

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

**Moderator: Irene Aihie  
August 12, 2020  
12:15 pm ET**

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer session of today's conference. At that time you may press Star 1 on your phone to ask a question. I'd like to inform all parties that today's call is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the conference over to Miss Irene Aihie. Thank you, you may begin.

Irene Aihie: Thank you. Hello, I am Irene Aihie, of CDRH's Office of Communication and Education. Welcome to the FDA's 21st 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, in the Office of Product Evaluation and Quality, here in CDRH, will provide a brief update. She is joined by Dr. Brittany Schuck and Dr. Kris Roth. Following opening remarks, we will open the line for your questions related to today's discussion. Please remember that we are not able to

respond to questions about specific submissions that might be under review.

Now, I give you Toby...

Toby Lowe: Thanks, Irene. Thanks, everyone for joining us this week. As Irene said, Tim is not here this week. He's taking a much-needed break. And so I'm joined by Brittany Schuck who is helping to lead our COVID-19 Serology Response and Kris Roth who is one of the Branch Chiefs in our Division of Microbiology Devices. A couple of quick updates this week.

We have now reached well over 200 EUAs related to COVID-19 testing. Last week we actually revoked one of the EUAs. That was for the autobio antibody test. And just yesterday two new FAQ pages were posted by the agency related - one is related to importing during - or importing devices for COVID-19 and one is for registration and listing related to COVID-19 devices. So those are available on the FDA Web site. They're easy to find if you look at on yesterday's Daily Roundup press release and hopefully they'll be helpful for some folks. And with that, we can start question and answer.

Coordinator: At this time we begin our question and answer session. If you'd like to ask a question please press star then 1, unmute your phone and record your name clearly when prompted. If you'd like to withdraw your question press Star 2. We ask that you please keep the limit of one question. One moment while we wait on our first question. The first question comes from (Cory Jaycal). Your line is now open.

(Cory Jaycal): Hi. Thank you for taking my question. If possible we are interested in modifying CDC's Multiplex Assay in performing a bridging study to leverage their EUA. Does the bridging study policy apply to multiplex tests?

Toby Lowe: The bridging policy only applies to the single SARS CoV-2 assay or assays. It's not just for the CDC assay. But if you do have questions about what would be an appropriate way to modify or to validate a modification to the CDC's multiplex test please submit into the mailbox and we can have further discussions with you about that.

(Cory Jaycal): Okay. Thank you

Coordinator: The next question is from (Lonnie). Sir and your line is now open.

(Lonnie): Hi. this is (Lonnie) from (iAssay). last week I tried to get a question in. There was a mention that a smartphone app can get its own EUA. And we have an open platform that does any kind of serology test or hopefully antigen tests that come up. Can we get our own EUA independent of the manufacturer of this script and then add addendums maybe as we onboard those scrips working with those manufacturers in doing the 30, 75 tests?

Toby Lowe: Thanks for that question. So I think it will probably depend a little bit on what it is that your app is doing and how it integrates with the different tests. It is possible that you'd be able to do that in such a way that you could pair up with a specific test to start out and then add additional tests going forward.

The best way to get feedback specific to where a device would be to submit a question or to submit a pre-EUA to the EUA mailbox so that we can take a look at the specific details and make sure that our feedback is tailored to your situation.

(Lonnie Ab): Okay thank you.

Toby Lowe: Sure.

Coordinator: The next question is from (Cynthia Flynn). Your line is now open.

(Cynthia Flynn): Hi. Thank you for taking the question. My issue is more of a comment. On the FDA EUA Web site for SARS CoV-2, it seems like now that the section that was for tests that other - that used and could get and institute at your institution are now kind of mixed in with tests that are specific to single institutions. And the lists aren't separated as they were earlier.

Toby Lowe: Yes so that...

Toby Lowe: ...they're - you're right. There are single lab tests and commercial manufacturer test kits that are both included on the individual EUAs list. There is still the list for single lab tests that were added to the umbrella EUA for molecular diagnostic tests. That is the separate table just underneath the individual EUA table.

(Cynthia Flynn): Yes, but you're just not going to get into that anymore. Is that the idea?

