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

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

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode until the question and answer session of today's call. At that time, if you would like to ask a question, you may press star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the meeting over to Irene Aihie. You may begin.

Irene Aihie: Thank you. Hello. I am Irene Aihie or CDRH's Office of Communications and Education. Welcome to the FDA's 33rd 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 lines 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 and thanks everyone, for joining us again this week. So I just have a quick update and I have seen that yesterday we issued a letter to Clinical Laboratories staff and healthcare providers regarding false positive results with antigen tests. So we put that out because we have become aware of reports of false positive results in nursing homes and other settings.

And as we continue to monitor and evaluate these reports, we wanted to share some information with stakeholders about this risk and about stuff that can be taken by clinical laboratory staff and healthcare providers to help ensure the accurate reporting of test results. So that's available on our website and was also sent out by email yesterday.

So a few of the key points there are to be aware of the information in the package insert for each test, which does include information about appropriate handling of the test cartridge or card -- excuse me -- at appropriate storage of those components. If they're not handled properly that can impact the performance of the test.

And also about the time that it takes to read the results and being sure to read the results at the appropriate time since reading the test before or after that timeframe, can result in false positive or false negative results. We also include some information about minimizing the risk of cross contamination and pointing to the CDC guidance and recommendations about the use of PPE and changing gloves and also cleaning the instrument and the work area in between specimens.

Then the other point that is made in that communication is about the positive predictive value. And just reminding everyone that false positives are expected with all tests. You know, any test that's out there will have some false positives and some false negatives. No test is perfect. And particularly with some of these tests being used to screen individuals in low prevalence areas, we do expect there to be a higher incidence of false positives as that prevalence decreases.

So you can find that on our website and take a look at that and let us know if you have any questions. The only other update I have is just to remind everyone that we will not have a town hall next week. Wednesday of next week is Veteran's Day so we will be taking a break next week and we'll be back on the 18th. So with that, we can open the line for questions.

Coordinator: If you would like to ask a question please press star 1 and record your name clearly when prompted. To withdraw your question you may press star 2. One moment please, for our first question. Our first question comes from (Mark Hackman). Your line is open.

(Mark Hackman): Yes, good morning. Can you hear me?

Toby Lowe: Yes. Good morning. Or good afternoon I guess.

(Mark Hackman): Yes. Good afternoon. I'm sorry. It's morning on the West Coast still. Good morning, Toby. IT's (Mark Hackman). It's been a while since I've spoken with you. It's been a couple of months since I've been on this call. But I'm going to ask the same question that I asked a couple of months ago. And it's kind of a two part question. But it's really short.

My first part is when are we going to see a fully at home test approved by FDA? And my second part of the question is, is here currently any over the counter devices, and I'm talking about lateral flow devices, that have been approved by FDA to this date? I've checked the website and I didn't see any.

Toby Lowe: Thank you for joining us. I'm glad you've come back. So to - I'll start with the second half of your question. There are currently no over the counter COVID-19 tests authorized. We are working with any interested parties that come to us with, you know, looking to do that and we have set out some information in our templates, about over the counter. So we do look forward to that.

And the same is true for fully at home tests. I can't give you any timeline on that unfortunately, because that is dependent on developers submitting those EUA requests and making sure that they are - that the data is there to support that use. But we have, you know, as we've talked about on this call previously, we are very interested in that and we have put out information about, you know our recommendations as well as our flexibility to consider different approaches.

So we are looking forward to getting to that point.

(Mark Hackman): Thank you very much. Have a great day.

Toby Lowe: You too.

Coordinator: Our next question comes from Shannon Clark. Your line is open.

Shannon Clark: Hello. This is Shannon Clark from UserWise Consulting, a human factors feasibility testing consultancy. I'd like to better understand the FDA's

rationale for differences between the molecular and antigen templates, specifically related to studies that support a point of care claim. They're not OTC or home use but point of care.

There are pretty significant differences between the molecular and antigen template where the molecular template specifies at least four different operators while the antigen template remains silent on the matter. The molecular template specifies prospectively collected positive specimens, while the antigen template allows for either prospectively or retrospectively collected samples.

And also, the molecular template implies no training for healthcare professionals, which is very common for human factors and usability testing while the antigen template does not comment regarding the use of instructions.

So if you're allowing retrospective sample collections for the antigen template but not for the other ones, as well as just one healthcare provider instead of four, does this imply that the FDA is uninterested in the process for collecting the sample when using antigen tests in the point of care setting?

So - and then if so, can we use this one expensively trained healthcare provided for the antigen point of care study as the point of care indication?

Toby Lowe: There is a lot in that question. I'm going to try to get to it. But so there are differences, you know, obviously there are differences in the templates because there are differences - there are four different types of tests and that's why there are different templates for them.

I would have to double check the details. Unfortunately don't have all the templates completely memorized, especially as we update them. But I believe that we do request multiple operators for the different templates. And I believe that, you know, there's the differences in the test design, you know, visually read versus, you know, a more complex instrument, would also impact our recommendations for the study design.

Shannon Clark: Also, perhaps molecular solutions are more complex and require more operators, maybe more evidence that untrained users can use it. While antigen tests might be so simple that maybe you're less interested in having more than one operator, etc.

