

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

**Moderator: Irene Aihie  
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12:15 pm ET**

**Coordinator:** Good afternoon and thank you all for standing by. For the duration of today's conference, all participants' lines are in a listen-only mode until the question and answer session. At that time if you would like to ask a question press Star 1. Today's call is being recorded. If you have any objections you may disconnect at this time. It is my pleasure to introduce Miss Irene Aihie. Thank you, ma'am, you may begin.

**Irene Aihie:** Thank you. Hello, I am Irene Aihie of the CRHs Office of Communication and Education. Welcome to the FDAs 18th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality and Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health both through CDRH and provide a brief update. Following opening remarks we will open the lines and take your questions related to today's session. Please remember that we are not able to respond to questions about specific admissions that might be under review. Now I give you Toby...

Toby: Hi everyone. Thanks for joining us today. Just a couple of updates from last week or since last week rather. Earlier this week we issued a new FDA Voices blog post by Dr. (Shuren) and that discusses our ongoing work supporting and advancing COVID-19 diagnostic test accuracy and availability. And that can be found on the FDA Web site.

We also earlier this week issued a guidance document on transport media. I know we've had a lot of questions on that topic in the town halls recently. And so I hope that everyone finds that useful. The document is about our enforcement policies for viral transport media during the COVID-19 public health emergency. And it outlines a few different policies for commercial manufacturers of VTM and sterile PPS and saline as well as high complexity CLIA certified laboratories that are developing their own transport media.

Along with that guidance we've put out a new FAQ page specific to viral transport media and questions related to that new guidance document. The easiest way to find that FAQ is probably from the testing FAQ page where we link over to that new FAQ page. We also updated a couple of the testing supplies related FAQs on the test FAQ page. There were a lot of FAQs in that sentence - sorry about that.

And then the last update that I have today is that we have revoked the umbrella EUA for serology tests. From our perspective we see this as fairly administrative. In the three months since we issued that umbrella EUA no tests have been added to it because we found that it is more appropriate for us to individualize the EUAs for each specific test so that we can allow for a broader indication for scopes of authorization on individualized conditions of authorization that are specific to each unique test.

So this is - we had intended for the umbrella EUA to remind the administrator

of progress from our end. But it turns out that doing individual EUAs is actually the more streamlined process for us. So this does not change anything from the perspective of what we expect to see in EUA requests. We're still using the NCI data to inform our decisions for the individual EUAs as we have been doing and we will continue to do that. But we did just want to flag that for you.

And with that I'll turn it over to Tim.

Timothy Stenzel: Thank you Toby and hello everyone. Thanks again for joining us. I'm just going to give you some updates. So maybe that can address some potential questions. We are working on a number of template additions and updates. And unfortunately, they're not publicly available yet although if any developer has any questions on any of these topics send us an email to the template email address box. And we've given quite a bit of thought to most of these already and can provide feedback.

So that includes what we used to call home testing for molecular diagnostics indirect antigen. That will be transitioning to being called a non-laboratory testing because the setting may not always be home could be schools or places, et cetera.

We're working on updates to the regular molecular template to include more information about pooling, more information about simple, or Dorfman pooling as well as what to do if you want to pool swabs. We're also updating language having to do with development of multi-analyte tests including things, like, Flu A, Flu B in addition to SARS.

We are working on finalizing what used to be called the serology home collection which will now be the non-laboratory serology collection template. We are working also a little bit further out will be what we used to refer to as

serology home testing which will now be serology non-laboratory testing.

And then finally we've been requested to update our direct antigen template to allow for recommendations for multi-analyte testing. So just like molecular with direct antigen you can put more than one target on the direct antigen test so you could for example look at Flu A and B again in addition to SARS.

And so with that update from Toby - those updates from Toby and me we can go ahead and take some questions now. Thank you.

Coordinator: Thank you. If you would like to ask a question please unmute your phone, press Star 1 and record your name clearly when prompted so I may introduce you. If you would like to withdraw your question you may press Star 2. Again to ask a question press Star 1. It may take a few moments for questions to come in. Please standby. And our first question is from (Jackie Chan). Your line is open.

