

**Virtual Town Hall Series - Immediately in Effect
Guidance on Coronavirus (COVID-19) Diagnostic Tests
Moderator: Irene Aihie
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11:15 pm ET**

Coordinator: Welcome and thank you for standing by. My name is Amber and I will be your operator today. Today's conference will be on listen-only until the question and answer session. At that time you may press Star 1 to ask a question. Today's conference is being recorded. If you have any objections please disconnect at this time. I know like to turn the meeting over to your host Irene Aihie. You may begin.

Irene Aihie: Thank you. Hello. I am Irene Aihie of CDRH's Office of Communications and Education. Welcome to the FDA 11th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS CV during the public health emergency.

Today Timothy Stenzel, the Director of Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, Sara Brenner, Associate Director for Medical Affairs and Toby Lowe, Associate Director in the Office of In Vitro Diagnostics and Radiological Health all from CDRH will provide a brief update.

Following opening remarks, we will open the line for your questions related to today's discussion. Please remember that we are not able to respond to questions about specific submissions that might be under review. Now I give you Timothy.

Timothy Stenzel: Good day. Thanks for joining us again today and apologies for the technical glitches. And we know that we'll have a number of folks probably joining over the course of this call. And we'll make sure that this is all resolved next week.

There will be a transcript from this call for the folks who couldn't join at the beginning. We can get updated and we endeavor to get those transcripts reviewed, edited for correction of the actual spoken word and out - back out to folks.

So just a high-level overview we've now authorized 120 (one-two-zero) diagnostic tests. We have also authorized 15 serology tests. When those serology tests have had testing performed at the National Cancer Institute as part of the Interagency Serology Testing Program that information while usually if not always be immediately available in the instructions for use section of the posted authorization for that serology test.

And then as soon as we are able to, we will launch and link the product-specific report from the NCI testing. So be on the lookout for those. But once serology tests has been posted and is authorized check the ISU for NCI data.

And then I also wanted to update that there are now 31 removed serology tests removed from the notified list. We have that removal is posted on our FAQ page. Next, I wanted to cover updates to the Abbott ID Now. Monday this week updates to the Abbott authorization ID NOW authorization were made.

Now formally as we previously announced negatives by the Abbott ID NOW tests are classified as presumed negative tests or negative results and as clinical situation warrants it is recommended that those negatives be reassessed to another molecular test.

In addition in the letter of authorization that is posted on our Web site for the Abbott ID NOW, there is an additional condition that includes a requirement for a formal post-market study that's agreed-upon with the FDA. And the time period in which that has to be performed and reported back to the FDA is also listed in that updated letter of authorization. So the FDA will be monitoring this and any other potential situations closely.

We always welcome input on performance of any of the tests that we've authorized or any other situations that you feel would be important for us to know about and we thank you in advance for that. With that, I will turn it over to Toby Lowe who has a brief announcement.

Toby Lowe: All right, thanks, Tim. Thanks, everyone for joining us today. We wanted to plug a safety issue that's come up as we've discussed previously, I think on these town halls and we've included in our FAQ on our Web site there are certain types of transport media that are not compatible with certain testing platforms. When materials that contain one of these guanidinium thiocyanates interact with bleach the resulting chemical reaction produces dangerous cyanide gas.

On our FAQs we have a warning about this specifically regarding the (Prime Store) MTM which contains guanidinium thiocyanate that it should not be used with a Hologic Panther or Panther Fusion System since those systems have a disinfecting step that involves bleach.

We've recently become aware that some transport media are being distributed without appropriate labeling which makes it difficult for laboratories to know which media they're using and what the ingredients are. Because this is a big risk, we want to make sure that all labs are aware of this issue and we're working with manufacturers to correct it. We're also working on providing further communications to laboratories about this issue.

So we want to make sure that labs are aware that the (Prime Store) MTM the Zymo DNA RNA Shield and the Spectrum Saliva Collection device, as well as any other transport media that contains guanidinium thiocyanate and similar chemicals, should not be used with the Hologic Panther or Panther Fusion System or with any other systems or laboratory processes that use bleach.

If there are any questions about this or if you come across any issues with transport media or come across any media that is being sent your laboratory without appropriate labeling, we would appreciate you coming to FDA and notifying us about those issues. And you can do that through the normal Medwatch process and you can also email us at the CDRH EUA templates email address.

Timothy Stenzel: Okay I think we're ready to open it up for questions.

Irene Aihie: Operator we'll now take questions from our participants.

