

**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: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the Q and A session, if you'd like to ask a question, you may press Star 1 on your phone. Today's call is being recorded. If you have any objections, you may disconnect at this time. Now I'd like to turn the call over to Ms. Irene Aihie. You may begin.

Irene Aihie: Thank you - hello this is Irene Aihie of (CDR) Office of Communication and Education. Welcome to the FDA's 8th in a series of virtual town hall meetings to help answer technical questions about the development and delegation 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 and the Office of Product Evaluation and Quality, (Sara Brenner), Associate Director for Medical Affairs, and (Toby Lowe), Associate Director of the Office of In Vitro Diagnostics and Radiological Health. Now I give you (Timothy).

(Timothy Stenzel): Hello everyone and thank you for joining again this week. (Sara Brenner) and I have some very brief opening updates and then we'll go into Q and A that's been our pattern here.

So following our May 4 guidance update, we did make a few updates this week. The updates were we added a template for direct antigen test and then we also updated our molecular template. So those will be updated and they're available as editable documents on our website. We are still working on a home collection template, and we'll update as soon as we can for that. We do see a lot of continued and growing interest in-home collection and so we think this will be helpful as well.

The main updates for molecular have to do with the fact that now there are positive patient samples. We are shifting from the use of contrived samples to supplement applications to the recommendation that actual patient samples are used for the clinical performance testing. And as a result -- for molecular tests -- there will also be comparisons to the recommendation as to make a comparison to previously authorized molecular tests in order to assess whether an accurate performance has been established.

For the direct antigen test, we've outlined the recommendations for validation for those tests. Of course we authorized the first one last week on Friday. We have minimum performance expectation of 80% sensitivity relative to a high sensitivity molecular asset and we also are recommending that the specificity be very high so that a positive result can be relied upon.

Of course with lower sensitivity tests for the virus, there is the concern that there may be false negatives. So we do have language in the authorization dealing with what to do with a false - with a negative result. And that is a reflex from a direct antigen negative result to a molecular result to be considered for depending on situations. So with that, I will turn it over to (Sara Brenner) for her opening remarks and then we'll open it up for Q and A.

(Sara Brenner): Thank you (Tim), just a couple of quick comments on topics that have been of interest in these Town Halls. One is on laboratory data harmonization. The COVID SHIELD effort that was launched a couple of weeks ago with CDC is live and I'll just remind people that information - including aLIVD Test Code Mapping tool for SARS-CoV-2 and COVID-19 related tests - is available on [CDC's website](#). If you are interested in engaging with the agencies including FDA on that effort, you can email us at SHIELD-LabCodes@fda.hhs.gov.

And the other comment I wanted to make was on the topic of 3D-Printed Nasopharyngeal Swabs (and swabs in general) for use during the pandemic. This is a very hot topic and is of much interest to the community. We will be hosting a town hall on this topic this Friday, so that is coming up quick and apologies for the short notice, although we've been sort of indicating it will come for many weeks now. It will be this Friday as mentioned, May 15th from 1 to 2:00 pm and information will be forthcoming by email and available on FDA's website. Partners from NIH and VA will also be on the phone for the discussion with the community. And that's it - thank you.

Woman: Operator will now open the line for questions.

Coordinator:Man: The phone lines are now open for questions. If you would like to ask a question over the phone, please press Star 1 and record your name. If you would like to withdraw your question, press Star 2. One moment for the first question.

First question is from (Robin Steinberg). Your line is now open.

(Robin Steinberg): Thank you - Dr. (Brenner), Dr. (Stenzel), I'm (Robin Steinberg) with Auburn Health Strategies. I appreciate you hosting these calls. They are really quite helpful. My question involves controls. Is it acceptable for a control

manufacturer to label controls for use with a specific assay without having an EUA or a 510K. And if you would let me know, does your response apply to researchers only, IDD or both?

(Timothy Stenzel): That's a great question. I'm pretty sure of the answer but I'm going to want to confirm that. You know that (Toby Lowe's) on the line. I think she might be able to confirm this, but if specific claims are made about a control with a specific assay, I do believe that authorization will be required. (Toby Lowe), are you able to confirm that or do we need to pull that back in.

(Toby Lowe): Yes.

(Timothy Stenzel): Yes.

