Virtual Townhall

Moderator: Irene Aihie
July 28, 2021
12:15 pm ET

Irene: Hello, I am Irene Aihie, of CDRH's Office of Communication and Education. Welcome to the FDA's 64th 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, Dr. 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 from CDRH, will provide a brief update. Following opening remarks, we will open the line for your questions related to the development and validation of tests for SARS-CoV-2. Please remember that during this town hall we are not able to respond to questions about specific submissions that might be under review. Now, I give you Timothy.

Tim: Thank you Irene and hello everyone and welcome to this week's installment of the FDA CDRH town hall, where we, Toby and I, and sometimes other special guests really try to be informative and transparent and direct as possible with our current thinking and our recommendations for test valid validation. This is in an effort to assist in the public health response. We continue to see this pandemic evolve and stay with us, unfortunately, in a very significant way, and so we stay very close to the situation so that we can always provide the priority for those tests that are going to best meet the needs at the moment, and this has evolved over time. Our priorities are listed on our website. You can go there, and you can you can review them. They're all designed to increase the volume of tests significantly and the access to test

significantly, and that is primarily focused at diagnostic tests, in the home, point of care, and in the central labs. And we are most focused on those tests that are high volume tests in certainly safer point of care or home, no single point of care side or home site is going to do a significant volume. But in distributing that test in as many homes as possible and as many point of care sites possible in supporting those sites with significant production of the tests, you provide that possibility and that's what we are focusing our reviews on at this time. I did want to briefly mention the CDC lab alert that we have had multiple questions over multiple days and multiple forums. The CDC has announced that after December 31st they have requested the US Food and Drug Administration to withdraw the EUA for their original SARS CoV-2 test it was interested in getting used in February of 2020 for the detection of SARS CoV-2 only. The impact, and I'll go into this later I'll go into some of the questions, is it only on the CDC test and not on anyone else, and so only those who are currently receiving the CDC test and either directly through the CDC or through Bio Search or IDT, those are the only labs that will be impacted by this decision and so we would direct any other further questions to the CDC if you are impacted by this. If there's something that the FDA can do to alleviate access issues by alternative means we are all ears and you can send an email to the template email box. We also have a theme, the many questions around branding. So we do allow private labels for authorized tests, so this is an effort to expand access through the use of different sales channels and oftentimes those sales channels want their own brand for any EUA authorized test. That's a simple procedure to update that. The EUA authorization holder can simply request this and by submission to the templates email address, and we'll make this update and will post, the new brand name or additional brand name on the FDA website where we post all the authorizations. That's' in the drop down plus sign on the website. And this is an effort to provide complete transparency so because it may not be as

evident that this new brand name or another brand name is an EUA authorized test, and so folks who want to know this can go to the FDA website, make sure that that brand is attached to that EUA authorization. So that's our desire to be totally transparent and clear and make this very clear about what tests are authorized, and perhaps which aren't so that purchasers of tests can be totally sure of what's authorized. Toby, do you have anything else to add to my opening remarks there before we go into the pre-submitted questions?

Toby: No, I don't think so. Not today. Thanks.

Tim: Okay, great, the first question, and there are a number of questions on serology tests related to this. There is a tremendous obvious interest in whether serology tests can be used to measure immunity or protection, either from a natural infection or from vaccine administration and, you know we've spoken to this in prior town halls and I've spoken about this, and in many other public forums as well. You know, we are at the FDA are looking for the data from outcome studies and we know of many studies that are ongoing and in those studies we hope are going to inform what can be said about serology tests. So, a pre-submitted question asked where can they find the study design. Where can they find additional information and then they comment they cannot find these studies on clinicaltrials.gov To my knowledge, all the ones, many that we're aware of at the FDA, are listed on clinicaltrials.gov. I'll give you one specific example, so that you can look it up. So there are numerous studies ongoing and they to our knowledge are listed at clinicaltrials.gov. One is NCT and you can simply Google it or go to clinicaltrials.gov and search for it and NCT 04373148. Again NCT 04373148. It was simply the first one on my list, and there was no other selection bias about why I'm providing that but I'm just trying to give helpful hints about how you can find these studies. You know our Center at the FDA CDRH, does not have any direct involvement with these studies. We are simply awaiting the result when