Coordinator: Thank you. We'll now begin the question and answer session. If you'd like to ask a question please press star 1. You will be prompted to record your name. Please be sure to unmute your phone. Once again if you'd like to ask a question please press Star 1 and we'll pause for just a moment to allow those questions to start coming through. Our first question comes from (Val). Your line is open.

Val: Hi Dr. Stenzel. I have a question for you and your colleagues. In regards - is there - sorry. I just (unintelligible) an FDA guidance in regards to a pathway for 510K for serological assays? Here at (Boca By) we're supporting companies and what we're doing is redoing collections of samples from COVID positive patients and want to see was there any particular time point that you could recommend as far as like getting patients who are acute all were through convalescence, were there specific time points whether it's 14 days posted from onset, 28 days and then 60 days post from onset? I wanted to get your feedback on that as well as what would be a considerable number in regards to number of subjects that would be significant in regards to these 510K case studies.

Timothy Stenzel: Are you familiar with our Q sub-pre-sub constants?

Val: Yes.

Timothy Stenzel: Okay great. So this is a great question and a timely question. The first type of test that comes through for COVID or sorry, COVID-19 and SARS CV-2 that comes to us for our routine normal authorization will of course likely be a de novo and likely be classified as Class 2 with special controls. So that means the first one comes through the de novo, the subsequent ones would come through with 510K.

We are going to follow our usual and routine manner in processing these when they are converted to a normal submission from (EUA) submission and include our normal expectations from performance evaluation all of the clinical and analytical studies and all the ancillary requirements of those submissions.

We are recommending or we are suggesting I mean it's very wise to come in with a pre-sub or a Q sub especially in the early stages or in - for those who are coming in first. That is a process by which Q subs or a pre-submission process

and there's a link on our Web site that perhaps if it's not already on one of our related Web sites we can post it up there so that it's really easy for developers to see this.

So the process is first of all it's not required but it is obviously probably a very wise thing to do because to just study or ask questions for this normal submission process. And then that will go into the experts on our team and we'll assess those questions or our protocols and provide very specific and timely feedback back to the developers. So I think even for you who are advising others and are trying to learn about this I think that's a useful way for you to approach us as well.

But then we just use specific documented feedback that it's our practice to adhere to that once we've given written feedback back to a sponsor or somebody who comes in with a question you have that documented and established with us so that you can rely – you can have good assurance or expectation that you can rely on that information that we provide in a written form.

Val: Thank you very much. I appreciate the reply. Thank you.

Timothy Stenzel: You're welcome.

Coordinator: Our next question comes from (Susan Sharp). Your line is open.

Susan Sharp: Hi. Thank you again, FDA, for everything that you're doing in this time. It's very helpful to all of us. And I was just wondering if you could tell us and I know Tim you said early on the phone call today that the Abbott ID NOW should be reported out as a presumptive negative. Can you tell us where we can find that wording in the FDA FAQ? I was looking yesterday and could not find

it. Has that been added?

Timothy Stenzel: So that is not in the FAQ it is in the Authorization Page. And since I didn't specifically mention this particular test in my open now, I will answer about the specific test, but usually we don't. But that would be present on our FDA New Way Authorizations Page.

If you go to the avid ID NOW document and you look at (lease) Testing Instructions For Use link you will have that updated instructions for use, intended use statement and any - and I believe it's also in the limitations portion of that new ISU as well.

Susan Sharp: Thank you.

Timothy Stenzel: You're welcome.

Coordinator: And next we'll go to (Michael Campbell). Your line is open.

Michael Campbell: Hi. Thank you. I was just wondering if you can give me an idea on the general timelines we can expect for reviews of the EUA submission? I understand from a previous town hall meeting that basically on receipt there's basically an intermediate for completeness review and in contact with the submitter.

I've been submitted for four weeks now and I have not heard one word other than a reviewer has not been applied. As soon as we do that, we'll let you know. You know, it doesn't really line up with an emergency if you ask me. If you could just give me some guidance so I understand what to expect in terms of timing that would be great.

Timothy Stenzel: So we have obviously received a large number of applications.

Michael Campbell: Sure.

Timothy Stenzel: And our policy is for developers to be able to notify us and then begin – if he doesn't get a response from us that we've reviewed your notification and basically, it's accepting to that. And then you are allowed to go ahead and begin selling and distributing the test in the US. Because we have allowed for that we focused our review system on those that require the EUA authorizations prior to be able to come onto the market place. So that would include things like home collection and home testing.