(Toby Lowe): Yes, that sounds correct to me as well.

(Timothy Stenzel): Okay all right thank you.

(Robin Stanberg): Thank you.

Coordinator: Next questions from (Erin Richards). Your line is now open.

(Erin Richards): Hi, I'd like to first thank you for all the great information on serology testing. In one of the FDA press releases, reference was made to publishing the results from NCI from multiple manufacturers but I've only to date) been able to find those results for the Euroimmune test and perhaps I'm not understanding exactly where to look for that other information. And can you direct me to that?

(Timothy Stenzel): Yes that is correct. We do intend to make all those results public.

However, as I stated before, we're going to make those results public following our regulatory decision and in the case of Euroimmun IgG, we did make a regulatory decision based on part on the MTI data and therefore we posted those results. So we are in the process of making additional regulatory decisions based on in part at least on the NCI data. And as those decisions become public, we will oppose the data essentially contemporaneously with those decisions.

(Erin Richards): Thank you.

Coordinator: The next question is from (Sue Warner). Your line is now open.

(Sue Warner): Hello and thank you for taking my question. My question today is related to serology clinical evaluation. The serology EUA template indicates that a prospective clinical evaluation is ideal. In the case of an evaluation for finger stick samples -- when it's necessary to use freshly collected samples -- is it acceptable to compare finger stick serology results to previously obtained RT-PCR results or must the results be obtained concurrently?

(Timothy Stenzel): Yes, I would want to refer to the template on this. We would prefer that you do a comparison to another blood sample - either whole blood, serum or plasma -- rather than to a previous molecular result. If you want to pursue a different pathway for that, I would have a conversation with our team about that. And you can either -- if you have a primary reviewer already -- you can discuss that with a primary reviewer or if you want to just email us a template. I would say that there is a little bit of a risk using a previous molecular result and performance may not be exactly correlated depending on how long ago that patient turned positive, how long ago that patient developed antibody or had symptoms and also about particular antibodies that have been raised and

still in the early stage or they've been - so depending on what your serology test are. So, you know, any sort of thoughts about, you know, following a different pathway I would just recommend that you discuss it with our staff.

(Sue Warner): Understood, thank you very much.

Coordinator: Next question comes from (Brad Fox). Your line is now open.

(Brad Fox): Hello and thank you for taking my call. I know this will probably be addressed on Friday, but I have a question on what governs the use of an (NP) swab versus an NS swab and how that might correlate to asymptomatic patients and strategy for testing going forward. Anything you can share with us today?

(Timothy Stenzel): Yes, I'll start it off and then if (Sara Brenner) has anything else to say, I (didn't) hear it from the person about 3D-Printed swabs, so I may be able to handle this. So we still feel that NP swab is probably is the better swab. But obviously we've authorized other swabs - nasal anterior nasal swab or a pharyngeal swab, mouth saliva and sputum and BAL.

So and as far as what is best to use for asymptomatic patients, I would say that that is an area that hasn't been established yet. It's going to really depend on the viral titers that are present in asymptomatic patient. We have a number of developers who are interested in pursuing an opportunity to put into their intended use, the inclusion of testing in asymptomatic patients, and their working with our team about appropriate study design.

We have written the intended use statements for at least a molecular assay authorization to allow for the testing of - in asymptomatic patients with a physician clinician order. So we don't see any issues with using a EUA

authorized test for testing of asymptomatic individuals. And we have not specified a swab type to use. And that's simply because we don't have strong signs yet and there's also the practical consideration that there are sometimes limited supplies of nasopharyngeal swabs.

And if you are testing an asymptomatic population and perhaps you're doing consecutive testing or successive testing where you're testing those individuals on a regular basis, excellent compliance may be achieved using say swabbing both anterior nares rather than doing NPswabs. So we do want to give discretion to the providers who are performing this specimen collection in testing. Hopefully that's helpful.

(Brad Fox): Yes thank you.

Coordinator: Next questions from (Tammy McKee) - your line is now open.

(Tammy McKee): Hi there - thanks again for doing these updates. I kind of missed what the Friday meeting is going to be about and I didn't hear if it was going to include (VTM) in addition to swabs.

(Timothy Stenzel): (Sara Brenner), can you handle that?