Toby Lowe: But the - you're right, based on the specific needs for each test we determined what the most appropriate authorization for that test is and most of the time they do receive individual EUAs, and that's why...

(Cynthia Flynn): Okay.

Toby Lowe: ...they've been added to that first table. The easiest way...

Toby Lowe: ...to tell sort of at first glance which are which is under the authorization documents. Generally, if there's a document titled EUA summary, that's a single lab test. And if there's a document titled IFU, Instructions For Use that's a distribute and test kit.

(Cynthia Flynn): Right, right. That's what I figured. But it's just a little more confusing than it had been, yeah. But that's okay. Okay, thank you. I just wanted to...

(Cynthia Flynn): ...clarify that.

Toby Lowe: Great. I appreciate the feedback.

Coordinator: The next question is from (Daniel Marcus). Your line is now open.

(Daniel Marcus): How we doing? So my question, we spoke last week about what reference standards for validation in terms of sample tests you prefer. I know and NP is probably the number one determinant number two. I'm wondering if there is an internal take on tongue scrapings, i.e., cellular material that's picked up from the tongue and what kind of validation or reference standard we need to use in terms of the amount of sample tested as well as you know whether RT-PCR should still be the reference standard or whether you can use a more sensitive reference standard out there like a ddPCR?

Toby Lowe: Thanks. So I'll take a first stab at this and then see if (Kris) wants to add anything. We have not as far as I'm aware authorized any tests with tongue scrapings as a sample type. We do have in the EUA template we have a section for validation of alternative sample types. So I'd point you to that for validation recommendations. And (Kris) do you want to add anything there?

Dr. Kris Roth: Yes hi. This is (Kris). You know, I think we're always looking for a head to head comparison with an NP swab specimen. And, you know, what we want to see is that if it is an alternate specimen type it's taken kind of within a reasonable time period of the NP swab. I think we say typically within 24 hours but certainly, the shorter time period between those two samplings will be, you know, more quickly result in a higher agreement.

It also depends on technology of your device itself. If you're doing your point of care lab test, I think there's a lot of variables that could be guiding the test design plan. And so I think, you know, just having more interaction with us specifically what you're trying to do would help. But certainly, I think in the EUA templates that that alternative respiratory specimen is the kind of section we want to look at.

(Daniel Marcus): So you wouldn't - so I'm thinking is you wouldn't recommend doing a tongue scraping as the analyte for a reference standard to put it - put through RCPCR assay or whenever we're using it as a reference standard but rather NP is the preferred. And then if we also do a tongue scraping and run it through RCPCR to show performance that wouldn't be objected to, but the number one preference is NP swab?

Dr. Kris Roth: Right.

Toby Lowe: We don't - I'm sorry. We haven't authorized anything with a tongue scraping, so we would want to see a comparison to a EUA authorized test including the EUA authorized specimen type.

(Daniel Marcus): Okay, all right, that pretty much answered the question. Thank you.

Toby Lowe: Great.

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

(Sue Hiplin): Hi and thank you for taking my question and having these calls every week. I was actually just looking for some advice on our situation. We've been in the EUA pipeline for more than three months now with a reviewer since June 19th. And we hear each week on these calls that certain products like the one we submitted would be a priority. But we've had very limited communication and no visibility as to why it's not being reviewed as a priority.

So I guess I'm just looking for some advice. You know, I get asked by our board and our CEO every week like, you know, these questions and I don't know what to tell them. You know, and we all know, like we all have colleagues and, you know, they have similar products that are being reviewed in less time. So I'm really just looking for a bit of advice from you guys. Like how do we get on the radar for this to be more of a priority if, you know, we submitted studies that supposedly meet the qualification for priority?

Toby Lowe: Sure I definitely understand the frustration. Without knowing your specific device, I can't give you any feedback right now. But if you can send an email to me directly or to the EUA mailbox and ask them to forward it to me with a little bit more information about, you know, what your submission number is and what your test is and why you think it is, it should be prioritized, I can look into that and get back to you.

(Sue Hiplin): Okay thank you. I appreciate it.

Toby Lowe: Sure.

Coordinator: The next question from (Codu Modine). Your line is now open.