Jackie Chan: Hello, good morning. We have a total antibody test that can also measure acidity and it is also a neutralizing assay. And for the neutralizing assay we have correlation data to PRNT so that's the plaque assay and also to the pseudovirus neutralizing assay. And then right now we are trying to prepare for the pre-EUA discussion with FDA. And aside from the basic requirements of the serology test so that's the clinical agreement and cross reactivity and stability.

We also plan to do linearity and also have supporting co-relations data to the two gold-standard method. And for the acidity claim so the K on and K off, we plan to use BLI as the gold standard method in the measurement. We are just wondering if you think this is enough for the initial pre-EUA talk and if there are other data that your team might want to see in the application for neutralizing assay and for the acidity assay. Thank you.

Timothy Stenzel: Yes, I think so. I think you're very well prepared for the first conversation. And you've hit on all the important points for neutralizing tests. Those could either be, like, you said the PRNT which is considered by us to be the gold standard method for determining neutralizing antibody. Or it could be as you said for your - sounds, like, for your assay that you're developing an assay that could correlate to results on the same samples with a neutralizing reference method.

And absolutely open to that. We are looking for those strong correlations. We also realize that semi-quant or quantitative serology assays are going to be required probably to do this well of course. And so you talked about linearity there, dynamic range, how you calibrate, how you quantify, is all going to be important information. And we've been working with our other federal agency colleagues to understand this landscape to adopt new criteria that we can use to assess these technologies.

So we are making substantial progress on being prepared to review these submissions. And of course as soon as we are thinking it's more crystallized, we'll do a template that will deal with semi-quant, quant and neutralizing type for serology assays. Okay?

Jackie Chan: Okay great. Thank you. And then for the acidity part the K on and K off measurement because so with a neutralizing assay it would tell you if the antibody is actually neutralizing the virus. But then it does not show anything about the acidity on whether that antibody is actually sticking to the virus. So our assay can also do that and it can also measure that.

So right now we plan to use BLI technology to like as the gold standard for the K on and K off measurement. And I'm just wondering if you think this will be acceptable.

Timothy Stenzel: I'm not expert enough in that kind of test validation method. You know I'm fairly familiar with bicore and other technologies, like, that. But not actually measuring that in an assay. So - and seeking EUA authorization for that it sounds very intriguing and, you know, perhaps could be important to not just measure the presence of neutralizing antibodies. But maybe the strengths of those bonds.

But - and I don't know yet. It's the first time, you know, that I've been thinking about this. The team's probably thought about this already. So I would defer to the team on this. And so I'm not even familiar with the technology mentioned. I'll have to look it up. But it sounds, like, you're very knowledgeable so I expect you're going to have a very well-informed discussion with the FDA. And I look forward to following your progress.

Jackie Chan: Okay thank you.

Coordinator: Our next question is from Mark Heston and going forward we will just be taking one question per caller. Again Mark Heston your line is open.

Mark Heston: Yes good morning Tim and Toby, Mark Heston calling. I have a couple questions but I'll stick it to one. My main question is a reclarification. You said that you were updating the templates from to a non-laboratory status for at home. I was wondering if there's anything on the Web site about that. And my carryover question is when are we going to see a template for fully at-home testing?

Timothy Stenzel: Oh yes so that's exactly the template that I'm talking about. We're just instead of calling it at home because we've gotten developers say well, we want to be in other locations that are not in labs that have a CLIA certificate and could be

performed entirely by non-healthcare workers. The home is a subset of that. Workplace is another subset. Schools might be another subset.

So that it will be an umbrella template for all those situations. So it's very far along and I just wanted to give an update before the call because we get that question every week and we're working hard on it and we'll get it out as soon as possible.

Mark Heston: Okay thank you very much.

Coordinator: And our next question is from (Raphael Rubio) you may go ahead.