(Sara Brenner): Yes sure can. So the Friday call will not necessarily address (VTM). We will specifically focus on the 3D-printed swabs and the questions that have been coming in around their performance, their clinical use, mechanical properties, and that sort of thing. So it's really intended for researchers, clinical laboratories, manufactures, the makers in the community who have a lot of questions around, you know, how to determine if their swabs are safe and effective and if they will perform similar to traditional swabs.

(Tammy McKee): Okay okay so.

(Sara Brenner): Go ahead.

(Tammy McKee): All right yes, I didn't mean to interrupt you just because I didn't hear that part and I don't want to take up too much time. But basically I work at a contract manufacturer called Launch Works and we currently have a lot of customers that have (EUAs) or are trying for (EUAs) and there's a huge lack of (VTM) media out there. And I talked to one of your agents about an accelerated pathway for VTM and I'm wondering if you guys are any close to determining an accelerated pathway for VTM for manufacturers to take?

(Timothy Stenzel): So I would say that that is good questions about this that speaking relative to (templates) email address and our expert reviewers that are SMEs of that topic will address your question. We know that it's - that there's a great need for that sort of thing. And we are working with developers now and we are - and our thinking is definitely evolving in this and we want to provide the best feedback we can if you want to do this. We have worked with a number of entities to do this already and have authorized that formal authorization but we've advised them on how to move forward and they have done that. So we look forward to working with you and others - thank you.

(Tammy McKee): All right thank you.

Coordinator: Our next question is from (Cody). Your line is now open.

(Cody): Hello thank you for taking the call. I have a question related to is there any reference sample panel available for the developer to use? Is the NCI panel do they have it on the (unintelligible) samples instead of sending the kit, is there any way the panel can be made available for the developers - thank you.

(Timothy Stenzel): Yes, we are working on the availability of, you know, the interagency panel or subset of the panel to developers. That has been spearheaded by BARDA and I forget. (Toby Lowe), you may know. I forget whether or not public announcement has been made about its availability -- but if not -- we are working quickly to do that. There are a growing number of other entities that are doing this as well and to the extent that we can help connect people, we are happy to do that. And I'm not - (Toby Lowe), you might be able to let me know if there's anything on our FAQ stage about this at the moment or not, but it's certainly been in discussion. (Toby Lowe), is there anything on our (FAQ) about this?

(Toby Lowe): Not about the panel or the availability of it. We do have information on the FAQ about validation material.

(Timothy Stenzel): Okay so I would check that out.

(Cody): Is it difficult getting from commercial vendors are getting data from two or three different tests and there is no correlation - some test positive, some tests negative. So which one you will carry or use it as a competitor for many commercial vendors they have samples but they are not in the real sense characterized samples to be used at the competitor test.

(Timothy Stenzel): Yes, we understand and which is why we are moving forward with the interagency effort to make at least a subset of the samples that we're vetting for the NCI testing program available. And so it's not already publically made known. It hopefully will be made known in the near future.

(Cody): Thank you.

Coordinator: The next question in the queue is from (Annabel Tie). Your line is now open.

(Annabel Tie): Hi thank you for holding these town halls. They have been very helpful. My question is for clarification regarding the umbrella EUA pathway versus the regular EUA pathway for serology. I'm curious what studies might be waived if the FDA evaluation is performed and whether there's a difference in review time if testing has to wait for NCI results.

(Timony Stenzel): So yes, so there's quite an interest in the NCI testing program, and we are doing (some) amounts of testing. But as the interest grows, there may be the development of a (backlog) there. Once results are known from the NCI testing and its beneath the umbrella authorization threshold, if there is an assay that does not differentiate IgM, IgG, or other isotypes, there is an expedited pathway to authorization.

If there is additional information that a sponsor would like us to review, that may add some time to the review. We look for whether the results are consistent between what data the sponsor has generated and the data generated with the NCI testing. If a developer distinguishes say between IgM and IgG, that particular test is not currently being performed at NCI so we would ask the developer to provide us information about the accuracy of distinguishing IgG and IgM. And so that - once the NCI test results are available, that umbrella pathway is very expedited and we do encourage it. And no other than if you distinguished isotypes no other data is required.

(Anabel Tie): The cross reactivity of the clinical evaluation would be void - would be unnecessary if we had the NCI evaluation. Am I understanding correct?