they become available and are not in control of any timing. You know, obviously any individual developer can confirm their own outcomes study and submit their data to the FDA. That is likely to be a very large study and we understand that and so these large studies that are being performed that we're looking forward to the results from are a real efficient way to accumulate that. But, again, we're open to data being submitted by any that supports this use and the outcome that can help us decide whether a given test, most likely a very specific level of antibody, has any indication of protection or immunity. We have fully authorized this type of serology test previously. Non-SARS related, rubella is one good example where we know in international units with sterilizing level of antibodies directed to rubella and that has been authorized, along with some others. So let's see, what else? And I just want to make sure I've covered all the questions related to serology and immunity. I think I have so we'll move on to the next question. The next question has to do with the CDC lab alert that I mentioned at the top of the hour, where the CDC is withdrawing, at the end of the year, their original authorization and, as I said before, it only impacts their test. So, and you know they have announced that the test that they're going to support is their other EUA authorized test, which is a panel test. And it's for SARS CoV-2 and influenza A & B. It's a great test. And we continue to review, as a priority, panel tests, at our Center and these remain a priority for review. That may not be so clear but we've said this publicly and many times before, and I just wanted to reiterate that and we understand why that is the priority. We do, even for that, we will not be prioritizing for review, low volume tests and it's not really going to help at this stage in the pandemic. So we're we are looking at high volume tests that, as I spoke to at the beginning of the call that can make a significant impact on this and we have plenty of work among tests that have been submitted, that are high volume and make the public and are designed to meet the public health needs. The next

question also, and there's three questions, has to do with the CDC announcement. I'm going to run through these questions and then answer them combined. The first question is, does this withdrawal indicate the EUA pathway from molecular manufacturers is closing at the end of the year? First the answer is no. Is FDA planning to end the pre-EUA submission process for new EUA products by the end of the year? That the answer is no. If a manufacturer of a currently manufactured EUA assay references or leverages the CDC EUA assay in their IFU and analytical studies, what steps will the manufacturer be required to take after the CDC EUA is withdrawn? That right-of-reference still exists to the data and for all tests that have been authorized using that right-of-reference from the CDC, they are intact. It does not impact their EUA reauthorization at all. They will remain intact as long as there's an obvious performance issues, specifically related to them. So that should give good reassurance to anyone that is currently using the CDC design or elements of the CDC design and wants to in the future utilize the CDC design. And, as I said at the beginning, this only impacts those labs that are directly receiving the CDC original tests – that's usually just public health labs. Or is only public health labs. There were two other manufacturers IDT and Bio Search that were authorized to provide the exact CDC reagents under the CDC authorization, unfortunately, they will not be able to provide labs with that test as authorized under the CDC authorization. We urge those labs that are doing that right now to look at one of the many options and that those labs have for alternative tests in its stead. The FDA did not request this. This is at the request of the CDC. I think that covers my responses to the CDC question. Toby do you have anything to add about that?

Toby: No, you covered all of it.

Tim: Okay. I think you're up next right. Nope nope, I am sorry I'm next one for one more so, there have been continuing and multiple questions about development of SARS CoV-2

serology tests to neutralizing antibodies serology tests, and this is currently a priority, as long as it meets the expected high volumes and we have continued to provide on our website a template for developers for developing tests for the new neutralizing antibody assays as a recommended validation. So we would urge developers to just follow those recommendations. There's no requirement to submit a pre-EUA. If you're following our recommendations and go, you know just go and do it and submit your EUA with your validation and the FDA will review that. There may be some very targeted specific questions that you may have, for example, it's probably good to check the PRNT test that you're going to use to validate your neutralizing test with the FDA to make sure that that's you know, an acceptable choice for you. So by and large, you know, the only question, I think that is of significance, where developers really sort of need or could use that input from the FDA and that potentially could be handled just through an email to our template box, rather than through a pre-EUA. Toby, anything else on that topic?

