FDA Virtual Townhall

Moderator: Irene Aihie
April 14, 2021
12:15 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants are on listen-only mode until our question-and-answer session. At that time if you would like to ask a question please press Star then 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. And now I would like to turn the meeting over to Ms. Irene Aihie you may begin.

Irene Aihie: Thank you. Hello. I'm Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's 51st 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 Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health and Dr. Kristian Roth both from CDRH will provide a brief update. Following opening remarks we will open the line for your questions related to development and validation of tests for SARS-CoV-2. Please remember that during this townhall we are not able to respond to questions about specific submissions that might be under review. Now I give you Toby.

Toby Lowe: Thanks Irene. Thanks everyone for joining us again. I have a few updates of actions that we've taken recently. Last week we authorized the Lucira Check It COVID-19 tests for over-the-counter use for single use at-home screening tests. And this one was previously authorized for prescription home testing.

We also authorized the amplitude solution with the TaqPath High Throughput Combo Kit from Thermofisher. And that is a test that has the ability to perform up to 8,000 reactions within a 24-hour period. And then we also reissued the Saliva Direct Test from Yale for serial screening with self-collected saliva samples at home. So those were a few notable authorizations from last week.

And then we also had a question last week that stumped us a little bit about the difference in terminology that we use in the email updates to CDRH new email updates that our Comms office prepares to send out updates to the listeners about Web site updates. And those include new or newly posted EUAs.

So we did check into that and I think clarified that when the email says that it is a new posting, that it is a new test that did not have any previous EUAs and we issued a letter of authorization. If it says that it is a reissue that means that we reissued the letter of authorization and that's generally used for updates that change any of the details in the letter of authorization including updating the intended use and the conditions of authorization, et cetera.

And then revised generally means that we issued what we refer to as granting letters. So those are the letters that you'll see if you expand the little plus sign on the EUA list and that will be letters that we grant to update some details about the EUA. And those are generally used for updates that require FDA

concurrence such as changing to labeling or changes to labeling but they don't impact the letter of authorization.

And then if the email says updated then that is referring to updates to labeling where we might have posted new labeling without issuing any letters. So without reissuing the letter of authorization and without issuing a granting letter. And that's usually used for minor changes to the labeling fixing typos, minor clarifications, things that are generally not substantive to the performance of the test or don't involve evaluation of new data. And then we also use that updated labeling when we are adding results from the reference panel to the labeling of the test.

Okay so those are my updates from last week. And now I can go through the questions that we received ahead of time. So one of the questions is asking whether a test developer needs to notify FDA if they want to take their EUA off the market and asking whether they would be removed from the EUA page.

So we do ask the test developer to inform FDA if they intend to take their EUA off the market. You can do that just by sending in an email to the CDRH EUA template's mailbox and we will respond to you and go through the process with you that way. Generally if you're planning to take a test off the market we will revoke the EUA. And the revocation will note that it was per your request and we would remove the test developer from the EUA authorization list on our Web site.

Similarly if a developer has notified FDA through the policy in our guidance we would also ask that you let us know through an email to the template's box if you plan to stop marketing that test. And then we would generally remove

you from the notification list and include - you can see on the removed list it includes an asterisk if their's was voluntarily.

Let's see. Next we have a question about the process and timing to discontinue EUAs and require 510(k)'s or Denovos. And we have discussed this a little bit previously on calls. And we've mentioned before that I can't comment on a timeline specifically but we are working on a transition plan for devices that are offered under EUA. And this is included as a guidance document on the center's guidance priority list for FY21. If you take a look there you'll see the transition plan for medical devices distributed under enforcement policies or emergency's authorization during the COVID-19 public health emergency.

Additionally it's important to recognize that generally unless they're revoked an EUA is in effect until the public health emergency is terminated. And the termination of a public health emergency does not typically happen on a particularly accelerated timeline. You can see that there are previous public health emergencies, like, Zika and Ebola that still have not been terminated.

Now we have authorized the first test for marketing beyond the public health emergency with the BioFire Denovo. And that does open up the 510(k) pathway for other molecular diagnostic SARS-CoV-2 tests both individual or a single analyte SARS-CoV-2 test as well as multi-analyte panels which the Bio Fire test is. But that Denovo does not impact any other EUAs other than the BioFire EUA for that same identical test which was revoked concurrent to granting the Denovo. BioFire's other EUAs and other developer's EUAs were not impacted.

