that window than later on in that window.

We really, you know, know that after a week of somebody shedding the virus that antigen test performance will fall. And, you know, whereas a molecular test may be very - a good molecular test may be, you know, quite positive after 14 days. But, you know, well beyond perhaps the days of symptomatology if someone would be having symptoms.

So sort of the best study design that will give you the best chance for showing excellent performance with an antigen test will be to link up with one of the serial testing programs. There's many on college campuses, maybe in workplaces, maybe in schools. And, you know, screening at a minimum say of every week with a molecular comparator that can be used for the comparator of record for your asymptomatic study.

And you can enrich, you know, so you can wait until somebody identifies positives with that screening program. You can contact the individuals and see if they're willing to test with your test. And then we'll also want you to throw in an equal number at least of negatives to keep everybody honest. So that's probably the best way to enrich for asymptomatic at levels of virus level

that we expect to see the antigen tests perform well in. I'll pause there in case you have any questions about that study design.

(Christine Shun): Thank you for all of that information. I will take that back.

Dr. Timothy Stenzel: Okay you're welcome. There'll be a transcript of this that will be posted as soon as possible usually by Monday following for those who are interested, thanks.

Coordinator: And as a reminder if you'd like to ask a question please press Star 1 and record your name clearly. Our next question will come from (Corbin Vencut) your line is now open.

(Corbin Vencut): Good afternoon. Thank you for taking the call. I just wanted to I think Dr. Stenzel mentioned about the priority of different tests. Do you mind if you can just tell the priority once again? I missed when you were talking.

Dr. Timothy Stenzel: Oh yes just briefly. Point of care tests, home tests, in-home collection are primarily focused on diagnostic tests. So those would be molecular and antigen tests. But we will also make serology tests in these categories a priority. And then high throughput central lab testing that can really help drive down turnaround times for test results. These are usually on automated platforms or automated systems and those are the priorities.

(Corbin Vencut): Thank you. So as far as the serology now that vaccination is getting implemented do you - I mean what does your office and the FDA think about the serology test in vaccinated individuals with the infection? Do you have any thought and guidance that you can share with us?

Dr. Timothy Stenzel: Well first of all vaccines are reviewed by a different center. They are reviewed by CBER - C-B-E-R. And I would refer any questions you might have to them as well.

The data needed to show that serology can be predictive in any way would be important for us to be able to review for any submission related to vaccine. There is no prohibition in any of the serology tests that we've authorized for use by clinicians to try to assess them. But we do always urge caution because we have not authorized any serology tests for use with vaccines for any purpose either to determine whether a vaccine is needed or determine if a vaccine has taken effect and provides any sort of immunity.

In fact we haven't even authorized the serology tests around an immunity claim. We have authorized semi-quant serology tests and a neutralizing antibody serology test. Those perhaps could be more useful in assessing at least the question of immunity not necessarily that anybody can use them right now to declare immunity. That would be something that I think would be a bit dangerous right now.

(Corbin Vencut): My question is similar to what you were mentioning about the variants when you have - you were telling, you know, you are going to look at the serology test how in the variant how they are performing. My question is the people who got immunized in those people how the serology tests will perform and will it give a false-positive? I'm kind of asking in that context rather than looking at the immunity level.

Dr. Timothy Stenzel: Yes I mean I think your question is if somebody gets a vaccine can you tell if they've developed antibodies...

(Corbin Vencut): I'm not asking that.

Dr. Timothy Stenzel: We have not authorized the test for that. To get authorized for that purpose to allow marketing would require, you know, a potentially significant study, you know, in conjunction with the vaccine study or trial. So we're open to developers who want to pursue this. We would ask that you draft a clinical study plan and send it to us and we would assess its ability to answer the question and allow an authorization.

I do believe these are going to be very significantly large studies. And, you know, it's a bit dangerous for the FDA to say oh you've developed antibodies and the vaccine and now this is what it means you know? And so developing antibodies to a vaccine is potentially very similar to developing antibodies to the actual SARS infection. So, you know, but if someone who wants to pursue, a developer wants to pursue specific claims we're open to looking at the design. We would review this in conjunction of course with CBER.