Toby: No.

Tim: Okay, over to you.

Toby:Okay, so our next question is from a company that says they've licensed a molecular test from a sponsor that already has an EUA . And this new company intends to market the test under a different brand but fundamentally the technology is identical. And they are preparing an EUA submission for the new brand and would like to know how much of the original data needs to be included in the new submission, if they can reference the original data, or if they need to resubmit all of the data again. So, without exactly, the questions is that, fundamentally, the technology is identical. So you know, the question that we would have is whether it is the same test, where it is just being rebranded or whether there is something about the test that is changing. So generally if you have a right of reference from the original sponsor

you can leverage data from their submission. However, if the test truly is identical other than the brand name, a simpler pathway would be to have the original sponsor send in an update to their EUA naming this additional company as a distributor and they can submit the alternate labeling with the new brand under the original EUA. And then, as Tim mentioned earlier, we do include additional brand names on our website so that would be added to that original EUA rather than needing a new EUA there.

Tim: Sounds good. Next question.

Toby: The next question that we have is regarding IRB approval related to COVID-19 tests and EUAs. In response to this, we can clarify that, when a medical product such as a COVID-19 test is being used under an EUA, it is an authorized, though not an approved or cleared, medical product, for use in clinical care that has met the statutory criteria under Section 564 of the FD&C Act. This means that, when a test is used consistent with the tests authorized labeling and not as part of an investigation, IRB review and approval is not required by FDA. It is important to note that investigations involving human subjects which includes bio specimens for which the purpose is to determine safety and effectiveness of a specific device, including tests, and so that would include investigations that would evaluate a test prior to a submission of an EUA request are subject to 21 CFR parts 812, part 50, and part 56, including the IRB requirements in those parts of the CFR.

Tim: Okay, I will move to the next question. Next question has to do with an OTC home antigen test that was originally authorized without use of a mobile app to read the results, that is, it was manually read but whether or not an app was available for reporting those results or not, and apparently in this case, there was an app that was reporting that results as entered by the

user, but the device itself was not reading the test interpreting the test and making the call and they want to know what are the validation studies and requirements to be able to validate this. We do have some items in our antigen templates for this. And we do have a mobile app software group that reviews this and can answer questions for either EUAs or pre-EUAs, but this is pretty straightforward work at this point. We've we've authorized some of these already and the question is, you know, do they you need to do another clinical validation or analytical validation and the short answer on both of those is yes, we have seen widely different results from these kind of devices between manually read and visually read and we've seen some Apps that perform really well and others that we've not been able to authorize and so. it's important for mobile phone app readers to be developed in a way that perform as accurately or better than manually read results. Also there is this is home and there's a user interface here and it's important that the FDA have data that home users can can accurately use these reader devices in the home and get the right result so that obviously entails new usability and new clinical study in that situation. So that they can get accurate results, that they can still read the manual results, that they know how to handle you know certain conflicts between the app reading and the manual reading. So those are important considerations also, we know that analytically things like the LOD, cross reactivity, false results can,false positives and false negatives, can happen when you move to a device app to read the test. So yes, the analytical studies will be recommended to be performed, as well as the clinical studies to evaluate this new technology for the test. And I think that ends our questions. Doesn't it Toby any anything else to add?

Toby: That covers all of them.

Tim: All right. well. I was running the show which isn't really Toby and me. We want to open it up for questions.

Kevin Flinn (AV Support): All right, we have Patty Jackman.

Patty Jackman: Yes, I have a question. If the laboratory modifies a test system from a manufacturer that does have an EUA, should they still follow the manufacturer's patient result reporting guidelines?