Raphael Rubio: I'm calling on behalf of doctors and healthcare providers that need a current and plain understanding about COVID-19 screening. Earlier this year you made a statement that the FDA's diagnostic policy allows for the use of IgM and IgG fingerstick tests without FDA authorization as long as they're labeled correctly not used as the sole basis for diagnosis or exclusion of infection and not the results are used in coordination with a healthcare provider.

As the healthcare providers can you clarify for us if we have the right to purchase these tests from a distributor if they're properly labeled and use them for screening but not diagnosis at our point of care?

Timothy Stenzel: So we consider screening - it's not really a diagnostic for serology. But we'd consider that governed by FDA regulation. So we allow those tests to come to the market and be distributed. However prior to authorization they're restricted to the use in CLIA high complexity lab situations. So you could - a high-complexity lab could have a patient, you know, draw station. So as long as that testing is under a CLIA certificate that's from a high-complexity lab then that's allowed.

But as far as true point of care no, that requires a CLIA waiver certificate. No we haven't yet, unfortunately, authorized a serology point of care test for that environment. We're very interested in it. As soon as somebody submits acceptable data, we'll authorize it as a high priority.

Raphael Rubio: Okay thank you.

Coordinator: Our next question is from (Elaine Barry) you may go ahead.

Elaine Barry: Hi good afternoon. Thanks for taking my call. I'm a little new at this and I was listening, you know, I've been listening for a couple of weeks. I was just wondering if you could kind of take me through the process of the EUA template submission.

So, like, once the templates are populated and submitted how long does it typically take for someone to review it and respond and what kind of a response can we expect? Will it be, like, a feasibility assessment or specific guidance? One of the products that I'm facilitating has (unintelligible). I'm really anxious to get word from you to know whether we can proceed and how we can proceed.

Timothy Stenzel: You're breaking up a little bit when you were describing what the technology was that you were considering submitting. Can you just go over that again so I know what kind of test it is?

Elaine Barry: Actually I'm not really at liberty to say. But it does have military readiness applications. And we're just wondering, like, what kind of guidance might we expect from the EUA or the review and how long that might take once we submit to get some kind of response.

Timothy Stenzel: Okay can you tell me whether it fits in the bucket of serology, molecular or direct antigen?

Elaine Barry: Yes serology.

Timothy Stenzel: Okay serology. So serology are allowed to submit or at least validate and notify us. And then we'll review that notification and we can decide to post that notification on our Web site. And then if you certified that you validated for the intended purposes following the guidelines you can begin marketing that test while we review that submission. We will do an initial assessment of that submission to make sure there are no public health concerns. To make sure that it is complete. And to assess whether it is one of the high priorities.

The reason for high priority is we've gotten so many applications needing so many high priority applications that especially those that require EUA authorization to be able to market the test versus a serology test that can be marketed following notification. You know we want to get to those applications first that require our review and authorization.

So and both assessments will be done. If there's any concerns whether it's incomplete or we think the data doesn't look good we will reach back out to you. If it is classified as a high priority as soon as there is room on the reviewer's plate, they'll move that in ahead of lower priority application. And if you're deemed to be a lower priority application you will still be given a contact to keep you updated weekly on your submission and be able to ask questions, and get any sort of reassurances that you need about where things stand.

I've directed the office that within two weeks of those EUAs, hopefully a lot sooner than that now that we've cleared some backlog because there's hundreds

of applications, that we can get to that much quicker than two weeks. So you should hopefully get an assignment - a user, reviewer or somebody that you can otherwise contact to get a status update. Hopefully that clarifies that process.

Elaine Barry: Yes it does thank you very much. And in the event that we wouldn't be able to go down that EUA pathway should we just go ahead and, you know, start preparing for an IDE submission?

Timothy Stenzel: So an IDE we've typically not been reviewing IDEs for this pandemic. So it would depend on the particular situation. And say you want to use it in a clinical trial situation where an IDE would be required, then yes. So you can email us at the template email address to address any concerns you might have about potential need for an IDE. But in most cases, we haven't seen a need for an IDE but you may have special circumstances.

Elaine Barry: That's kind of what I thought. Okay great, thank you so much.