So we can't anticipate when the public health emergency would end but we are working on that transition plan and we are committed to, you know,

ensuring that the public has access to a wide variety of test options for COVID-19 and we have no intention at the moment of stopping review for EUAs or revoking based solely on timeline or anything, like, that.

Our next question is about the home collection template. And the requirement to establish a process with specific rounds to identify the process of shipping the collection kit to the customer and then the specimen back to the lab and getting the results back to the individuals. Asking about whether we would accept an EUA request with a general description of the process with specific logistics being established by each lab or whether it be the collection kit manufacturer to establish those partnerships with specific labs.

And so generally we do allow the submission of and we would consider submission of an EUA request for a home collection kit with the intent of it being used by multiple lab partners. We would recommend that you develop and submit an accessioning protocol that includes information about how long the shipping stabilities support, the sample stability rather. And the procedures that a lab should perform before accepting a sample for testing.

We would want to see that you've built in assurances that all the labs would use the same home collection kit instructions with, you know, minor edits for programs that we do through labeling review. And that there will be assurances for checking that purchasers of the product are using the appropriate assay supported by the collection kit. And we are happy to have further discussions in the context of your particular submission on those details.

We have a question about at-home tests and whether they can be performed in a public setting like a college, a school or workplace as opposed to strictly in a home. And if so are they exempted from CLIA regulations even if they're

performed by the facility and not the individual. So this one is really a question for CLIA. So we would recommend that you reach out to CLIA for a definitive answer. But our understanding is that an at-home test can be used for self-testing in a non-home setting. But if the test is performed by someone else at the facility then the facility would need to have a CLIA certificate which would generally be a certificate of waiver in that situation.

We had a question following up on our call or on our question we addressed last week about the validation of multi-analyte molecular tests and the use of archived rather than contrived samples. This question is asking specifically about validation of multi-analyte antigen tests and in cases where the sample types used by the antigen test does not survive the archival process. So the question is asking whether multi-analyte antigen tests can leverage contrived samples for the initial authorization with a closed authorization commitment.

And generally we would not consider it to be acceptable to use contrived samples for initial authorization of a multi-analyte test. We would want to see a prospective study to support the EUA request that includes an FDA authorized RT-PCR for the comparator for CoV-2 and an FDA cleared comparator for all the other claimed analytes. And if there are technological considerations that preclude the use of archived specimens such as what was mentioned in this question as the sample type not surviving the archival process. And we would encourage you to submit a pre-EUA to discuss the next steps for your specific situation.

We have a question about pre-submissions and if there's any indication on review priorities for SARS-CoV-2 pre-submissions. We have obviously seen delays in CDRH on pre-submission and 510(k) reviews during the pandemic. So this question is asking whether that applies - if a pre-sub is submitted for a SARS-CoV-2 assay that does not currently have an EUA authorization.

So generally we are broadly committed to ensuring that the public has access to a wide variety of test options for COVID-19 and we do intend to continue to review SARS-CoV-2 pre-submissions to address public health needs. So to some extent - so COVID-19 related pre-submissions are one of the categories of pre-submissions that we do continue to review. And the review of those would be prioritized based on the public health needs. So we would still consider the particulars about the device in question as to whether it would be a priority with you.

Our next question is about rapid antigen tests based on lateral flow devices and whether we continue to review submissions for professional use in point of care with settings with a CLIA certificate of waiver or whether we would view that as low priority unless the submission has data for self-testing in a home use setting.

So we do have many factors that go into our prioritization decision. And unfortunately not all of those factors are able to be made publicly evidenced since they do often consider other submissions that are in house. But we have previously stated that we're prioritizing review of EUA requests for tests that increase testing accessibility which includes point of care, home collection, at-home tests for example. Or that would significantly increase the testing capacity by reducing reliance on test supplies or tests that have high throughput and are widely distributed to address public health needs.

And, you know, in this case if it is a test that is designed for home use we would generally want to see that it is validated for home use. We are still reviewing point of care tests as well. But, you know, depending on how the test is designed and what it is intended for we would want to have further discussions about that. So if you have questions about a decision about your test in particular please reach out.

The next question is about a clinical trial design to enrich for asymptomatic positives asking for - this is for a nucleic acid test with a lateral flow readout. And asking whether it is acceptable to recruit asymptomatic subjects with recent positive test results if an equal number of asymptomatic subjects with recent negative test results are also recruited.

And the question additionally details that due to the workflow where the subject is guided through result interpretations with an app the individual would not know which - they would not know which readout is positive or negative before inputting it into the app. So their knowledge of their prior test should not create bias according to the interpretation of the individual asking this question.