Tim: I'm not sure that I understand enough details about your question to provide an answer, perhaps you could rephrase your question and I can try to make sure that I understand, so that I'm able, to the best ability, answer your question.

Patty Jackman: Sure, so if a laboratory is using a test that does have an EUA that they make a modification to that test system, should they follow the guidelines for actual patient results reporting like negative versus positive, detected, non-detected?

Tim: Yeah so we still have FAQs up and I'm going to let Toby weigh in on this one as well. For modification to EUA authorized tests and, obviously, you know, especially in shortage situations which, fortunately, at the moment at least, knock on wood, we don't seem to be into a severe crisis right now. There are concerns say with tips and things like that and we're working with proprietary manufacturers on what can be done and alternatives that can be used. But at a high level, if a laboratory makes a modification to a test and it no longer follows the instructions for use of that test, it could impact the performance and it does take that test out of the realm of an EUA authorized test. The lab can no longer claim that it is such a test, and do we have some recommended language, Toby? This is a question that has been coming up recently, so I'll turn it over to you to sort of complete the response.

Toby: So as Tim was saying, making a modification does make the test basically not an authorized test anymore. You know, I think it sounds like you're referring to you know

something like using the interpretation table in the manufacturer's instructions, is that sort of what you're getting at?

Patty Jackman: Yes, like in regards to, yeah like whether they say report negative or not detected or positive thing, because each manufacturer is different.

Toby: Right, so I think some of that will depend on what it is that you're modifying and how it impacts the performance of the test. You know, we do have recommendations in the COVID test guidance, the policy guidance and some additional information on the FAQs about our recommendations for validating such modifications and what to do in those situations. But you know I mean if it changes the LOD, if it changes the CT cut offs, then it may impact the result interpretation and reporting. If it does not change those things, it may not. So I think the you know sort of the key is that making a modification generally would make the test, no longer you know the authorized test, and we would expect the new version, the modified version of the test to be validated, including the cut offs and the reporting.

Tim: Yeah nothing much to add to that. Yes, the labs if they make modification and then fail to them to fully validate those changes and if there's any changes in performance that should be reflected in the reporting. And the other thing to add is that EUA authorization holders should not be advising labs on modifying their test and validating the changes. If an EUA authorization holder wishes for there to be a modification to their tests then they should validate it and submit it to the FDA and seek an amendment or supplement authorization from the FDA so that they can then legitimately promote that modification. Toby, anything else?

Toby: Just a little bit to build on what you were just saying Tim, you know if a lab is interested in modifying a manufacturer’s test. You know, particularly if it's to add a component that is more readily available to them. It is also very beneficial if the if the lab can reach out to

the manufacturer, and if it's a modification that could potentially benefit more broadly than just the single lab, then you have the ability to collaborate with the manufacturer, give them the ability to use your validation data, and encourage them to submit it as a supplemental EUA request to update their authorization. And I think with that we can probably go on to the next question.

Kevin Flinn (AV Support): Okay, we have Diego Blandon up next.

Diego Blandon: Hi I have two quick questions. The first one, I just wanted to confirm, I think, from what you were saying earlier, the answer is yes, but given that the CDC test will still be authorized until 2021, will it continue to be an appropriate comparator for future submissions as long as the study was completed prior to them withdrawing the EUA?

Tim: That's a valid EUA and it will remain enforced and data collected using it can be used for FDA submission. Toby, anything to add?

Toby: No nothing to add.

Diego Blandon: Okay, great, and the second one, given that the viral load of the delta variant's initial data suggests that it's significantly higher than the original variant or the originally-identified virus, will antigen EUA requirements be modified from the the current requirements of 10 to 20% low positives with CT values greater than 30 in light of this development, or is that not on the FDA's to do list right now?