Timothy Stenzel: Yes.

Coordinator: And before we go to the next question just as a reminder, we are taking one question per caller. Our next question comes from (Todd Lewis). You may go ahead.

Todd Lewis: Hello. Our lab is conducting a lateral flow assay for COVID. And my question is who is responsible for reporting the results? Do you know that answer? Is it the clinical lab or is it - if we're going through a practitioner do, we report to the practitioner and then practitioner reports it to the...

Timothy Stenzel: Yes, if the testing is being done in a CLIA lab and they're high, moderate or waived. It is the laboratory's responsibility to report that result. If you're going

to develop a test that might be used in a non-laboratory setting, then we are asking reviewers what your plan is to make that data available to the government so that we can track that information. So we just upfront want to hear your plan about how you would do that. But if the testing is all done within a CLIA lab it's the CLIA lab's responsibility.

Todd Lewis: Okay. And is there a central location to report that or what agency would that be through?

Timothy Stenzel: Well those are details you would - I think (Toby) do you know? I think you go through the regular reporting which may be directly to the CDC. But I know the department also has a different system. You know what this was set up I believe by the CDC not by the FDA...

Todd Lewis: Okay.

Timothy Stenzel: ...and/or the HHS. So I would refer you to them unless, Toby, you can provide any additional assistance.

Toby Lowe: There's a guidance that HHS put out about laboratory data reporting and what goes with it.

Todd Lewis: Okay.

Toby Lowe: We have that linked from our FAQ page. So if you go to our FAQ page to the section titled COVID-19 related test data and reporting FAQs, the first question has a link to the HHS guidance.

Todd Lewis: Okay thank you.

Toby Lowe: Yes.

Coordinator: Our next question is from (Wendy Jule) your line is open.

Wendy Jule: So I thank you for taking my question and thank you (Toby) for doing all those things. So Tim just mentioned that the FDA is updating the pooling guideline in the template. And we are actually following the current guidelines and had all the validations that are collected and analyzed. We are actually will submit our EUA very soon like this week in a couple days.

So I'm just wondering will the new guidelines affect us or are we just don't have to worry about it?

Timothy Stenzel: It should not. We're basically providing some more helpful information. The criteria are essentially the same. So we're adding, for example, if you want to pool swabs there's some additional studies that would be important, you know, if you put multiple swabs in one VTM you would accumulate potentially more mucin which can inhibit DTR reaction.

Also you could have really, really high virus. If the members of the pool all had high virus and then suddenly you have a sample that has a lot more virus than a normal sample would be which can potentially inhibit the reaction as well. Well not necessarily inhibit the reaction but use up the reactants more quickly than expected and potentially give you a false-negative result.

As far as simple Dorfman pooling or even combinatorial pooling the guidance, recommendations aren't going to really change. What we're doing is providing some more helpful information to those labs that want to develop this. We'll likely have an efficiency table so you can look at the percent positive in your population. You can look at what the ideal pooling ratio would be and what the

efficiency of that pooling would be.

Obviously the lower the pool the less the efficiency. The higher the percent positive, the lower the pool that you want to do because otherwise you're breaking apart every pool. So it's just a little bit more theoretical calculation, information to help labs figure out, you know, what pooling ratio do you want to use and what can they expect as far as efficiency gains and some additional helpful details.

We're hearing that some labs for example are struggling to de-convolute and maybe even convolute because some of the - especially the high through-put systems don't have an easy way to do that. They may not have a lab information system to do that. And so we're providing some more helpful information about software because right now some of the labs we're talking to are doing manual de-convolution and manual report editing. And that's obviously a challenge for lab workflow. And a potential risk for misidentification of patients okay? Hopefully that's helpful.

Wendy Jule: Yes thank you very much.

Timothy Stenzel: Yes.

Coordinator: And our next question is from (Jess Teribary) your line is open.

Jess Teribary: Yes hello, good afternoon. I just - we are developing a multiplex and we want to report the isotypes separately and I just wanted to gain a little bit more clarity on the sensitivity requirement for A and M. And if you do have visibility on the antigen specificity for those, like, is there a difference in the sensitivity requirements for the spike versus the nuclei captured? But if not, what is the general sensitivity for M and A in reporting separately?