(Timothy Stenzel): So we have a panel of 80 negatives and...

(Annabel Tie): Right.

(Timothy Stenzel): ..and that is - we size that panel to address both specificity and cross-reactivity. As long as specificity is at least 95% or greater, we waive their acquirement to do cross-reactivity testing. And that minimum of 95% specificity is required for their umbrella pathway. And then on the positive sample side, you asked that suffices also for the clinical performance. So there's no requirement for additional data on clinical performance, negative-positive samples and cross-reactivity as long as the minimum thresholds are met.

(Annabel Tie): Great thank you so much.

(Timothy Stenzel): Yes.

Coordinator: For the questions remaining in the queue, please limit yourself to one question. Next question in the queue is from (Jafar). Your line is now open.

(Jafar): Yes I thank you for taking the call and thank you for this town hall meeting. It has been very helpful. My question is (there any) kind of with any updates or guidance on saliva testing, whether there any studies or information about their performance characteristics or are the labs who are planning to bring them over. Can they use bridging studies based on a previously approved test or they have to do for a full-blown validation? Any guidance there would be very helpful - thank you.

(Timothy Stenzel): Yes so with the template update on Monday this week to our guidance including updates to molecular and the addition of the direct antigen, I don't believe the direct antigen has saliva, it may not. But at least for the molecular, we have proposed some recommended studies to do the comparison testing.

We recommend that you compare to a previous swab type and that minimum number of positives and negatives. I believe it's 30 and 30. And that need at least the bar threshold of 95% (concordance) to the previously authorized test performance. And so those recommendations are now in our templates where we have made recommendations about how to validate saliva. We think that it's important that no sputum be collected, so patients will want to be given guidance that they should not cough say or produce any sputum when they're given the (slightest) sample. We think that may interfere with the accuracy of the saliva sample.

And then of course home collection of any sample type and as well as home testing does require its own EUA. Hopefully, that's helpful. While we're on the call here I will look up the direct antigen template and see if we include the saliva there as well.

(Jafar): Thank you - this is very helpful.

Coordinator: Next question is from (Tom Aherst). Your line is now open.

(Tom Aherst): Again, I also thank you for the openness of these meetings each week. They have been very helpful. I'm not sure if this is the right form, but I noticed the reimbursement changes for the antigen and/or the virus tests for \$100 and the \$50 per collection. And I also see the new CMS codes for the antibody, however I have not seen reimbursement figures. My colleagues and I have not been able to figure out what the new reimbursement figures are for the antibody or serology testing. Do you have any direction on where to get that information or when it will come out?

(Timothy Stenzel): So that is not in the FDA's purview as far as coverage and reimbursement and coverage amounts. That is in CMS's purview, so I would direct you to

them. (Toby Lowe), is there any helpful hints we can give in how they approach CMS about that question?

(Toby Lowe): I know that CMS recently put out guidance about testing and that's where they did include some of those numbers. I believe there is contact information on that document, so I recommend reaching out to that group.

(Tom Aherst): Thank you.

(Sara Brenner): I will also mention that there is a clinical laboratory COVID-19 response weekly call that happens on Monday afternoons where CDC, CMS and FDA often participate. So if you look at CDC's website, you can see (dial-in) information where there's often issues like this that (fall) under shared responsibility amongst the agencies. Questions like this are often discussed.

(Tom Aherst): Thank you - appreciate it.

(Timothy Stenzel): And then I just looked up the antigen template, and it does describe the recommended study for saliva or oral fluid if you wish to include that.

Coordinator: Next question is (Jacqueline Fontain). Your line is now open.

(Jacqueline Fontain): Hi, as everyone has said I wanted to echo, thank you so much for all of your hard work in this time. Our question is about the diagnostic EUAs where they require the product to be distributed only by an authorized distributor who's been notified to FDA. What is your definition of an authorized distributor? Is it only for those that take possession of the product and physically move it into commerce or does it apply to all entities that take, you know, take title to the product even though there might be no possession?

Also, what is the mechanism by a EUA sponsor is notifying FDA of these authorized distributors? Is there a list somewhere connected to the EUA or (list) to FDA doing any vetting of these authorized distributors before they are notified - thank you.