Tim: The reason for their recommendation is, we want to make sure that results within the first five days or seven days or whatever the antigen test developer, is seeking for authorization of patients suspected of COVID-19, we want to see a normal distribution of those results and I don't know that we have enough data yet on delta and it's you know, certainly, it looks very convincing that the peak viral amount that those peak amounts do peak higher than

potentially other variants but you know it could be that they fall as quickly by end of the window. We do like to see you know for inclusivity on clinical studies to know when the study was done so we know what variants are out there. It could impact what additional inclusivity testing that we want, but you know it's a good point and I'll be sure to the tracking that. If you're having a challenge obtaining low positives, engage with our review staff and we'll look forward to working with you on find a path forward.

Diego Blandon: Thank you so much.

Kevin Flinn (AV Support): All right, forgive me for my pronunciation, Sreyashi Samaddar.

Sreyashi Samaddar: Hello everyone, thank you very much for the wonderful webinar and information.

Tim: You're, a little bit soft. A little bit soft can you speak a little bit louder closer.

Sreyashi Samaddar: Can you hear me now?

Tim: Little better now.

Sreyashi Samaddar: Thank you, thank you very much, so my question was regarding a test which we're trying to validate it for asymptomatic screening or surveillance testing. So the template, which was the July template, it does not exactly I mean if I've missed it I'm really sorry but the number of samples that need to be tested in order to validate our test for asymptomatic screening, can you give me some idea about it?

Tim: Yeah what kind of test, are you talking about?

Sreyashi Samaddar: RT PCR tests.

Tim: And is it a point of care, home, central lab?

Sreyashi Samaddar: CLIA lab test.

Tim: Okay, so moderate and high complexity. Yes, um so you know I will answer your question directly as well, but be aware of the serial testing option. So if it's a molecular test, the high sensitivity central molecular test. The serial testing pathway allows you to validate on basically symptomatic patient that allows you to collect data more quickly, get your authorization, as long as it meets our performance expectation. And those would generally be for central and molecular test, you'd be at 95% PPA or greater. Then, then you can simply agree to do serial testing in your IFU package insert and have the test performed at least once a week. and get that asymptomatic screening claim, without having to test premarket asymptomatic patients. Now you can also pursue EUA authorization, as others have successfully done testing you know, in the symptomatic population for screening and, Toby you're going to correct me here, please, but I think it's pre authorization, we require a minimum of 10 asymptomatic patients and then an additional 10 premarket that can be from symptomatic patients but that are matched in the viral loads as seen in your asymptomatic sample. So we will look at 20 results in the pre-authorization phase only 10 of which have to be from asymptomatic patients. Then post market if you only you have the minimum number of 10 asymptomatic premarket, we will go ahead and authorize you with a screening claim and then post market, you would agree to complete testing for additional 10 positive asymptomatic patients, so that we can have a greater assurance that it's performing well in the symptomatic screening population. The same pathway is available for essentially all the other direct test types as well. Hopefully, that answer your question.

Sreyashi Samaddar: Yes, thank you so much, I just have one clarification, so when post market when we will have to go ahead and do 10 more positive asymptomatics, do we also have to do, equal viral loads 10 symptomatic like we needed premarket?

Tim: No, that's just for us to understand. You know, we have seen differences in viral loads and typically, well, I don't know of any case where viral loads were higher in the symptomatic population at least to date studies that have reviewed and our team has reviewed so. So that is just to get enough information as a viral load in your studies that are asymptomatic patients and comparable to asymptomatic patients, so we can make up our best decision premarket with only see 10 asymptomatic positive results.

Sreyashi Samaddar: And the other thing that I had to ask you, was the matched and viral loads. Do you consider compare like similar CP values or should we do a separate testing where we can measure the viral loads and the concentration on the RNA?.

Tim: No that's not needed. Just use an EUA authorized appropriate high sensitivity molecular comparative result that reports out CTs. In different molecular tests that report CTs - the CTs don't mean the same thing - so ideally you use just one EUA authorized by sensitivity molecular asset that report CTs for your study and then we look at those relatives CT numbers. So you know, whatever the distribution average and mean and median are for on your asymptomatic that's what we're going to look for in the matched symptomatic sample to complete our data review for authorization premarket.