Timothy Stenzel: So we haven't - I don't know that we've authorized an A yet. For M we have authorized M within a multiplex. And we've also authorized M alone. So M in the presence of an IgG say we are allowing it to be down in the 70 percent range for positive — percent positive agreement or sensitivity whereas IGG, those same devices are expected to be 90%.

We're really wanting serology and then IGM alone, we set the bar at 90% because we're really wanting to hit the 90% bar for sensitivity to make these tests as useful as possible. We think that's importantly clinically to not have false negative for serology and otherwise it lowers the usefulness of those tests.

For IGA like I said we haven't authorized it so it's probably best for me to say that it's good to engage in a dialogue here because A-M combination is not something that we've authorized yet. I would expect that we still want to see one — at least one of those analyzed to be positive at the 90% level.

But again I think it's best because it's not something that we've — made a public decision on yet, that you engage with our team through either the Pre-EUA pathway or the EUA pathway. If you already have data you can just go right to EUA.

Man: Okay thanks and so yes, if we're hitting the target of 90% for G and then A could be a little bit lower then.

Ben: Like I said, G definitely at 90%. M alone definitely 90% and in combination 70%. But we have not authorized an A yet and until we do and set that performance expectation based on actual data that we see it's premature to say anything.

- Man: Okay. Okay, thank you for your guidance.
- Ben: You're welcome.
- Coordinator: And our next question is from Dale Schwab. You may go ahead.
- Dale Schwab: Hello. Thank you for publishing the data — the guidance on the transport media. That was very helpful. I do have a question on the transport media guidance. Whether it applies only to testing for COVID-19 (SARS) or if it's also applies to other testing for other viruses such as influenza because coming up, we're going to have people submitting those other transports that haven't been 510K authorized for other tests besides SARS.
- Woman: Right. That's a good question. The guidance applies to transport media that — as described in the guidance so it is not all transport media but the types of transport media validated in the way that is described in the guidance, for use with molecular or antigen assays during the COVID-19 public health emergency so that it's not limited to SARS-CoV-2 to molecular and antigen pathways.
- Dale Schwab: And also culture? Is that applied to culture or just molecular and antigen?
- Woman: I believe just molecular and antigen if I read it. Let me just double-check exactly how we wrote it.
- Tim: The guidance has to do primarily with you know, either adherence or close proximity to the CDC's VTM formulation which should also as long as it meets all the other criteria should work for culture. Of course, if you're going to try to culture virus during this pandemic, be sure you have a BSL3 or above facility.

Man: They may use it for other herpes cultures, I mean, herpes virus cultures and cell lines that don't support SARS but that's causing some confusion, the guidance on what exactly it should be for. And some of these media are not going to be the exact CDC media. We're seeing a lot of that out of China.

Toby: The guidance applies to transport media that is validated as described in the guidance which does tie it to the CDC formulation. So other formulations would not fall under this policy.

Dale Schwab: Unless you talk to the FDA I think which is in another section in the guidance.

Woman: That's correct.

Woman: Thank you.

Woman: You're welcome.

Coordinator: And our next question is from Pervy. You may go ahead.

Pervy: Hello. We have a nasal swab EUA under the review right now and our customers/potential customers have been struggling trying to get the nasal swab and the VTM to send us the samples. They are requesting if we can provide that to them. We are non-direct manufacturers of either of those.

But we can put together a convenience kit where we can source the nasal swab and the VTM from different suppliers. And if we chose to do so would that require the company's label identifying it as a part of our kit even though it's an LDD submission? And would that mean we would have to create an IFU around it and send an amendment to the EUA? Thank you.

Tim: Toby this is somewhat of a challenging one, right? So can you tell us if the provider of the collection kit is already sort of FDA-authorized either by the existing exemptions or authorizations that have been given to that company or would this be something outside of that sort of setting?