Coordinator: And our next question will come from (Teresa Hermietch) your line is now open.

(Teresa Hermietch): Yes thank you so much for taking my question. My question is regarding the use of controls. Does FDA have any recommendations regarding the use of endogenous or exogenous controls for using an antigen test?

Dr. Timothy Stenzel: An antigen test. What kind of exogenous control?

(Teresa Hermietch): We are in the process of developing so I just need a general guidance. If there is a guidance document or recommendation as to how we should be looking at controls for antigen tests.

Dr. Timothy Stenzel: You know I mean it's obviously nice to have controls especially endogenous control that could assess the quality of the sample. But it's not a

requirement for EUA authorization. We will assess test performance without such. The only requirement regarding such controls or the only recommendation for controls has been to date with unobserved home collection samples. Where we just have no idea if a patient has self-collected a sample well enough for performance in an assay that doesn't have endogenous controls.

We have updated authorizations for some developers after they had already launched with an endogenous control and assessed performance in their home test looking at literally thousands of datapoints and have been able to back off on the requirement for endogenous controls in some cases. But for right now for a new developer with a new home collection we would like to see that data.

(Teresa Hermietch): Thank you. I have another question regarding the use of antigen tests for screening purposes because the current antigen test they have intended use claims for a certain number of days post onset of symptoms. If you are planning to develop an antigen test for screening purpose given the antigen test is normally most effective the first week or 10 days post onset, how does FDA look at the clinical trial and also samples that are being collected? Do they have to because this is for asymptomatic what would be FDA guidance in that regard?

Dr. Timothy Stenzel: Yes. One of the previous callers had that same question and I went into long detail on that. So I would recommend that you - I'm not going to repeat it here. I would recommend you look for our transcript that should come out on or about Monday next week of my remarks on this call. It does suggest an optimized study design that will give antigen tests the best possible situation to show excellent performance in asymptomatic patients.

(Teresa Hermietch): Thank you.

Coordinator: And as a reminder I'd like to remind each caller to ask one question throughout today's Q&A. And if you'd like to ask questions you may press Star 1 and record your name clearly. Our next question will come from (Wendy Strongen) your line is now open.

(Wendy Strongen): Could you comment on what are acceptable enrichment strategies for an antigen - a rapid antigen test and specifically would screening everyone coming to a COVID testing center for the presence of symptoms to COVID be an acceptable enrichment strategy?

Dr. Timothy Stenzel: This is people with symptoms or people without symptoms that you're looking for?

(Wendy Strongen): No we're looking - we want to get positives so people are presenting to a COVID testing center. Some of them have symptoms, some of them don't have symptoms. So in order to try to enrich to get symptomatic positives not for an asymptomatic claim we want to screen for people who have had symptoms in the last eight days or symptoms that started no more than eight days ago.

Dr. Timothy Stenzel: And is this for an antigen test or for a molecular test?

(Wendy Strongen): A rapid antigen test.

Dr. Timothy Stenzel: Yes. Well we might be amenable to that. I would send in, you know, a pre-EUA requesting the input on that. I don't think it's a particularly good study design. I'm just being honest. I mean the positivity rates out there are sky high. And, you know, you don't have to run a lot of tests in the clinics

that's seeing patients with symptoms to get your minimum 30 positives. And yes you'll have, you know, a number of negatives.

But unfortunately the virus is running pretty hot out there right now. And that kind of enrichment I don't believe is needed and there are some challenges. We have expressed flexibility for enrichment around asymptomatic testing just because to do this well for an antigen test I believe it should be a population that is serially tested as they'll give the antigen test the best opportunity to show its excellent performance in the first five to seven days of shedding a virus. But for those that have symptoms the virus is just, you know, hot out there.

But if you really want to pursue that send in a request for a study review and a pre-EUA and we'll look at it. I just don't - I don't know what our team is going to say and I wouldn't recommend it.