Sreyashi Samaddar: I appreciate so much, thank you for answering my question and again like, if I have further questions, maybe I will just send this to CDRH, for EUA IVD email right?

Tim: Yeah that's fine.

Sreyashi Samaddar: Thank you, thank you so much.

Kevin Flinn (AV Support): Next up is Jeanna MacLeod.

Jeanna MacLeod: Hi can you hear me?

Tim: Yeah.

Jeanna MacLeod: All right, I'm just looking for clarification. I feel like this has been covered, but I just wanted to double check. So if we're doing for an antigen test prospective collection of the full 30 positives, what are the expectations of the viral distribution? So would we still expect to need to have the 10 to 20% low positive distribution for fully prospective or do those requirements only apply to any retrospective or enrichment type of evaluations?

Tim: We want to see a normal distribution prospectively as well as if you're allowed after conversation with us to submit bank samples or for some situation for bank samples, you said antigen test, though. Yes, it's not all situations, or is it appropriate for bank samples to be used, but typically point of care we have allowed bank samples, the first antigen test authorization was actually mostly on bank sample but that developer ended up moving away from VTM samples, because there were issues with VTM so if you're going to use VTM samples rather than bank, direct swabs, that those are issues to work out with the FDA. We want to see freeze thaw studies, because for many tests, we've seen an increase in sensitivity, through a freeze thaw cycle. And, and we want to understand how that could impact the performance measurement and therefore what goes in your package insert for performance, because you know if your LOD is better on frozen samples, and your clinical validation is better on frozen samples, we want to know that. And we want to know, then basically with fresh samples that your performance is meeting expectation. So it's a bit complex and at first authorization, even though we allowed a bank VTM sample we wanted to see a complete set of VTM samples 30 positives and 30 negatives, and then we also because they didn't want instructions in their tests to you got to freeze the samples before you use it. I mean we're open to developers who want to put that into their instructions for use and that's what the authorization they speak, but that would be you know a bit of an impediment

for most point of care to another. For the lab after we see the sample fresh and then freeze it before using it, so we wanted to see you know some fresh sample data now fresh negative should be no problem at all. And it's the fresh positives that have, at times, been a challenge, right now, unfortunately, you know if you're having you know, a challenge getting fresh positives, you're probably not you know you haven't picked the right clinical trial sites and unfortunately right now, there are so many opportunities in the country with high positivity rate that that should not be a problem. But if you want to speed access to your test, you can use bank samples just you know, make sure that you engage with the FDA review staff, make sure all the appropriate studies are done and, if you have at least 30 positive I mean 30 negative fresh samples and five positive fresh samples with showing good performance you can't like show PPA of zero percent on those five samples and expect to have to authorize the first sample.

Jeanna MacLeod: yeah so if it is 30 that are fully prospective, or are we still looking at that 10 to 20% low positives or are we, is it just sort of saying.

Tim: yeah OK, so the the distribution you got it's.

Jeanna MacLeod: yeah yeah I guess we're just sort of wondering if we can continue collections to get those low positives.

Tim: Our current thinking is low positives really have to do with the molecular competitor and we're looking at aligning our recommendation for low positive with that, and so our current thinking, is we really like to see those low positives 20 to 25%. within three CTs of the LOD of the comparator molecular assay, so that that's going to have to be an assay that reports out CTs obviously And LOD is different than the cut off. Cut off may be let's just say 40 cycles, but the LOD, may be 35, so we're really looking at between plus or minus, 3 cycles of the LOD which is 35 so you go from the math with a 32 to 38 is where we'd like to see 20 to 25%. I

mean if you're struggling with that we want you to come in with those 10 to 20% low positives and and have a discussion with us, but. You know our thinking on that is evolving a little bit, and that is our current thought, but again, you know if you're struggling right out you've done 30 positives you know, and you can show us your CT distribution and the comparator test and discuss your struggles with us, we will try to brainstorm with you to figure out a way to help you get over the last hurdle. We've done that frequently. We've done that this week with antigen test developers, so okay?