So generally there are a variety of ways to enrich this clinical study. The proposal in this question generally appears acceptable. We would want to make sure that you are using the comparator method as the result that you're using to enrich your clinical study population. And if you have further questions or want to talk through the design you can reach out with a pre-EUA to discuss that study design as well.

Kris did you want to add anything about that one about the study design or just to come in with a pre-EUA?

Dr. Kris Roth: Yes I think a pre-EUA probably is the right method because there are, you know, I think nuances to this approach. You know you could also consider, you know, other patient factors, risk factors where folks may be exposed to kind of further mix populations. There's a number of ways to do this.

Toby Lowe: Great, thanks Kris. All right the next question is about multi-analyte RT-PCR tests specifically SARS-CoV-2 and influence AB. And whether we would

find it acceptable to have an asymptomatic claim for SARS-CoV-2 in a case where the software associated with the test is capable of reporting only a SARS-CoV-2 result if only that analyte is ordered. The question notes that there appear not to be any multi-analyte EUAs that have an asymptomatic claim. And so they're asking about that.

So the questioner is correct that we do not currently have any multi-analyte EUAs that have an asymptomatic claim. At this point we don't have any - we don't have sufficient data supporting device performance or a public health need for an asymptomatic influenza screening claim. For SARS-CoV-2 we obviously know that there's many reports of asymptomatic infection and numerous studies that show detectable viral load in asymptomatic populations. So we have obviously granted asymptomatic screening claims for many SARS-CoV-2 tests at this point.

So a test that's capable of reporting either a SARS-CoV-2 result alone or the multiplex result depending on the patient population that's being tested or the individuals' circumstances may be appropriate. We would want to see that there are sufficient controls to ensure that the user has the tools to report the appropriate results to the appropriate individual.

So we would recommend that you submit a proposed plan and then we can discuss that further including, you know, what the labeling would look like and how the workflow would be handled there. Kris anything you want to add on that one?

Dr. Kris Roth: No that's perfect, thanks.

Toby Lowe: All right let's see. Our next one is another one about respiratory multiplex panel. This one is about transitioning from an EUA to a 510(k). And the

inclusion of multiple RT-PCR instruments. The questioner is asking whether the prospective clinical studies of the 510(k) could be conducted on the instrument with the worst limit of detection.

This is something where we would generally want to have some further discussions about your approach. The proposal that you laid out might be acceptable. We would recommend providing data establishing that performance at low analyte levels. Precision and reproducibility are similar between the instruments. And we would recommend that when you're pursuing the 510(k) pathway that you submit a pre-submission to discuss your proposed validation strategies and your comparative method for review.

Right now there's quite a bit of information in previous 510(k) decision summaries of the flu and RSV. And we hope to get the decision summary for the BioFire Denovo posted fairly quickly. And so since the studies that establish performance of the flu are likely to be similar to what we recommend for SARS-CoV-2, we would suggest that you take a look at those flu decision summaries together since what we would be looking for is there.

And then since we do have limited resource capacity for pre-submissions right now we recommend that you maximize the efficiency of that interaction by including specific questions that are targeted to your test and the remaining questions that you have after reviewing the publicly available information.

Anything to add on that one Kris?

Dr. Kris Roth: No I think there are, you know, instances in the 510(k) pathway where we're redundant. And so I think you can find information there. We also have, you know, the migration pathway. So I think that's got some good information -

sorry migration guidance has some information about comparing, you know, two systems.

Toby Lowe: Great, thanks. And then the last question that we have is about serology tests. And the template that they're asking about going to the geeneral template asking for a plan to affect the impact on new variant. And specifically they're asking for me to develop a test protocol and perform testing on new variants and to clarify the output required for that section of the EUA template.

So the template does state that for any viral mutations and variants that are identified as prevalent and/or clinically significant you should assess whether the resulting predicted amino acid changes in the viral proteins are critical to your test design. And if so we would ask that those mutations of variants should be evaluated using clinical specimens or contrived, you know, depending on availability to assess the impact of the mutation or variant on your test performance.

And then specifically the template suggests that you provide your plan for monitoring for new and emerging SARS-CoV-2 viral mutations and variants on an ongoing basis and for assessing the impact of mutations and variants that have been identified as prevalent and/or clinically significant on the performance of your assay over time. And this includes providing your plan that includes information on the potential impact of the initiations and variance on your test performance or explaining how the risk associated with the unknown performance of your device and samples from individuals with the variant can be adequately mitigative.