(Timothy Stenzel): Yes, so during the review process, you know, it would work with the primary reviewer for a sponsor's applications and then subsequent authorization, any updates can be addressed to that. As far as what are the legal definitions and requirements of a distributor, that is not my strong area. And (Toby Lowe), can you help address that question or should we take that back and provide an update on the subsequent call?

(Toby Lowe): Yes, there's a little bit of information on our website about distributors sort of generally, not specific to under an EUA. Excuse me, but we think, you know, your questions are probably a little bit more specific and if you can email them to the mailbox or to your lead reviewer, we can make sure we get those answers.

(Jacqueline Fontain): Great thank you - and just to make sure about the templates inbox - right?

(Toby Lowe): That's correct.

(Jacqueline Fontain): Great thank you both so much.

Coordinator: Question is from (Anora Estes). Your line is now open.

(Anora Estes): Hello, thank you for taking my question. Mine should be pretty easy. It appears that the FDA has required all EUA tests to require prescriptions, but test offered prior to any EUA or under the state authority is basically falling under the clear requirements for an order with a - from an authorizer person or

an authorized provider which would depend on the state regulations. Is that correct?

(Timothy Stenzel): We would defer to the state largely on this. Our EUA authorization up-to-date have been by prescription only to help mitigate any risks, especially in the EUA - relax EUA environment that we have. But I would defer on prescriptions and who is allowed to prescribe to individual states and their laws.

(Toby Lowe): And that information has also been updated on our FAQs maybe over the weekend, so there is a new question about prescriptions.

(Anora Estes): Oh okay - thank you.

(Toby Lowe): Yes.

Coordinator: Next question is from (Tim Hendricks). Your line is now open.

(Tim Hendricks): Yes, thank you - my question revolves around point-of-care testing and your policy change last week in regards to the manufacturers having to resubmit their data for approval. If you could shed some light when you will come back with some of these results for these manufacturers. We represent a large group of physicians and physician accounts, and they are interested in point-of-care testing both for PCR as well as the serology testing. Right now it's all lab-based. There's capacity issues and some of the labs are offering these tests anywhere from \$160 to 250 per employee. So it's getting quite expensive for these physicians to restart their practices. If you can shed some light when they can get some information or feedback and which point-of-care finger stick devices will be authorized per your new guidelines - thank you.

(Timothy Stenzel): Okay yes so our website -- sometimes in multiple areas -- does identify all points of care authorized devices and the category. This is designated with a W on our website for CLIA-waived, or deemed waived. And so we've authorized a handful of molecular assays and believe the direct antigen authorization on Friday was also a waived. However, we have not yet authorized a waived serology test. We look forward to doing so. We are working with a number of developers and are primarily awaiting completion of their clear waived studies in order to be able to authorize those serology tests.

(Tim Hendricks): Okay thank you.

Coordinator: Next question is from (Susan Rolly). Your line is now open.

(Susan Rolly): Hi and thank you for giving me the opportunity to ask a question. I have a question regarding the new policy that came out earlier this month and specifically it has to do with a statement on Page 17 with NCI testing where it states that the FDA has issued an EUA for certain serological tests evaluated in the NIH independent validation study or by another governmental agency designated by FDA. And I - my question is to that phrase --other governmental agency designated by FDA Are there any yet or did some of these involve other countries, governments that may have a memorandum of understanding with either the FDA or CDC or both?

(Timothy Stenzel): That was intended for US government agencies.

(Susan Rolly): Okay.

(Timothy Stenzel): We just wanted flexibility to be able to use testing sites within US Federal - within the US government, and so that 's why that was in there. But at the

moment, all testing for the serology test is still being performed at NCI. They just wanted flexibility. We will however incorporate information we might have about an assay to our TPLC Program -- Total Product Life Cycle Program -- where we evaluate pre-market and post-market. Any data that can affect performance of the (assay) and we do look at the publication. We do look at other government authorizations and reports. So we do keep our eyes and ears open about this.

But as far as the serology NCI testing program, again right now that is the - that's the only program that stood up right now. We just want a flexibility. Hopefully, that helped.

(Susan Rolly): It did - thank you very much.