Woman: They are authorized under different EUAs and several places and they are quite well established in terms of providing swabs to most of the people who require it. It's just that the customers are like, if we can have a one-stop solution we would not have to source VTM and nasal swabs ourselves. We're just providing it, yes.

Toby Lowe: Yes. I think that you could include in your EUA submission.

Woman: Okay. And would that mean I would also have to create an IFU and put the company's label on that kind of convenience kit?

Timothy Stenzel: Let me handle this one Toby. So if the company you're working with already has been authorized for this collection kit, if they're willing to give you basically a letter, — right of reference letter. That's going to really ease anything that you might have to do. And if they give that in the right of reference and the data all support what you're going to do in all likelihood that is essentially a paper exercise to update in your EUA with it.

I'll just say that it's important that whoever provides such — and we considered collection kits to be a device - to make sure that it works, that it's not — got contaminated media, it has the right swabs, maybe — hopefully that are sterile, those kinds of things. But it sounds like it's already been reviewed by the FDA which makes this potentially very, very simple to use. So you can ask the company for a right of reference to their data and their submission. They're willing to do that then just update us with information about it either in your —

with your existing review or your existing contact here at the FDA.

Woman: Thank you.

Toby: So I would also encourage you to look at the convenience kit guidance. If these are all components that are already legally marketed and you're not modifying the labeling. The convenience kit guidance would apply to you.

Pervy: Perfect. I will do that. Thank you so much. That really helps.

Coordinator: And our next question is from (Nadia Herminez). You may go ahead.

Nadia Herminez: Hello. I have a question regarding researches only. I notice there are several products out there, the serology products that are for research use only. Are those the ones being used by the screening by CLIA high-complexity labs or how are these research use only being monitored?

Timothy Stenzel: You want to handle this one Toby?

Toby Lowe: Sure. So research use only test kits should not be used for screening. Screening is considered to be clinical use. They're considered to be IVD tests and we would expect appropriate IVD labeled products to be used for those clinical uses. RUO products really should only be used for research and that would not include clinical testing and returning the results in a CLIA lab, that we do have a guidance document on RUO labeling of IVD products that would be good to reference.

Nadia Herminez: So because I'm seeing ROU on the market and how is the FDA regulating this and...

Toby Lowe: If you see specific RUO products that you have concerns about, we would appreciate you sending that information to us and you can send it to the CDRH EUA template mailbox.

Nadia Herminez: I know we can't do more than one question. So does the FDA regulate sales outside the U.S. for the COVID project or only within the U.S.?

Timothy Stenzel: The short answer is inside the U.S. but there are certain probably expert requirements that the FDA may, if it's manufactured in the U.S. then it's exported, that the FDA may need to get involved with. (Toby) if you have any more details or do we direct specific questions on that to our templates email address?

Toby Lowe: Yes. I think that would be best if there are export questions.

Woman: Great. Thank you very much.

Coordinator: And before we go to the next question as a reminder, we are allowing one question per caller. Our next question is (David Hong). You may go ahead.

David Hong: Yes thank you. Can you hear me?

Timothy Stenzel: Yes.

David Hong: Last week you answered a question regarding saliva and serology and described that your serology notification template was really designed for blood analytes rather than saliva. I wonder if you had considered serum coming from oral fluid which is then used in both the animal and human communities for antibody testing in other context for almost 20 years. Would that type of serology run in an ELISA test count for the serology test plate since that serum ultimately

comes from blood through mucosal tissue?

Timothy Stenzel: That is not the exact same sample type that we've set up the current templates for. And so we haven't authorized anything for — until — for that yet. That's definitely something that we're very willing to engage with you on and to figure out how to validate that — that sort of test and make sure that it performs well. So if you've already engaged with the FDA on this and we're getting good feedback great. if you haven't yet, I encourage you to do so and we look forward to the discussion.

David Hong: Thank you.

Coordinator: Our next question is from (Mark Wagner). You may go ahead.