And other categories where an EUA is absolutely required. So if there is a particular reason why you were – you haven't – why it's been sort of urgent in the EUA authorization, please send an email to the template's email address and ask them to refer it to me, Timothy Stenzel, for review okay?

Michael Campbell: Well I've been communicating directly with Toby for the last week or so specifically on this issue and it also - it still doesn't seem to move forward. Sorry Toby but, you know?

Toby Lowe: Yes, we understand. I think as, you know, as Tim just said we do have a large volume and we are trying to prioritize as much as possible.

Coordinator: Our next question comes from (Margot Enright). Your line is open.

Margot Enright: Yes thank you. And this kind of follows-up with the question that was just asked. Last week you mentioned that the EUA submission reviews that have already been notified or are not prioritized over the new EUA submission. So is it possible that we can file the EUA submission and then after we file the EUA

can we file a notification so we can put it on the market immediately?

Timothy Stenzel: So what type of test do you have just so I can make sure I'm giving you...

((Crosstalk))

Margot Enright: It's an antibody test, a serology test.

Timothy Stenzel: A serology test. So serology test is covered under our current policy. You have - can notify us that you have validated the test. We are almost on a recent guidance update on this. You then have two weeks, ten business days to submit a validation package to stay compliant with that guidance.

And then once you notify us though that you've completed validation and wish to begin distribution, we will review that notification and we will get back to you with documentation that assures you can begin distribution prior to EUA authorization.

And that's the same for all serology kit manufacturers. And that repeats actually what we said before. So you are allowed to distribute after you've notified us. And we review that notification and give you feedback and then that you adhere to the rest of the guidance which requires...

((Crosstalk))

Margot Enright: Is an possible if this is already filed - file the authorization that we can then notify you though in that...

Toby Lowe: Yes.

Margot Enright: ...because I know that's reverse order.

Toby Lowe: Yes as long...

Margot Enright: Is that possible?

Toby Lowe: Yes, the order doesn't matter as long as you have completed the appropriate validation and are following the policy under the guidance you can notify why or while we're reviewing the EUA.

(Margot Enright): Okay great. Thank you.

Timothy Stenzel: Yes, the order doesn't matter. If you've already filed and you haven't notified you can still notify us.

Margot Enright: Right, great. Thank you very much.

Coordinator: And next we'll go to (Tim Hendrix). Your line is open.

Tim Hendrix: Yes thank you. This is in that earlier question I think posed from (Mike) and just the one just now regarding the EUA and the serology testing and the authorizations. We understand that you can continue to promote the test as long as you follow the template in the submissions.

But the challenge right now is the market and especially the CLIA abs are all under the impression now based on the May 4 policy that the FDA is coming out with formal EUA approvals and authorization. And so they're disregarding previous policies.

Is there anything that you guys can do from your side to clarify this or make a

clarifying statement to the market because it's extremely confusing now that the policy has changed multiple times allowing individuals to understand that if you're taking a first come first serve basis and you're your prioritizing on your side some of these EUAs may take time before their release to market. Is there anything you can do on your side?

Timothy Stenzel: Yes so, I'll just make the statement of the policy. One change, the major change was we weren't requiring EUA submissions for serology tests and now we are. We are still allowing the test to be distributed after notification which includes - after notification which includes that we were saying that you were validated and the requirements of submitting that, that was stationed within ten days if you haven't already submitted that validation package.

And I will say on this call that it will be recorded in the transcript that those tests can be distributed and used in the US after those developers name show up on our notification list on our Web site and after they receive a formal response from us following the request for notifications but they can also show to everyone who may wish to purchase those tests that are in high complexity labs so that they that – and then if there are any issues on any specific interactions we're happy to try to help out, just send us an email to the company's email. Yes, thank you.

Coordinator: All right the next question comes from (Omar Habib). Your line is open.

Omar Habib: Yes good afternoon. My question I'm going to switch gears a little bit. We are looking at pool PCR testing for asymptomatic individuals. And I understand I've contacted you by email. I understand that guidelines are forthcoming. I was wondering if you could provide an overview or preview for what those might be? And again it's primarily for asymptomatic individuals which we found to have a very low prevalence of positivity. Thank you.

Timothy Stenzel: So can you tell me whether you are a kit manufacturer or you have a laboratory-developed test and if you have notified us?

Omar Habib: So I'm a CLIA medical director looking at implementing this across our market. And we have – we are using in our market different platforms of - so we have (unintelligible). We have Roche platforms and what have you all FDA approved tests. Obviously, this would be kind of an LDT or modification of those if you wanted to move forward.