(Timothy Stenzel): You're welcome - and my apologies. It's unusual, but I will be dropping off the call here after probably the next question and turning over the mic to (Sara Brenner) and (Toby Lowe) for the rest of today's town hall but anticipating being here next week for the full length of time.

Coordinator: Next question is from (Marie Miller). Your line is now open.

(Marie Miller): Hi, thank you for taking my question. My question is about control solutions for a lateral flow antibody test. I noticed that several manufactures have recommended using control solutions with their tests but they don't all provide them. So does the FDA have recommended suppliers for antibody control solutions or materials, especially for positive control samples?

(Timothy Stenzel): Yes that is a continuing challenge we ask that of developers to make that available as soon as they can. These materials in control that will function well and consistently and reliably are a bit of a challenge in the short term to

develop. But we do engage with the developers on this. So as soon as these are available, we will be sure to make that publically known. In the interim, it may, unfortunately, fall to the lab to acquire a known positive and negative they can use.

(Marie Miller): Thank you.

(Timoty Stenzel): Yes, okay (Toby Lowe) and (Sara Brenner), I will turn it over to you.

(Sara Brenner): Thank you (Tim).

Coordinator: The next question is from Mellissa Marky. Your line is now open.

(Melissa Marky): Hi there thank you so much. I'm wondering if you have any estimates of how long this is taking to evaluate the validation data and issue or decline an EUA for the serology antibody tests that are being distributed under Section 4D of the policy for COVID-19 testing?

(Toby Lowe): Yes thank you for your question. Go ahead (Sara Brenner).

(Sara Brenner): You can go first. You might have a little bit more insight on the timeline.

(Toby Lowe): Sure, so it really depends a lot on what we received from the sponsor - from the developer. We do - as soon as we get in a submission, we do at least the first pass through it to see if there are any issues and work with the manufacturer to address anything that we find concerning. And then we, you know, we do more of a systematic review of the documentation that the sponsor provides. And depending on, you know, how much back and forth we need to go through with it - with the developer, that will affect the guideline.

And, you know, for the submissions that we've had in so far across the board - not just for serology -- we've authorized some of the EUAs within 24 hours. Others have taken a week or two to get through. And so it really does depend on a case-by-case basis but we are working through them as quickly as possible.

(Melissa Marky): Thank you so much.

Coordinator: Next question is from (Monaleu Shaw). Your line is now open.

(Monaleu Shaw): Hi my question is regarding EUA and the establishment and registration. For one, for a product just using EUA, is it necessary to go for an establishment and registration? And if it is, by whom, by the manufacturer or by the importer or it will be both - thank you.

(Toby Lowe): So I believe that the manufacturer we generally not enforce registration and listing for the EUAs. I believe we may for importers though. If you would like to send that question into the mailbox, we can get you a firm answer on that. Unfortunately, that is not exactly my area of expertise.

(Monaleu Shaw): Okay all right - no worries, thank you so much.

(Toby Lowe): Sure.

Coordinator: Next question is from (Marianne Williams). Your line is now open.

(Marianne Williams): Hi (Sara Brenner) and (Toby Lowe) - thank you so much for hosting these meetings. My name is (Marianne Williams) and I'm with a (surgeon) and I have a follow-up question regarding the use of the controls. The question was whether RUO controls can be used in EUA devices that's how I understood it.

And if I understood correctly, it sounded like the (RUO) controls needed to go through the EUA process themselves, however in the FAQ -- in the testing FAQ questions -- it provides a number of resources for both RNA extract classes and synthetic RNA so most are RUO products. Wouldn't their authorization for using an EUA be inherent to the EUA application from the controls used in the test?

(Toby Lowe): Right at this time we don't have labeling recommendations for controls. And we are, you know, we would want the laboratory if they're using controls that are not provided as part of the EUA to follow your normal procedures to verify them.

(Marianne Williams): Okay thank you.

Coordinator: Next question is from (Amy Derk). Your line is now open.

(Amy Derk): Oh hi, thank you for taking my question. I see that the new molecular testing states that FDA recommends natural clinical specimens. And at the same time, the new guidance states contrived clinical samples will be considered. My question is -- especially with respect to pending EUA applications under review that are prepared with (contrived) samples -- how quickly and retroactively are you planning to apply this new template language - thank you.

(Toby Lowe): We would encourage you to discuss, for submissions that are already in the works -- we would encourage you to discuss those issues with your (lead) reviewer.