(Wendy Strongen): All right thank you.

Coordinator: Our next question will come from (Isha Varilee) your line is now open. Again if you called in from the line of (Isha Varilee) your line is now open. If you've pressed Star 1 to ask a question your line is open. Well then as a reminder if you'd like to ask a question you may press Star 1 to ask that question. Again to ask a question that would be Star 1. One moment please to see if we gather additional questions. And I'm currently showing no additional questions at this time. Oh there is a last minute question. Would you all like to take that or would you like me to turn that call back over?

Dr. Timothy Stenzel: Oh no we'll take that it, you know, we'll give some period of time after we have a last question for someone else to dial in up until the closing time. We don't want to close out the call so yes we'll take it.



Coordinator: And I believe that question comes from (Homer Pia) your line is now open.

(Homer Pia): Yes hello (Homer Pia). Just a quick question around the mutation UK. You mentioned that CDC has agreed to perform, you know, some testing there for existing EUA tests. And I wonder would that be also available for the developers that are in the process of their developing an antigen test?

Dr. Timothy Stenzel: So, you know, I think that there is the right timing to do that. It would probably be after the assays have locked down. There may eventually be live virus of the UK variant positive in BEI bank and/or irradiated or heme activated virus. There also are pseudo virus constructs you can make to assess on your own. But I think we don't necessarily want to inundate the CDC in early stage of development.

We're hoping that none of the antigen tests are impacted but it is important. And we'll get a good idea I think with the first tests we look at. Frequently it's the N gene that's targeted by antigen tests. And that probably is a bit more conserved in some respect than the spec protein, okay?

But once you've locked it down and you're going to come in with submission I would reach out and check the status of this situation because I think, you know, it's probably going to be beneficial for us to, you know, at this moment I would say it would be beneficial for us to know what the reactivity is of a developed test that's being evaluated through FDA for the UK variant. We each want to time that correctly in your development process.

(Homer Pia): Thank you very much.

Coordinator: And our next question will come from (Isha Varilee) your line is now open.

(Isha Varilee): Hi can you hear me? Hello.

Dr. Timothy Stenzel: Yes.

(Isha Varilee): Okay. You said my name before. You just didn't pronounce right. I didn't realize it was me. Anyways I thank you for having these townhalls they're really helpful. So we are developing a point of care, over the counter test that is meant for workspace, for work, for schools. It's a breath test. We sent - we submitted a pre-EUA in July in the beginning of July. And we were appointed a reviewer. We just haven't received any feedback on our questions. And, you know, it's been quite a while now and we really want to continue performing our validation study.

So is there any advice you could give on that? And just the end of that question is would this validation study that's appropriate for the EUAs could be appropriate for submitting a - for receiving a 510(k) clearance? Thank you.

Dr. Timothy Stenzel: So yes hang on the line a little bit. So if you reached out in July I don't know that we would have had prepared recommendations to share with developers. Did you get any information back when you reached out that we had prepared because I know we now have prepared at least a subset of recommendations for breath test developers?

(Isha Varilee): We have not received any recommendation for breath test developers. And we have tried to be in contact, in touch with our reviewer.

Dr. Timothy Stenzel: Okay. Well I apologize for that. Send an email back to the template email box and ask for Dr. Stenzel and Toby Lowe to be copied on the request and we'll make sure that you get feedback relatively immediately with those

recommendations and I'll look into why your pre-EUA has not been responded to.

(Isha Varilee): Thank you. Just to make it clear. Should I send the pre-EUA together to the template now?

Dr. Timothy Stenzel: Yes you can copy that. You can copy that again, you know, advise the...

((Crosstalk))

(Isha Varilee): After - and we rewrote it after you published the template in the end of July so I could put both versions there.

Dr. Timothy Stenzel: Okay yes that would be great. Make sure that your reviewer has both versions. But you can again send an email to the template team mailbox. Put both versions on. I'll make sure that you get the feedback that we can immediately give for those that are seeking to understand what our recommendations are about breath tests. And again I will look into the pre-EUA and either Toby or I will get back to you with an update on that.