Timothy Stenzel: All right so you're modifying some EUA offered test kit and from kit manufacturers for...

Omar Habib: Yes...

((Crosstalk))

Timothy Stenzel: ...and use in asymptomatic.

Omar Habib: Correct.

Timothy Stenzel: So our current asks for anybody who is wanting to claim asymptomatic use of their test that we would ask for a EUA for that use for any asymptomatic population. We have on our FAQ page stated very clearly that if it's already a EUA authorized test and there's a prescription order, a clinician order for a test that happens to be from an asymptomatic situation that we think that it's okay for the labs to process that sample and report out that result. However, if there is a claim about performance and asymptomatic individuals, we – our current thinking is that we fire an EUA for that.

When it comes to pooling, we are looking at the situation very closely. For our – we are going to have some recommendations coming up hopefully in the very near future on validation for pooling to provide some more granularity.

The bottom line that we're interested in is accurate testing even in the pooling situation. We would want that all either low positive patients who get pooled, the samples get pooled by one of a number of potential schemes are not missed in the pooling of samples.

And then as you go forward in the validation process you test that that is the case with at least significant - a minimum number of samples that you know that you have good assurance that you're getting accurate testing and you're not having false negatives in a pooling situation within some statistical margin.

And so those are kind of some of the details that we're working on to be able to provide to the community. Of course our current – and so we're working on that as we speak and we hope that gets out in a short amount of time. And I know that we've had a number of inquiries on this and we're trying to do our best to ensure that accurate testing is able to take place.

We know that there is a number of folks that are interested in this and we have engaged in some dialogue with folks about, you know, how they go about validating this and being able to have a EUA authorization for it. So that's probably the most I can say all right today. But we – this is a very important topic and we are working on this very hard and hope to have great clarity and more clarity about what our recommendations are in the very near future.

Omar Habib: Thank you.

Timothy Stenzel: I'll ask for patience, thank you.

Coordinator: Our next question comes from Symphony - (Cynthia Flynn), excuse me. Your line is open.

Cynthia Flynn: Hi. Thank you very much for the informative calls again. My concern is with antigen testing vis-a-vis the presumptive negative results for the Abbott ID NOW. Why aren't we resulting any kind of inefficient testing with the same presumptive negative for results since it will have probably a similar, you know, positive or negative predictive value?

Timothy Stenzel: Yes actually OUR direct antigen test if they are below the expectation for a molecular test we'll have and do have the same language in the ISU. if you look to the ISU in the direct antigen test that they've authorized it is the presumed negative language is there.

Cynthia Flynn: Oh okay. I didn't see that.

Timothy Stenzel: And so our expectation is that for any test that directly detects virus whether it be protein or nucleic acids that if it's below the expectation for a molecular test which we set the bar at 95% for a comparison to another molecular test if it's below that level our current thinking is that it's best to be a presumed negative.

And when we authorize our tests, we will ensure that that language is in the instructions for use and that it's clear to all who might consider using that test. And as we did with the Abbott ID NOW it's already been distributed and we updated for public health purposes we will announce it in formats like this that we have updated it that it was also a press release but this sort of updates to the Abbott ID NOW with - was going to be forthcoming.

But yes anytime that a direct detection assay is below the performance we

expect say of a molecular assay that this presumed negative language we plan on having in the instructions for use in any authorization. And we also have in mind and we set this very clearly for the direct antigen test in the template that those direct antigen tests are required to have at least 80% sensitivity relative to a high-sensitivity molecular test. So that's sort of the bins that these things fall in and how we label them. So thanks for asking.

Cynthia Flynn: Okay good.

Coordinator: Our next question comes from (Howard Urnivich). Your line is open.

Howard Urnivich: Hi. Thank you very much for this town hall. My question is where would I find information related to developing a laboratory-developed test using next-generation sequencing?

Tim: That's a great question. We know that that technology is kind of forward and that it's going to be a tremendous help in this battle because we will be able to — you will be able to - presumably you'll share it with others. Just note whether the sample positive or negative for SARS-CoV-2 but also the sequence information instead ends up being important.

And we would urge anybody who is collecting sequence information from SARS-CoV-2 we put this in the typical areas so that developers included to survey the sequence information and keep track of the mutations just in case those mutations might occur in (unintelligible) and the (unintelligible).

So the recommendations are likely to be very similar to the current molecular recommendation for (LDT). We expect that the performance be established on actual patient sample that the performance being very high, at least 95% (sensitivity).