(Codu Modine): Good afternoon. Thanks for taking the call. My question is similar to the one that was asked earlier. We have submitted UEA for a serology assay end of May. Still, we have not been assigned a reviewer. Can Dr. Brittany Schuck can give us some more information about how long it will take for review and are you getting because I was told that the serology test is of lower priority. So you are going to get additional support to review these applications and how long it will take for our applications to be reviewed? Thank you.

Toby Lowe: Thank you for that question. Now have you - you said you have not been assigned a reviewer?

(Codu Modine): Yes.

Toby Lowe: Have you been assigned a point of contact?

(Codu Modine): No, not yet. There - we are getting that there is a lower priority and then we are expediting. We will let you know. But we submitted the application on May 26. Still, we have not been assigned a reviewer.

Toby Lowe: Okay so you should have received a point of contact who reached out to you at least weekly. If you have not been assigned a point of contact, please reach out to me and let me know so that I can look into that. If you - and also please make sure you include information on whether you've submitted your test to NCI for evaluation.

(Codu Modine): Yes actually we submitted our test to NCI on May 19 even before we submitted our EUA application on May 26 because our original we intimated and our name is on the list on May 11 in the FDA web site. And we submitted our test to NCI on May 19. And then the EUA application submitted on May 26. Still, we

have not been assigned. And we even wrote about the NCI. We haven't heard anything about that so far.

Toby Lowe: Okay. You can send an email with the information about your test. I can look into that.

(Codu Modine); Thank you.

Toby Lowe: Sure.

Coordinator: The next question is from (Damia Lavine). Your line is now open.

(Dee): Hi. this is (Dee) from Darwin American Labs. When you're validating saliva and we want to know if we need to launch a full clinical study for patient samples or can we use biobanked or borrowed samples from our lab partners that have confirmed positive negative samples specifically our partners that are validating saliva?

Toby Lowe: So there are recommendations for validation in the EUA template including the alternate specimen section. And I would see if (Kris) has anything to add about whether the other recommendations discuss using leftover samples. I think that is discussed there but I can't recall off the top of my head.

Dr. Kris Roth: Yes this is (Kris). You know, I think the two important factors when you're talking about banked samples for saliva specifically or because they want to see a range of viral loads in that...

(Dee): Okay.

Dr. Kris Roth: ...specimen type is to make sure that you're able to detect, you know, accurately

across the entire range so especially close to the cut off. And the other question I think we would be asking would be fresh versus frozen study...

(Dee): Okay.

Dr. Kris Roth: ...to ensure that that freezing is not enhancing or detracting from the performance of your assay. But I think as Toby mentioned there are some additional recommendations in the template as well.

(Dee): Okay because I didn't - I guess I'll have to look where saliva was. I guess I didn't see that that portion. And if they're left at room temperature you'd obviously want to see that as well because these are able to be stored at room temperature so you'd want to see the RT data versus the fresh.

Dr. Kris Roth: You know, I think our - the data on saliva is evolving and, you know, the saliva certainly is a complex matrix. So instability is a very important parameter to establish this. So I mean any kind of recommendations given to your users about sample stability storage, anything like that should certainly be tested and, you know, that even goes more so for saliva.

(Dee): Okay. Thank you.

Toby Lowe: And just to for clarity the section that's titled Alternate Specimens or something like, that Validation for Alternate Specimens is what would be applicable to saliva.

(Dee): Okay, fantastic. Thank you.

Toby Lowe: Sure.

Coordinator: The next question is from (Tom McDougall). Your line is now open.

(Tom McDougall): Hi. This is (Tom McDougall) with NIC. First of all, thank you for running these meetings every week. They've been extremely helpful. And I just had a quick question based on the executive order last week from the White House on ensuring essential medicines in the US. Wanted ask if there's any kind of preliminary predicted impact on COVID testing and if nothing right now when we can expect to maybe hear any impact from that order on this EUA process?

Toby Lowe: I am not sure that I'm going to be the best person to answer that. I think I have not at this point been aware of impacts on testing from that executive order but it is something that I can look into. But I think at this point that's not something that we would be able to provide any feedback on this call.

(Tom McDougall): Okay. Thank you.

Toby Lowe: Sure.