Mark Wagner: Hello. Can you provide an update on the timeline for a EUA request for review? Earlier you mentioned that point of care testing for serology tests would be reviewed as a high priority. We submitted an EUA for a fingerprint 50-minute IGM, IGG serology test more than 10 weeks ago and the only updates we've received is that our request is in line for review, and we'd really like to see some movement on the test.

Timothy Stenzel: So yes. I can personally check on that. This is Dr Stenzel so just send us an email at the templates email address and ask to connect with me and I will look into it for you.

Mark Wagner: Thank you.

Coordinator: Our next question is from (David Adams). You may go ahead.

David Adams: My first question — my question was going to be similar to the one that just

came up about the timeline of submitting status of long ago submitted — submissions for the review process. So I guess I will follow that and then I will — so rather than ask that question, I will ask a different one, and that is can you give any estimation or any information about what type of information would be needed for the non-lab testing you mentioned. Are you preparing a template for that or — because it sounds like you want — you're encouraging submission of that and have not received any. Can you give any more information about the

Timothy Stenzel: Is this serology?

Man: Yes.

Man: The non-lab.

Timothy Stenzel: So we haven't authorized a non-lab collection and we haven't authorized a non-lab test, and we are working on a template to provide the recommendations for that. It really helps us to get it right if we have been actively reviewing such submissions and seeing the data and seeing what the important things are to look for prior to putting out a template.

So I would encourage you to engage with us through the template email address to ask about how you would undo that. We can definitely provide at least some significant feedback on how to do that now because we've been discussing it for a while now.

(David Adams): Before that template comes out are we able to submit in any case or do we have to wait for the template?

Timothy Stenzel: Yes. You can submit. It's just that there's lots of questions. Is it going to be

OTC? Is this going to be prescription? What are the user studies? What are the validation studies? It depends on all those things. So I hate for you to do a lot of work and then have to go back and redo some work because it didn't achieve the end that you wanted.

But yes, we're always willing to take in any EUA submission with your data and really to get the high priority, all the application really needs to be complete, we can't prioritize something that's not a complete submission.

David Adams: Okay, all right.

Coordinator: And before we go to the next question as a reminder if you would like to ask a question please unmute your phone, press star 1 and record your name clearly when prompted so I may introduce you. Our next question is from Leigh Mariano. You may go ahead.

Leigh Mariano: Thank you for taking my call. So I want to know how long that they take after we submit our sample to you for — to your lab for the product evaluation and also do you encourage us to submit whole blood test for the antibody test to you.

Timothy Stenzel: So I take it this is the serology test and you submitted something to the NCI for testing already?

Leigh Mariano: Yes.

Timothy Stenzel: Okay. And have you submitted an EUA for the file?

(Leigh Mariano): Yes.

Timothy Stenzel: Okay. So our process is to — if it's been more than two weeks you should have somebody assigned to the submission. If not email me (Dr. Stenzel) and I'll track it down why you don't have it within two weeks. But the process is we take a look at your EUA package and make sure that everything looks okay. If you notified us that you want to launch then we give you confirmation of that notification.

And then if everything looks good you go into the queue at NCI and currently the time once a test arrives at NCI it's about three weeks before they can do the testing. So there's a fairly significant backlog. But you know, once you get in you get assigned a place in line and we track that, okay?

Leigh Mariano: So where can we get that tracked? Do we get it? For example, if we submitted to or if we submitted to that do they do an online status link so that we can track where our test is in the process. After they send the sample to NCI, we have not heard from them more than a month. So do we wait longer to hear from someone or do we check or where can we check?

Man: So have you been assigned a contact within our FDA office?

Leigh Mariano: Yes. We already submitted an EUA and then they told us to send a sample to NCI. We already did that two weeks ago.

Man: So that contact can tell you where things stand.

Leigh Mariano: Okay got it. And then you don't have anything like the (unintelligible) that is the report that we can track where we are for our submission?

Timothy Stenzel: It's through your contact at the FDA that we provide you that information.

Leigh Mariano: Okay got it. So we want to see if we can submit the whole blood or fingertip for our antibody test. Do you encourage us to do that or you have — if we do that, if you approve that, that would make it so much easier if we can use the physician office lab to make it a test and more efficient to fully utilize the rapid test so do you encourage us to do that?