We're not sure that's the developers but if you're interested in that shoot it to — and developers necessarily have to go into extreme detail elevation of the sequence. And likely will have authorization around the liability of their sequence.

We see this technology as being able to provide an accurate positive/negative result for SARS-CoV-2 and in addition provide sequence information as wanted and desired by those who run the testing or who order the testing. But better expectations for the performance would be no less than the net for any other molecular test and for our molecular template for (LDT) it's a really great place to start. If you see anything missing and other questions about what's the rare opportunity email, I sent a template email address.

But we are absolutely seeing developers interested in this area and as required or as helpful we will update the molecular template for MDS sequencing. As we know the large backing can be done. Hyperlinked sequencing can be done and in addition to the other badges that I mentioned earlier.

Howard Urnivich: Can I - thank you very much. I have a follow-up.

Tim: Sure.

Howard Urnivich: Good, that's very useful and what we're doing is we're collecting two packaging tubes for patient and we're using one for discovery. The question is that the (unintelligible) will be frozen and not alive. Is there a format by which we can use that kind of collection system and then I guess what I'm hearing is we should probably also have a perspective study also? So we would do the retrospective with the samples we're collecting now and submit that data. And then we are wondering how many we have to do in a prospective of

environment that would meet all of the requirements.

Tim: So I — what is the sample type that you're going to be looking at?

Howard Urnivich: What we're trying to accomplish is we're taking packaging tubes so that we can extract total RNA then we sequence everything. And then with our pipeline is we would like to separate out all the COVID sequences as you mentioned but also if there's any co-infection going on if there's a micro plasmin prevent (unintelligible) there's something that needs to be flagged.

We should do that all in one sequencing run so that's really the objective we're trying to meet here to see if we could add further clinical utility. If we're going to sequence the RNA we might as well just sequence everything and see what's in there.

Tim: So you're putting respiratory specimens into the packaging tubes.

Howard Urnivich: We're putting — I'm sorry. We're putting blood so we're collecting whole blood and we're finding that the preliminary data in another viral study is that we can find fragments of the virus infection in the blood, even though there isn't a (unintelligible). We are finding that there are biomarkers associated with the presumptive viral infection.

Tim: Yes. So just as a — we have not authorized blood as a sample type before.

Howard Urnivich: Okay.

Tim: And I was referring to typical respiratory specimens. And so we would like to see prior to you launching this tested data on blood and get the specific authorization out. We also want to (test) the respiratory samples for (MDS)

(and) follow the typical notification pathway for (LDT) but (also) we want to make sure that there's accuracy on the blood.

We have not authorized a blood base (NGS) So this would be something that we work through together to make sure that the proper validation is done so that we know the accurate testing is done in particular (pitfalls) are prevented. And our expectation for this kind of test would be that it would give 95% positive agreement with another molecular test that's been (authorized).

Howard Urnivich: Excellent. We are collecting also respiratory samples too to do exactly that and then present the data to you.

Tim: Right. And (along with) the sample (and the) test that you're running with those respiratory samples is (compared to an) authorized test.

Howard Urnivich: Correct.

Tim: And you can use that at a more (unintelligible).

Howard Urnivich: Thank you very much.

Coordinator: Our next question comes from (Kimberly Bunker). Your line is open.

Kimberly Bunker: Hello. Thank you. So my question is about the 31 serology tests that can no longer be distributed. If a clear (unintelligible) lab had already purchased that test that ended up on that list and validated it, can they still perform serology tests using that test and simply not purchased (unintelligible) from that manufacturer?

Tim: Yes. Well you should not be able to purchase anymore once they show up on

the (unauthorized) list. If you do — if anybody does, we would like to hear about it because that's on the — it's not intended. And you do put coming in from outside the country we do stop it at the border and having import alert to the border.

So you know, it's probably best in a situation that you're in to (send an email) or somebody else on our team to know which test that you're using and we'd have a brief conversation about what validation did. And I don't know (if) we can you but specific advice and you're welcome to send an email to a template email address.

And I — in these situations I am currently getting involved in the discussions and we've had these discussions already so I'm happy to engage with you on this. Right now we're kicking on a case by case basis providing the targeted specific advice because sometimes we know more than an email about a particular case, okay?

Kimberly Bunker: Okay. Thank you.

Tim: All right.

Coordinator: Our next question comes from (Steve Skanks). Your line is open.