Coordinator: The next question is from (Eric Leaphart). Your line is now open.

(Eric Leaphart) Good afternoon, (Eric Leaphart), (Med-Pros). While waiting for your EUA can we go to market and collect data? And how can you assist with us importing products from overseas serological test?

Toby Lowe: So if you are looking to validate your test you could potentially do that under supervision of an IRB as a study to collect that data. In terms of going to market prior to a EUA. Otherwise, the notification pathway is available but we would expect that your test to be completely validated prior to using that policy.

(Eric Leaphart): Thank you. And on the imports?

Toby Lowe: On the imports if you are notified and on our notification list for a validated test or if you have a EUA you are able to import.

(Eric Leaphart): Thank you.

Toby Lowe: Yes.

Coordinator: The next question is from (Pat Linehart). Your line is now open.

(Pat Linehart): Yes thank you. My question's regarding the cross-reactivity samples from the serology template for commercial manufacturers. References greater than 75 samples collected are tested from a population with a high prevalence of vaccination or infection against the listed viruses. How is that determined, you know, meaning how do you know - how do you - can - what does it take to consider a population to have had a high prevalence of vaccination or infection?

Toby Lowe: Brittany do you want to take this one?

Brittany Schuck: Yes, thanks. You can provide the information in the EUA request to support that the, you know, geography and the demographics of the samples are from a region where those viruses have a high prevalence of vaccination against or exposure to the circulating virus.

So we look at the information that's provided in the EUA request to support that the population that you - population samples is used in your evaluation come from a population that has those viruses circulating or have a high prevalence of vaccination against those viruses.

(Pat Linehart): Okay. So it's possible that our population may have a prevalence, high

prevalence for certain of those viruses but say not - there may be some listed on there that may not have that high prevalence and we would need to do the cross-reactive testing against them then?

Brittany Schuck: Yes that is possible, yes. And we'd be looking for that type of information in your EUA request.

(Pat Linehart): Would that be is that information then from like the local health departments or is that available information or...

Brittany Schuck: So it depends on the - on where the samples were collected from obviously that you're using in your evaluation. So it's dependent upon the samples that you have collected and included in your clinical agreement study. So we would be looking for you to provide that information in your EUA request.

You know there are other organizations that collect this type of information, independent organizations, CDC may have some of this information as well also. But we'd be looking for that information to be provided by the sponsor in a EUA request.

(Pat Linehart): Okay thank you.

Coordinator: The next question is from (Kelly Turner). Your line is now open.

(Kelly Turner): Good afternoon. Can you hear me okay?

Toby Lowe: Yes we can. Thank you.

(Kelly Turner): Okay. I have a clarification question actually related to the antigen template for manufacturers versus the new template for manufacturers for molecular and

antigen for the nonlaboratory use. My question is related to the original antigen template has a section in there for point of care. And the new template is - has nonlaboratory use.

And so and I was - my understanding is that many of the specific locations that are called out in the new template would be under a CLIA waived environment like schools and airports and also my assumption was that they would be still by a health care provider in that setting. Can you help me understand when the right time is for each one of these and if it's just more specific for maybe one of them is used for a screening device versus a doctor's order? Or...

Toby Lowe: Yes.

(Kelly Turner): ...I'm just trying to understand which one is appropriate for a point of care setting.

Toby Lowe: Sure absolutely So generally when we refer to point of care we are still referring to a laboratory environment. Facilities that are - that operate under a CLIA certificate of waiver that we often refer to colloquially as a CLIA waived environment...

(Kelly Turner): Yes.

Toby Lowe: ...are considered laboratories by CLIA. So when we refer to a non-laboratory environment we're referring to a home environment or, you know, a school that does not have, you know, a CLIA Certificate of Waiver. We know that some physicians' offices have CLIA certificates of waiver so they can operate devices that are authorized for use in such environments.

But some physicians' offices may not have any CLIA waiver at all. And then

they would be considered a non-laboratory environment. Same with workplaces, airports -- things like that. Those would all be considered non-laboratory environments because they operate without any clear certificate at all.

(Kelly Turner): Okay that is perfect. So it really comes down to if they have a CLIA certificate or not.

Toby Lowe: That's correct.