So generally in the protocol that indicates how you would do that testing along with the other information requested in the template included to serve as

that plan at the time of your EUA request. And, you know, as we do that with you we would discuss that protocol and plan with you as needed.

And that is all of the prepared questions and answers that we have so we can turn it over to the live portion.

Coordinator: Thank you. If you would like to ask a question over the phone please press Star then 1, record your name clearly when prompted. If you need to withdraw your question you may do so by pressing Star then 2. One moment as we wait for our first question. And our first question comes from (Annie Wright) your line is now open.

(Annie Wright): Hello. Last week we had a question about using clinical sites in the UK for the SARS-CoV-2 study. So we were wondering if we had a clinical site in Canada along with other clinical sites in the U.S.? Would that be acceptable for the agency?

Toby Lowe: We do accept data from outside of the U.S. with the exception of generally for the point of care and at home validation studies we would want those to be done in the U.S. due to variations that we have seen particularly in those areas. And then Kris do you want to touch on this one at all?

(Annie Wright): Yes this would be a point of care study.

Toby Lowe: Yes we would…

(Annie Wright): Also…

((Crosstalk))

Toby Lowe: …done in the U.S., yes.

(Annie Wright): Yes I mean if we did have data in the U.S. but also included a site in Canada.

Toby Lowe: I think that would probably depend on the volume of data that you have from the U.S. I think we would want to see the data specified in our template from the U.S. If you have supplemental data from Canada, you know, you could certainly submit that as well.

(Annie Wright): Okay with the predominent basically - as long as you meet the minimum criteria for the template - by the template and that's in the U.S. then that would be acceptable if we include additional in Canada.

Toby Lowe: Right.

((Crosstalk))

Toby Lowe: Right, I think so. Kris do you want to add anything on that?

Dr. Kris Roth: Yes I mean that's the safest bet right? I mean if you have international data from, you know, from POC sites then, you know, we start perhaps asking questions about well, you know, what exactly is the standard of practice at these POC sites, you know, so potentially, you know, you could make that argument that it's similar to the U.S. But, you know, if you can avoid having to make the argument, you know, that's just kind of one less thing that you have to justify to us.

(Annie Wright): Okay, all right. Thank you so much.

Coordinator: Thank you and our next question comes from (Elizabeth Brunelli), your line is now open.

(Elizabeth Brunelli): And this question is about home collection kit EUA submission. Is it important to include product branding information in the EUA submission or can that be submitted post EUA?

Toby Lowe: So, you know, that may depend on exactly what you mean by product branding information. But generally we do review the labeling. And so that would probably include the product branding that you're referring to. We do usually include in the EUA a condition about adding labeling where, you know, for distributors that might distribute under a different name. And that's something that can be added after the initial authorization if you're looking to partner with different distributors. But the testing is included in the authorization and the, you know, name obviously would go on the labeling that we would review and authorize as part of the EUA.

(Elizabeth Brunelli): So what we're speaking specifically to is that we have kind of a generic name for our home collection kit at this point. But we might change the brand name of it to include some branding that we've used previously for our laboratory test.

Toby Lowe: Okay. So you could submit it with the, you know, fairly generic name if that's what you're planning to use right now. And then if you decide to update it you would submit that update as a supplemental EUA request. And we would have to review and authorize that alternate labeling.

(Elizabeth Brunelli): Okay perfect, thank you.

Toby Lowe: Yes.

Coordinator: Thank you. And our next question comes from (Anna Powell) your line is now open.

(Anna Powell): Hi. My question is regarding developing a home use serology antibody test. Is it required to report - does it have a reporting requirement, like, some of the antigen home use tests? The second part is should we include vaccinated people in the performance study?

Toby Lowe: Okay. So this one is a little bit tricky. We don't have recommendations that we've put out yet for the home use serology antibody test. Generally if there is a healthcare provider involved which we would - which, you know, all of the serology tests that we have authorized so far are prescription use, we would - the coordination with the healthcare provider can be how the test results get reported. Otherwise we would, you know, discuss that further. And we would suggest a pre-submission or sorry a pre-EUA to discuss what we would want to see in that home use antibody test.

And similarly with your question about including vaccinated people that, you know, is an area that, you know, is emerging now obviously as more and more people are becoming vaccinated. And so we would suggest that you submit a pre-EUA with your proposal both for reporting and for inclusion in your validation study so that we can discuss the specifics of your approach.