Steve Skanks: Hello, good afternoon. Thanks for taking my call. I have a specific question. If one facility receives a EUA in our company, receives a EUA would it be acceptable for another manufacturing facility given the apparent need for tests in the marketplace to submit a separate EUA and manufacturer and (unintelligible) facility as well?

Tim: So given the manufacturer has EUA authorization can expand the number of

manufacturers but (hasn't) come in for a new EUA. And we may have — I would ask that you notify us that you're doing that so that we have it for our records and if you want to update the authorization with additional manufacturing codes you can do that. But there's no prohibition for a manufacturer (that) has a EUA to add additional manufacturing sites (where it) is fully authorized and there's fairly a need to expand the testing availability.

Steve Skanks: Okay great. Thank you, appreciate your help.

Toby Lowe: Just to expand a little bit on what (Tim) said what would be best would be to reach out to your lead reviewer on your EUA to check on what additional information they would need for the second manufacturing (site) and whether they're already (looking into) their EUA authorization about your manufacturing specifically so that we could update the authorization as needed.

Steve Skanks: Great. Thank you for your additional information. I appreciate it.

Coordinator: Okay. Next, we'll go to (unintelligible). Your line is open. (Unintelligible) you may want to check your mute button. Thank you.

Man: Okay, yes. Can you hear me now?

Coordinator: Yes.

Man: Okay. So thank you for taking my call and I have question-related to the clarification that have been made. As I look at it as on today and the 6-2 on the website there are 203 tests that have been in our (unintelligible) manufacturer on commercial and that have been modified and that are 4D for serology tests, of which 15 they got the authorization. So if I have understood from the (unintelligible) you went through earlier for a practical purpose on these 203

manufacturers they can sell the product because they have notified and they're in the list.

On May 23 the FDA — the CDC has given the interim guidelines (unintelligible) COVID-19 serology testing in that that accommodation site (unintelligible) so they mentioned the (unintelligible). It is mentioned here serological methods that have evidently (unintelligible) authorization (unintelligible) and clinical use since their test (unintelligible) data has been viewed by FDA.

So then we wanted to do our tests through some lab that say your test is not authorized even though we are (unintelligible) our test and our name is there on the notified list. But (unintelligible) that have gotten the authorization at least they (unintelligible) the customers. They think these are the best that they can really use other than second (unintelligible).

They have to get the (unintelligible) that only they can use and that I think you already mentioned that is not the case. Is it possible to clarify (unintelligible) some notification is given and even the interim guidelines of CDC can clarify these things (unintelligible) get some level of acceptance in the community?

Tim: Earlier on this call we addressed this question. We have obviously seen challenges with the number of serology tests and some practices by a number of serology tests.

We are working through the EUA authorizations as best as we can because of the many issues that have been seen. It's important that the EUA authorization is done properly, that we properly review the data that we need to make and assess on tests and only authorize those tests. Those tests that are on our notified list can be (put) in that formal position and (then) continues that. And that's

pretty much what we're trying to do.

Man: Thank you.

Coordinator: Our next question comes from (Annie Bell). Your line is open.

Annie Bell: Hello, thanks. I just had a pre-EUA that was converted to a EUA. So it was a pre-EUA for about four weeks and now we're about a week into the EUA status. I know FDA is working as best as possible but I was just wondering in light of this conversion what is the timeline we can expect to hear from the lead reviewers. So we've also been assigned a lead reviewer. I was wondering if you have any comments or insight on the timeline once assigned a lead reviewer.

Tim: I don't know the specific instance of your application. Usually the conversion is from a pre-EUA to a EUA happens when there's enough information and data in the package that (we) can begin to finish a final review of the data.

These are entirely dependent on the submission and if there any potential issues — if there any potential issues that need to be worked through. But your lead reviewer is the best source in all cases once you have been assigned a lead reviewer on timing and on the particular issues that are likely coming up in your application (to) close things down.

We ask that our reviewers be transparent with our developers in the situation but I don't know the specifics of your (particular) lead reviewers you keep contact and supervise on all (related) information for this.

Annie Bell: Okay thanks.

Coordinator: I'd now like to turn the call back over to Irene Aihie. Thank you.

Irene Aihie: Thank you. This is Irene Aihie here. We appreciate your participation and thoughtful questions. Please remember that today's presentation and transcripts will be available on the CDRH Learn Webpage at www.fda.gov/training/cdrhlearn by Tuesday, June 9th. If you have additional questions about today's presentation please email CDRH-EUA-template@fda.hhs.gov.

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

Coordinator: Thank you. And once again that concludes today's conference. Thank you for participating. You may now disconnect.

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