(Kelly Turner): All right perfect. Thank you very much

Toby Lowe: Sure.

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

(Sara): Hi. With flu season approaching and many manufacturers developing multi-analyte panels is the FDA working on updates to their guidelines and requirements for doing pool testing on these types of assays?

Toby Lowe: So we have put out some information in the latest version of the molecular template about multi-analyte tests. And we do encourage the development of those multi-analyte tests. Also included in that template is information about pooling. We have not included, you know, specifically discussion in the template about, you know, sort of combining those.

But that's certainly something that we are interested in talking with developers about. And you could take a look at the - at those recommendations. There's not any exclusion from using the pooling recommendations that are in the template for, you know, combining that with the recommendations for the multi-analyte

panel.

(Sara): Okay, I mean we're a lab using EUA method so we're just looking at pooling. I'm just wondering if you had any like if we're going to need to do the same analysis on each analyte if there's any - we're going to be any requirement for doing such things as co-infections in those samples to look for inhibition and that sort of guidance?

Toby Lowe: So we do consider adding pooling to be a modification to a test that would need to come in for a EUA at this point.

(Sara): Right.

Toby Lowe: And a lot of the discussions around pooling and the discussions around multi-analyte panels are still evolving. So we'd be happy to, you know, have further discussions with you on that. But we would expect that a test be validated for pooling, you know, test, for a multi-analyte respiratory panel that you're going to use for pooling we would expect it to be validated and to come in for a EUA.

(Sara): Right. Yes, I was just wondering if there were any upcoming more specific guidelines for the multi-analyte but we can reach out to the templates email when we're looking at a specific plan.

Toby Lowe: Great.

(Sara): Thank you.

Toby Lowe: Thanks.

Coordinator: The next question is from (Tara Viviani). Your line is now open.

(Tara Viviani): Hi. My question's regarding pooling as well. We have a previously authorized EUA where we provided data for testing on single-use samples or single samples. We're considering adding pooling so as a logistic question would you need to see all the single analyte data in the amendment to the EUA or just the pooled data?

Toby Lowe: So you said you're adding using adding pooling to an already authorized assay?

(Tara Viviani): Correct.

Toby Lowe: Okay so there are recommendations in the guidance for that particular situation or sorry, in the template. And that includes the data that we would expect to see as well as how we would want to present it. So we wouldn't necessarily expect you to revalidate it for the individual examples but we would be looking at, you know, for some data that shows that you're not dropping too much sensitivity and that you've established your CT shift when validating pooling. And (Kris) do you want to add anything to that?

Dr. Kris Roth: Yes this is (Kris). So I would just say there are different data requirements for assays that have previous EUA versus those that don't. So you've kind of already established your sensitivity specificity and the next piece is going to be just establishing that performance for pooling. So, you know, the amendment should just need to include the pooling data because you're going to have all the rest of the data with us previously reviewed from your EUA.

(Tara Viviani): Okay that's what I was suspecting but I just wanted to make sure.

Coordinator: The next question is from (Jennifer Rakman). Your line is now open.

(Jennifer Rakman): Hi. This is (Jen Rakman) from New York City. Thank you for taking my question. My question is about the recent announcements from Thermo-Fisher about the (tax pass) particularly about the software update requirement and vortexing updates to the instructions for use and whether there would be a specific announcement or documentation coming from FDA around this?

Toby Lowe: So we are aware of Thermo-Fisher's actions obviously and we are working with them on this issue. At this point, we're not able to indicate whether anything specific will be coming out from FDA but we are continuing to look into it and work with them to resolve the issues.

(Jennifer Rakman): Okay thank you.

Coordinator: The next question is from Anil Kaul. Your line is now open.

Anil Kaul: Thanks for taking my call. This is Anil Kaul from Oklahoma State University. We have validated paired saliva and nasopharyngeal samples and have also received a letter of reference from a previously approved EUA. My question is is bridging an option or do we have to submit a new EUA?

Toby Lowe: So I apologize I had a little trouble hearing part of your question. So you're saying that you're validating saliva for a test that is previously authorized by someone else. Is that correct?

Anil Kaul: Yes we did a validation study using saliva and nasopharyngeal paired samples and also...