Jeanna MacLeod: Thank you.

Kevin Flinn (AV Support): Okay next we have Kumar Duraiswamy.

Tim: Yes, we can hear you, you might want to speak up a little bit.

Kumar Duraiswamy: Oh perfect Okay, so I had a question, I think it was covered at the top of the hour, but I wanted to make sure I heard it correctly. So I understand the CDC 2019 NCOV assay EUA is going away at the end of the year. Did you mentioned that the CDC SARS CoV2 flu multiplex will EUA still be in effect or will that also be going away?

Tim: The CDC has informed us that they're converting everyone that they provide testing to to their combo panel tests that remains EUA authorized, and it appears to be a very good test and again the FDA did not request this withdrawal, the request is coming from the CDC.

Kumar Duraiswamy: That would need to ask the CDC if we'd want to keep that in place. Okay, thank you very much.

Kevin Flinn (AV Support): Alright, Donald Henton.

Donald Henton: Have to unmute myself sorry about that.

Tim: I do, that all the time I have my best conversations with myself on mute.

Donald Henton: Yes, so. These virtual meetings. The question I have is related to the pooling and screening guidance that you've put out and we've been looking at the specifically at the N equals three section and we're trying to grapple with is the guidance telling us that we can just move forward with that, with our existing EUA submitting information updating our labeling, or is the Agency looking for that notification to also include test data? Because it says no additional validation is needed, so I just wanted to be clear on what that notification would look like.

Tim: Yeah so if and Toby I want you to back me up on this and continue, that if you're just going for three x and you already have EUA authorization ,we're not going to need to see that data and expect you to authorize that. There's good reason for that, based on historical data from many pooling test submissions. And the ability of a test that's already high sensitivity to perform well in a three x pool basically you know if you're following specific recommendations and path that we provided there, we've never seen a good test fail at three x. Toby? I think there may be some caveats and I may have missed some details in the question of notification, all that is probably a good question to turn over to you.

Toby: Yeah I can definitely address that, so this is referring I believe you're referring to the EUA amendment that we issued on April 20 to amend certain EUAs to add pooled screening as part of a serial testing program, and so the letter of authorization for that amendment does include specific criteria for the tests that would fall under that amendment, as well as specific information that needs to be submitted to FDA as part of that notification to be added to the exhibit of the amendment. As you indicated in your question, and as Tim confirmed for both swab pooling and media pooling up to an N of three, we do not expect additional validation data,

we do expect the tests to meet the criteria laid out in the amendment, and to submit the complete notification.

Donald Henton: I just wanted to make sure that I'm unclear on what that notification since we're saying we don't need to submit data.

Toby: So if you look on I believe it starts on page four of the amendment letter there's a basically a paragraph that says, you know set forth in condition of authorization C developers must notify FDA by sending a message and then there's you know the subject line and email address and then a list a bulleted list of all of the things that we expect to be in that notification. So it's you know, obviously, your contact information, test information, the EUA being amended the indication that you're looking to add, your updated labeling. So, that would include your pooling procedure, so you don't expect to see additional validation, but we do want to see that you have a pooling sample and what that entails.

Donald Henton: That's clear Thank you sure.

Kevin Flinn (AV Support): Okay, there are no more questions so back to you Irene.

Irene: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions during today's town hall. Today's presentation and transcript will be available on the CDRH Learn webpage at www.fda.gov/Training/CDRHLearn, by Wednesday August 4th. If you have additional questions about today's presentation, please email, CDRH-EUA-Templates@fda.hhs.gov. As we continue to hold these virtual town halls, we would appreciate your feedback. Following the conclusion of this virtual town hall, please complete a short 13 question survey about your FDA CDRH Virtual Townhall experience. The survey can be found

now on www.fda.gov/CDRHWebinar. Again, thank you for participating. This concludes today's virtual town hall.