Timothy Stenzel: We are encouraging point of care test submission, yes. So yes, go ahead and get the data. I think the serology template has the information for point of care so you can follow that those recommendations and submit your data.

(Leigh Mariano): Yes. So far you approved all of those that are whole blood finger tip test. That's how we lead ours but we need to decide at what point we need to go back to submit. Okay, thank you.

Coordinator: And our next question is from David O'Connelly. You may go ahead.

David O'Connelly: Hello. Thanks for taking the question. I have a question about calculating the days post PCR confirmation versus days post symptom onset. We're preparing a serology application now, we have some samples that looked at days post symptom onset, some that were days post PCR confirmation, and I'm wondering if you can give some guidance on how to use those together in the application.

Timothy Stenzel: So yes. The serology template has some details on that and if it's not clear enough you can go to our template. Well, go to your direct contact for that submission, whoever your contact is at our office.

(David O'Connelly): We haven't submitted it yet.

Timothy Stenzel: So the most important date that we if you have days post PCR that's good.

Please include it. The most important date in the way that we assess performance is post symptom and that is because we expect certain performance by certain days after symptoms.

Basically, after 14 days, the test should have maximal PPA or sensitivity but prior to 14 days, the serology test may not have that. It's very important for us to know the days past symptoms in order to assess accurately and adequately assess the performance, and not bias against data that might be prior to 14 days that is falsely negative.

(David O'Connelly): So with both sets of samples, can they be used together in the same analysis?

Timothy Stenzel: Well we'll do our best but if you don't have days past symptoms in the sample it's going to be really hard for us unless you have — we'll take a look at different categories I'm imagining. I can't pre-speak. So submit what you have — if that's what you have then we'll assess the adequacy of that information and the adequacy of the performance.

And you know, we'll do our best to work with you but it'll be a little bit more challenging if you don't have days from symptoms on all samples. It doesn't matter at all about days with PCR because PCR can be done at any point after symptoms and it's variable.

(David O'Connelly): Right.

Timothy Stenzel: Its days post symptom that we've really been centering on to assess performance because those are — that's the most reliable way of assessing performance one test to another because that's why the patient symptoms not by when a particular PCR test is done.

(David O'Connelly): Great, thank you.

Coordinator: And our last question is from (Sean Gimmel). You may go ahead.

(Sean Gimmel): Good morning. Thank you for taking the call. With the letter that FDA issued on the 21st with respect to the revocation of IGG IGM tests. We are a high complexity molecular lab performing the Abbott test which was authorized on April 26. Has the revocation affected that assay?

Timothy Stenzel: Not at all. We didn't revoke any assay. We simply revoked an umbrella policy that was put in place to make our work easier. It's internal to the FDA paperwork saving situation. If something fits under an umbrella basically there's fewer — there's less review that has to happen because all the conditions have been pre-set for authorization so it is simply an efficiency internal to the FDA efficiency, our criteria for what is — what the bar is for something that's an accessible test has not changed at all. Our great use of NCI testing hasn't changed at all.

In the case of central lab tests currently we're not able to really assess central lab tests via the NCI because it would require to split panels — blinded panels to send out and we're — and those samples could get really well-annotated samples that perform well, that have been vetted extremely well by our process

is a bit of an onerous task so until we catch up with basically the amount of — with the huge volume of backlogging NCI with the current serology test there it's — that's our focus right now. Hopefully that puts you at ease. Anything — nothing with the revocation on the 21st no tests were revoked at all. It's just the policy that was revoked.

Coordinator: And this concludes our question and answer session. I will now turn the call back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. 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 Tuesday, July 28. If you have additional questions about today's presentation please email [CDRH-EUA-template@fda.hhs.gov](mailto:CDRH-EUA-template@fda.hhs.gov).

As always, we appreciate your feedback. Always at 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](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live discussion. Again thank you for participating and this concludes today's discussion.

Coordinator: And this concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please stand by for post-conference.

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