Toby Lowe: Okay.

Anil Kaul: ...received a letter of reference from a previously approved EUA.

Toby Lowe: Okay so that would be - we would want you to make sure that you've performed your validation according to the recommendations that we have for alternate specimen types in the guidance. Sorry I keep saying go guidance when I mean template today. The template has those recommendations for alternate specimen types. I believe it's a 30 and 30 paired study so sounds like that may be what you've done.

Anil Kaul: Yes.

Toby Lowe: And we would - so we would not consider that type of modification to be appropriate for a bridging study. If you have a right of reference from the original EUA holder you can use that to submit your EUA so that you don't need to repeat the validation that they've done for the NP.

Anil Kaul: Okay but we have already done an NP and a saliva paired sample so bridging is not an option?

Toby Lowe: Maybe I'm not understanding what it is that you're looking to do bridging for.

Anil Kaul: I mean to say that we have to submit a new EUA. That's what I'm saying, even though we have a letter of reference?

Toby Lowe: Sorry. So by bridging I was - we generally refer to as a bridging study - which is not an appropriate validation method for adding a new specimen type. If you are looking to add saliva under the modification policy in the guidance that there is the option to do that without a EUA if you're a high complexity CLIA lab and you have that right of reference from the original EUA holder.

Anil Kaul: Okay well maybe I can email to the template site and to see if I can get more answers over there. Is that okay? Maybe I can...

Toby Lowe: Absolutely.

Anik Kaul: ...share the data. Okay, thanks a lot. Thank you.

Coordinator: The next question is from (David). Your line is now open. (David) please check your mute button. The next question is from (Helen Paxton). Your line is now open.

(Helen Paxton): Hi good afternoon and again thank you for all you are doing. I have a similar question to earlier questions with regards to how long it's going to take to get out of the queue. We've been there since the first week in June. We have two EUAs and we have not been assigned a reviewer.

And we keep getting the same email over and over again saying, "You know you're a low priority and this is a serology - these are serology for IgG and IgM." And my sponsor is getting quite upset that we're not getting any kind of review. And so what I would like to know is whether which email can we send - I didn't catch the email. I know it was (Kris) but I didn't know the rest of it.

Toby Lowe: So this is Toby. And you can email the EUA templates mailbox which is [cdrh-eua-templates@fda.hhs.gov](mailto:cdrh-eua-templates@fda.hhs.gov) and you can copy me or you can ask them to send that to me and I can look into it. However generally if you have been assigned a contact who is reaching out to you weekly they will let you know if your priority has changed.

And if you are a - or if you're your submissions are for serology tests that you've notified for and you can offer them under the policy in our guidance. They may

not - you know we do have a large number of submissions in house right now so it may take some time for them to move up the priority list.

(Helen Paxton): Yes I have done several emails was to the template with regards to this and still get the same answer. So I just wanted to check to see if there was anything else we could do for the company.

Toby Lowe: So, unfortunately...

(Helen Paxton): So thank you.

Toby Lowe: ...you know, you can continue to reach out to the contacts that you've been assigned and that person will be able to provide you the most up to date information about where your submissions are.

(Helen Paxton): Thank you.

Toby Lowe: Sure.

Coordinator: I'm showing no further questions.

Irene Aihie: Hi Toby. Did you want to say any closing remarks? This is the first that we've run out of questions before time.

Toby Lowe: Sure. Thanks, everyone for joining today. And please, you know, as we said email the inbox if you have further questions. And hopefully, we'll hear from you again next week.

Irene Aihie: Thanks, Toby. Again everyone this is Irene Aihie and we do appreciate your participation and thoughtful questions today. Today's presentation and

transcripts will be made available on the CDRH Learn Web page at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Tuesday, August 18.

If you have additional questions about today's presentation please email [cdrh-eua-templates@fda.hhs.gov](mailto:cdrh-eua-templates@fda.hhs.gov). As always we appreciate your feedback. Following the conclusion of today's presentation please complete the short question survey about your FDA CDRH Virtual Town Hall experience. The survey can be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live discussion. Again thank you for participating and this concludes today's discussion.

Coordinator: That concludes today's conference. All participants may disconnect at this time.

END