(Anna Powell): So what is the response time if we use the pre-EUA to address the basics of protocol and the questions like this for the home use serology test? We heard that there's a very low priority for this particular test. Is that true?

Toby Lowe: So we would evaluate the priority of the request when it comes in in considering the public health needs at the time as well as the other submissions that we have in house. So I'm not able to give a specific timeline there.

(Anna Powell): Okay thank you.

Toby Lowe: You're welcome.

Coordinator: Thank you. As a reminder to ask a question please press Star 1. Our next question comes from (Stacy Hausman) your line is now open.

(Stacy Hausman): Hi. Thank you for taking my call. I have a question related to the molecular point of care templates specifically it says if we do a prospect enrollment looking for 30 positives in the symptomatic population. And after a period of two weeks the template states that we can move to using base samples. And so what I'm wondering is the two weeks - is the two-week time period just 10 days or is it wanting us to prospectively enroll for a period of 14 days? Just checking because the business days - if we only enroll on business days then, you know, that would be closer to a three-week time period. We just want to make sure that we're following that appropriately.

Toby Lowe: Sure. Kris do you want to address this one?

Dr. Kris Roth: Yes, okay. Yes I mean two weeks is 14 days. So I mean that's the kind of, you know, the face value.

(Stacy Hausman): Okay.

Dr. Kris Roth: You know the point there is that you've made some kind of good faith effort to collect some prospective samples to at least, you know, have that portion of it be kind of an all all comers kind of study. I mean that's very valuable information for us. So I would say, you know, just go with the 14 days.

(Stacy Hausman): Okay, all right, 14 days of enrollment. Yes, okay, thank you.

Coordinator: As a reminder to ask a question please press Star then 1 and record your name clearly when prompted. Our next question comes from (Elaine Allen) your line is now open.

(Elaine Allen): Yes, hi, thank you for this opportunity. Toby did I hear correctly on that there may be some information on the Web site somewhere regarding the transition plan from EUA to 510(k)? Is there some general information out there?

Toby Lowe: I did mention something being on our Web site. It might be overstating it to call it information. The name of the guidance document is on our guidance priority list.

(Elaine Allen): Guidance priority list, okay. I'm not sure where that is but I'll try to find it.

Toby Lowe: If you Google, like, I think FDA guidance AB list it should come up pretty close to the top.

(Elaine Allen): Guidance AB list?

Toby Lowe: Yes. We break the priority list down into an A list and a B list. And so we often refer to it as the AB list.

(Elaine Allen): Oh.

Toby Lowe: And I know that when I have Googled, you know, guidance A B list it comes up.

(Elaine Allen): Oh. In 20 years that's the first time I've heard of that one for FDA so thank you very much.

Toby Lowe: No problem.

Coordinator: Thank you. Our next question the first name is (Ella) your line is now open.

(Ella): Hi I have a question related to one that was asked previously on the point of care and at home test. So I understand the usability study for sure has to be done in the U.S. What about the clinical study with the 30 positives and negatives? Is that okay to be done outside of the U.S. here?

Toby Lowe: Since the setting does impact the clinicals for those tests we do want to see that they are done either in the U.S. or that you're able to provide justification demonstrating that outside of the U.S. sites are representative of the U.S. sites where those would be done. So we would want to see that the operators are representative of, you know, operators in a U.S. CLIA setting for example for a point of care test.

(Ella): Okay thank you. But the clinical evaluation is not done by the operator it's done in a lab correct with clinical samples?

Toby Lowe: The clinical evaluation should be done in the setting in which the test should be used.

(Ella): Okay. Thank you for…

Toby Lowe: Kris do you want to weigh in on that?

Dr. Kris Roth: Yes I mean an important aspect of performance is having a test that the user can, you know, perform correctly right? So I mean if you've got a POC claim I think ideally you're going to ask for POC users to be running those samples.

(Ella): Yes. But from the guidance I understand specifically for POC it is recommended to have five to six trained operators in one to two CLIA waived labs. So I'm just trying to understand the 30 positives and 30 negatives how do they interact with those samples done in the CLIA waived setting?

Dr. Kris Roth: So are you talking about bringing samples? Are you talking about testing banked samples for instance from internationally collected banked samples?

(Ella): No. So my understanding was that for let's say a high complexity lab you'd only need the clinical evaluation of a minimal of 30 positives and 30 negatives. And then for a point of care theme in addition you have the CLIA waived operators doing more tests.

Dr. Kris Roth: Sure.