I think you asked another question and I lost it. Could you re-ask the other question you had related to that?

(Isha Varilee): If we get the green light to go ahead with our clinical validation study - study design would that be applicable for a 510(k) clearance as well?

Dr. Timothy Stenzel: Oh yes. Yes, so, yes let me just talk about the transition a little bit from EUA to 510(k)s or De Novos if you're the first one in. And this applies to anything SARS related. And even for, like, some categories, like, molecular they'll be at the bare minimum. A single target SARS - a single virus assay,

like, SARS only category. And then there will be a panel category. Those each would be separate De Novo submissions.

Once a De Novo is authorized within one of the categories every follow on assay will be a 510(k) submission. For those developers who want to know about what is required for the - what is recommended for the conversion we are working on a guidance document that would be a draft at first. But it may not go into enough detail across the board for all EUA type products.

And so I have asked our team to draft some information that we can share with developers. Primarily it's going to be what is different about SARS from a standard say antigen in infectious disease, in a respiratory infectious antigen serology and/or molecular test. So our feedback is going to be focused on what's different because we're just swamped with work and submissions. And so we want to focus on the things that are truly different about SARS and our responses.

And then for, you know, the more common, factors for any of these categories of tests, you know, we would urge you to look at our recent decision summaries for De Novos and 510(k)s including any special controls for all the sort of commonly asked questions about a respiratory virus test. But we'll focus on the things that are different.

The other thing is there is - I do not perceive a need to rush to converting EUA. We still have so many EUA applications to process. And we get so many new ones every week. It's really, you know, an unprecedented volume and continued volume. And so our focus is really going to be primarily on getting the EUAs authorized. And, you know, until the emergency ends which I don't perceive this happening anytime soon, EUA submissions are going to be allowed, EUA tests are going to be allowed.

And even if it were to end at some point we're drafting guidance that will allow a very reasonable transition timepoint, a timeline so that there will not be something that we believe is unreasonable insofar as time goes to convert these.

But I do understand that, you know, we are going to ask more for conversion. And it probably is wise for all developers to start thinking about those conversions. And it leads to collecting the samples now when SARS is prevalent to be able to do those conversion studies if that's interesting and important to you to convert at the point where it's important to convert. So hopefully that answers the question.

(Isha Varilee): Thank you.

Coordinator: And our last question will come from (Alexis Sauerbudge) your line is now open.

(Alexis Sauerbudge): Hi thanks very much for taking my call. I had a question with regards to the CDC test and the current mutation. Do you have any indication or information that the CDC primers may be affected by any mutations that are circulating?

Dr. Timothy Stenzel: Yes I would, you know, to be formally correct in my answer I would need to check with the team. What I will say is that as soon as we have confirmed the potential impacts on a test whether it be molecular, antigen or serology, we will endeavor to make that information public as soon as possible. So certainly the primers and probes sequences for the CDC assay are published and people can look at, you know, mutations and see how they might affect those primers and probes. But I don't have anything to announce at the

moment about any test other than the test I mentioned before which was the TaqPath.

(Alexis Sauerbudge): Great, thank you very much. I appreciate it.

Coordinator: And that was our last question. I would like to turn the call back over to Kemba Ford, thank you.

Kemba Ford: Thank you. This is Kemba Ford. We appreciate your participation and thoughtful questions during today's townhall. Today's presentation and transcript will be available on the CDRH Learn Webpage at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by next Friday, January 15. If you have additional questions about today's virtual townhall, please email CDRH EUA templates at [fda.hhs.gov](http://fda.hhs.gov).

As we continue to hold these virtual townhalls we appreciate your feedback. Following conclusion of this virtual townhall please complete a short 13-question survey about your FDA CDRH virtual townhall experience. This survey can be found now on [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar). Again thank you for participating in today's virtual townhall. We hope that you will join us next week on January 13. This concludes today's virtual townhall.

Coordinator: This concludes today's conference. All participants may disconnect at this time. Thank you for your participation.

END