(Sara Brenner): This is (Sara Brenner) and I think the point is to be reasonable but make that transition as expeditiously as possible.

- (Toby Lowe): Right and we may ask that you consider doing some additional postmarket analysis if you've already prepared your submission with the contrived specimens.
- (Amy Derk): Got it and especially in cases where a natural specimen is really practically impossible to acquire for some applicants. A strict, rigorous standard won't be - it's unlikely to be as uniformly applied. Is that correct?
- (Sara Brenner): I think, as (Toby Lowe) mentioned, if you work with a lead reviewer who is actively handling your case, they'd be able to help indicate, you know, how far along that process is and sort of how reasonable it would be to incorporate, change course or add some post-market on. I think the intention is certainly not to slow things down but to, you know, improve the quality of tests over time as the situation is evolving.
- (Amy Derk): Got it.
- (Sara Brenner): ...one size fits all generally isn't an appropriate way to go, so we try to work with each developer individually...
- (Amy Derk): Thank you.
- (Sara Brenner): ...as soon as possible.
- (Amy Derk): Thank you so much.
- Coordinator: Next question is from (Cynthia Flynn). Your line is open.
- (Cynthia Flynn): Hello my question is regarding the antigen testing. First off, you know, we all

most hospital systems got rid of their antigen testing after the H1N1 epidemic but then, you know, and obviously we're going to have officially false-negative test. But - and I understand that you put the information in the package (unintelligible) for the antigen tests. But reviewing the one antigen test that did get approved, its own collection device would not allow for retest with a PCR result. You'd have to collect it in (UTM) media which they have as they - as an alternate device. But I'm worried that if we continue to have all these tests made with like collection devices that don't allow for retesting with our RT-PCR it's just not going to be done, you know.

(Sara Brenner): Yes, this is (Sara Brenner). That's an excellent and very pragmatic point in terms of how the testing strategy will go in the clinical world. Thank you for sharing that comment and those thoughts. I would like to capture that -- what you've shared -- and even more details in terms of the discussions that are ongoing on testing strategies. If you could summarize some of that and send it into our mailbox, that would ensure that we've captured your thoughts and they're taken into consideration moving forward. They are very important.

(Toby Lowe), do you have other thoughts on that?

(Cynthia Flynn): Well, you know, it's just the whole thing with antigen testing is concerning and I understand Dr. (Birks) and others that are involved in HIV like antigen testing is so important and, you know, it was a major breakthrough. But for upper respiratory tract infections, antigen testing has always been, you know, in theory, or two to RT-PCR and it's a big reason why RT-PCR is used now as the gold standard. And so, you know, whereas, you know, we get a lot of press now saying that antigen testing is going to be the big deal. But, you know, it usually causes more heartache than actual improvement.

(Sara Brenner): Yes understood and, you know, certainly I don't know that any of us dare to

hope that there's going to be a singular magic bullet that, you know, that will (in terms of testing) solve all of the issues going forward. So you definitely want to take into consideration -- the limitations and strengths -- of each type of testing to come up with the best comprehensive strategy for how they might be deployed clinically and what the information from them would indicate in terms of both clinical management and also population or public health level decisions. So thank you for your perspective. (Toby Lowe), did you have any comments on that specifically or should we move to the next question?

(Toby Lowe): Yes, I think you covered it, you know, if the antigen is one option in the testing toolbox if you will and, you know, we've been working to make sure that the information that's out there is available in terms of the pros and cons of, you know, the benefits of each different type of testing and making sure that we're labeling for each test is appropriate and includes all of the necessary mitigations.

(Cynthia Flynn): All right and definitely continuing the push the idea that serology is not a stand-alone test for diagnoses because, you know, it's just hard out there. People don't really necessarily understand no matter how much information you provide them. And a lot of us in healthcare systems are having to beat back people wanting antibodies tests while they still have symptoms and it's problematic.

(Toby Lowe): Yes, and that's something that we've made sure to have in the labeling for the antibody test and on all of the documentation that we have on our website that serology is not a diagnostic.

(Cynthia Flynn): Right and I certainly hope going forward that you continue to have these serology tests reviewed by, you know, scientific partners with, you know, and continue the umbrella policy. I think it's a great idea - thank you.