(Ella): And so the 30 positives, 30 negatives those should also be done in the U.S. or could they be done abroad?

Dr. Kris Roth: You know I think ideally all testing - validation testing for POC tests we would prefer it done in the U.S. Again, like, I mentioned before if it's done, you know, in an international site then the burden is on you to establish the procedures and practices using that site are, you know, are similar or identical to, you know, what would be done in the U.S.

(Ella): Okay thank you for clarifying.

Coordinator: Thank you. As a reminder to ask a question please press Star 1. One moment as we wait for any additional questions.

Toby Lowe: And I think while we're waiting on that I just want to clarify for the point of care question. Yes I think there may be some confusion about how to perform that study and about the language in the template. When the template is referring to including those five, six minimally trained operators, Kris that is for the 30 and 30 study is that correct?

Dr. Kris Roth: I mean I think our opinion is that POC test is going to be run by folks that are minimally trained. And therefore we want to have the validation performed…

Toby Lowe: Yes.

Dr. Kris Roth: …in a similar manner.

Toby Lowe: Yes, thank you to clarify that for that caller.

Coordinator: As a reminder to ask a question please press Star 1. One moment as we wait for any additional questions. And our next question comes from (Roxanne Chan) your line is now open.

(Roxanne Chan): Thank you. Yes, I have a question regarding the multi-analyte molecular test validation. So we are in the process of completing the validation work on a multi-analyte test that includes COVID and influenza. And we've been advised that it would be helpful if we put in a high throughput platform. So we are considering doing that. My question is that how extensive the validation has to be if we want to include now adding a high throughput platform? Do we have to - do we only need to do, like, adding an extra

instrument type of work or we will have to, you know, repeat a whole set of validation - analytical and clinical?

Toby Lowe: Okay. So, you know, to clarify the high throughput is really because, you know, that will help increase the testing capacity which is, you know, what is needed at this stage for, you know, as we try to get more routine testing done…

(Roxanne Chan): Right.

Toby Lowe: …through routine testing programs. Kris Do you want to talk about the validation that we would look for there?

Dr. Kris Roth: Sure. Yes I think, you know, if the test is going to be distributed with a high throughput workflow, you know, that's the workflow that should be validated. You know I think performance in a 96 wheel just for instance performance in a 96-wheel plate may be different than a 3-to 4-wheel plate right? Heat transfer is different. Optimal characteristics perhaps are different. So I guess what we don't want to see is, you know, like a manual workflow done in the, you know, validation. And then, you know, kind of maybe just an LOD study or something, like, that to validate the high throughput.

I think what we want to see is that the high throughput solution is kind of producing, you know, acceptable results because, you know, that's really the solution that's going to impact, you know, testing the most.

(Roxanne Chan): So what are you saying? Suggesting that it would be more than breaching studies then?

Toby Lowe: Kris.

(Roxanne Chan): Hello.

Toby Lowe: So it looks, like, Kris is having some technical difficulties.

(Roxanne Chan): Yes. So what I'm trying to understand is for instance in the validation package there will be, you know, of course the very first part is the LOD definition. And then after that there will be a bunch of inclusivity, exclusivity competition coinfection and clinical studies.

Toby Lowe: Yes, and I think that there are certain aspects of validation that would not be impacted. And obviously we wouldn't expect to see those repeated. The portions that would be expected to be impacted we would want to see, you know, the validation with the high throughput platform or justification of why, you know, what you're able to demonstrate is representative.

(Roxanne Chan): All right.

Toby Lowe: Unfortunately it looks like Kris dropped the call as he got disconnected. So - but if, you know, you want more specific details you can send them to the mailbox and we can try and get you more details on the technical side there.

(Roxanne Chan): Perfect, very helpful, thank you.

Toby Lowe: Yes.

Coordinator: As a reminder to ask a question please press Star 1. One moment as we wait for any additional questions. Okay. Seeing that there are no additional questions we'll turn the meeting back over to Miss Irene Aihie.

Irene Aihie: Thank you so much. This is Irene Aihie. We appreciate your participation and thoughtful questions during today's townhall. Today's presentation and transcript will be made available on the CDRH learn Webpage at www.fda.gov/training/cdrhlearn by Friday, April 23. If you have additional questions about today's presentation please email cdrh-eua-templates@fda.hhs.gov.

As we continue to hold these virtual townhalls we would appreciate your feedback. Following the conclusion of this virtual townhall 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 and this concludes today's virtual townhall.

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