(Toby Lowe): Okay thank you for your comments.

Coordinator: Next question is from (Mark Wagner). Your line is now open.

(Mark Wagner): Hi thank you - I was wondering if there is a process for importing commercial manufactured and validated serology test kits for distribution while in EUA is pending?

(Toby Lowe): Yes, so if you look through our policy document, the guidance document, commercially manufactured serology tests may be marketed while they are pursuing an EUA. So we would ask that notification be sent to FDA for the process in the guidance document and indicating that it's validated and including all the information noted in the guidance. And then within 10 days, submit an EUA request. And during that time, they - those tests are able to be imported.

(Mark Wagner): Okay thank you.

Coordinator: Next question is from (William Nelson). Your line is now open.

(William Nelson): Good afternoon - I appreciate the FDA be available for these calls as they've been quite helpful. With that being said, just one question as it pertains specifically around the EAU submission process. Two of our commercial partners have already applied -- one back in March and the other back in April -- and just trying to get some insights into the potential backlog because they were expecting to get responses back in 30 days. Is that -- moving forward -- is that looking like it's going to be closer to 60 days or 90 days before they get a response in via the review process? What is that currently looking like?

(Sara Brenner): (Toby Lowe), I don't know if we have any hard metrics on the rate of response in terms of data right now. Do you happen to know?

(Toby Lowe): No, you're asking about the response for a submission itself?

(Sara Brenner): Yes, he asked about two specific EUAs -- one submitted in March and April and if there's a prediction on a timeline for...

(Toby Lowe): No, no we're working through each individually. So I would recommend reaching out to the lead reviewer if you are looking for any updates.

(William Nelson): Oh okay thank you.

(Sara Brenner): Yes sorry that's a frustrating response.

(Toby Lowe): Yes.

(Sara Brenner): I understand that the community is very frustrated with timelines, and everybody wants things very quickly and the world needs things very quickly. So one thing I can promise you is our teams are working around the clock literally as fast as they can on these. But you should have received some sort of notification or automatic reply and a conduit for follow-up. So, the intent is to give you access to a person that can be your primary point-of-contact for each submission who can check in with you and you can ask questions, you know, with the specifics of each of the applications you mentioned and any others for those on the phone to get a status update and to see if there is anything else that can be provided and talk to us sort of on a human level. So please reach out to those points of contact. If you can't get someone, say by mid next week, feel free to reach out to me and I'll see if I can help you.

(Toby Lowe): Yes, and same with me if you're having trouble getting the response, feel free to reach out to me as well.

Coordinator: Next question in the queue is from (Jason Labothom). Your line is now open.

(Jason Labothom): Hi, my question was sort of answered I think it relates to distribution agents importing serology tests that are undergoing EUA or has EUA has been applied for. I guess the question is whether or not the distribution agent will need to be on the FDA registry list for diagnostic importers. It seems like the CDC guidance says that there's some compassionate use, emergency use device and that this COVID was allowed for some type of leniency but it hasn't been clear with our communication.

(Toby Lowe): Right that's correct because there is a code for compassionate use and there's a code for EUA. But before a EUA is authorized, the compassionate code would be used for importation.

(Jason Labothom): And then subsequently if the EUA is obtained, then the distributor wouldn't need to be added to the FDA registry page?

(Toby Lowe): So I believe that as an importer, you need to register and list -- but again -- unfortunately this is not my area of expertise, so I would ask that you send the specific question into the mailbox and we can make sure they get you the right response.

(Jason Labothom): Okay thank you.

Coordinator: And now let's turn the call over to Ms. Irene Aihie.

Irene Aihie: Thank you - this is Irene Aihie. We appreciate your participation and also

questions. Today's presentation and transcript will be made available on the CDRH webpage at (www.fda.gov/training/cdrhlearn@itbasemay19th). If you have additional questions about today's presentation, please email cdrh-eua-templates@fda.hhs.gov. As always, we appreciate your feedback.

Following the conclusion of today's presentation, please complete a short, 13-question survey about your FDA, CDRH virtual town hall experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live session. Again, thank you for participating. This concludes today's session.

Coordinator: This concludes today's call. Thank you for your participation. You may disconnect at this time. Speakers, please stand by.

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