Toby Lowe: Right. I mean as I said, they are very different types of tests with most antigen tests being visually read and molecular tests having additional steps involved.

Shannon Clark: It just seemed surprising to me that both - what was that?

Toby Lowe: Sorry. Go ahead, Shannon. I was also going to ask Kris if he wanted to weigh in at all on this question.

Shannon Clark: Yes, please, Kris.

Dr. Kris Roth: Yes, thanks. No, I mean it is a good question and we do struggle - I wouldn't say struggle, but we do try to accommodate, you know, different approaches for these two different tests. Right? So we know antigen is slightly, you know, less sensitive than maybe the molecular test. And therefore, you know, the testing can be, you know, slightly different. And again, I think the first part of your question which maybe of most interest is, you know, I think

molecular tests have instrumentation and you can have a visually read antigen test.

And so, you know, those need to be kind of, you know, taken into account when the validation is, you know, being performed.

Shannon Clark: Yes. So I guess when I read between the lines of these templates it just seems that the FDA is uninterested in the sample collection. Because many times both antigen and molecular will employ a swab. And I know when we do sample collection studies for home use, we're very interested in users' ability to correctly use that swab.

But the implication here to me is that for point of care use you're not that interested in swab, as you do allow prospectively collected samples as well as not requiring (unintelligible).

Toby Lowe: I don't think that was the intended implication. And it would be very helpful if there are things that you're reading in the templates that you think are confusing or you think, you know, are discrepancies between the templates that don't appear to make sense to you. If you can send those in to the EUA mailbox that would be very helpful, so that we can take a look at that and make sure that there are no unintentional discrepancies.

Shannon Clark: Excellent. Will do. Thank you so much.

Toby Lowe: Great.

Coordinator: Our next question comes from Christie Bergerson. Your line is open.

Christie Bergerson: Hi Toby, Kris and (Brittany). This is Christie Bergerson from Exponent Consulting. My question is not as detailed. I had a question pertaining to research use only components that are used as part of a submission.

So after the submission is authorized, do those components named in that submission, which might have been research use only before, need to change their labeling? So for example, if a company uses a certain instrument with their assay and that instrument is labeled as RUO, after authorization would that instrument marketing materials need to be changed to remove the RUO label?

Toby Lowe: So if you're distributing instrumentation that is covered under your EUA it should be labeled as an EUA instrument. Yes.

Christie Bergerson: Okay. Thank you.

Toby Lowe: Great.

Coordinator: Our next question comes from (Tom MacDougal). Your line is open.

(Tom MacDougal): Hi Toby. Hi all. I had a quick question about the study to support the asymptomatic claim that's in the new antigen template. I see it's now asking for 20 asymptomatic positives but also mentions that it may be possible to use archived specimens. And I just wanted to ask if you guys could maybe shed some light on what any maybe post authorization requirements would be if we were to go forward with archived specimens.

Toby Lowe: That's such an interesting question. Kris, do you know if we're including post authorization studies or requirements if we use archived specimens?

Dr. Kris Roth: So I mean typically, we'll have a post authorization study if there's some kind of open questions at the end of your submission. So if there are - I think, you know, during the review, you know, this is a very detailed question, right? I think there are a lot of aspects to what go into a post market study or not. And so I would tend to leave that up to the individual reviewer.

And I would say there's not kind of a blanket policy. So yes, if you use archived you must have a post market study. I don't think that is the approach. I think there are maybe some deficiencies that could be identified because we know that archived sample are, you know, or can be at least, somewhat of a biased population.

So if there are those questions at the end of the study then, you know, that may be applicable for a kind of post market approach, a post authorization approach. Excuse me.

Toby Lowe: Yes. I think that…

(Tom MacDougal): Great.

Toby Lowe: …would be a good question to discuss with your review team. And I did just pull up the template to take a look. And the discussion about archived specimens does ask that you contact FDA to discuss those alternate study designs. So that would be helpful for this one.

(Tom MacDougal): Great. Thank you so much.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Mark Wagner). Your line is open.

(Mark Wagner): Hi. Thank you. I was wondering if you could comment on what the FDA is looking for from distributors of at home collection tests. Are there any requirements for distributors of an EUA authorized at home collection test when the distributor does not hold the EUA?

Toby Lowe: Yes. So the - all of the EUAs include conditions of authorization for distributors in the authorization. So those would be spelled out there. And if you have any specific questions about those that would be a good question to send into the mailbox so that we can make sure that we understand the specific situation and can provide the appropriate feedback.

(Mark Wagner): Okay. Thank you.

Toby Lowe: Sure.

Coordinator: Our next question comes from Todd Lewis. Your line is open.

Todd Lewis: Hello. My name is Todd Lewis from DNA Diagnostics Center. And my question is if we have an EUA approved molecular test and we wanted to change the sample collection part of that and there was an EUA approved - say it was approved for nasal swabs and we want to use saliva collection that was approved, how should we go about that?

Do we have to send in a brand new EUA or is there some type of bridging study, or we do a verification study?

Toby Lowe: So we do have recommendations in the molecular template for validation of saliva including validating adding saliva as a specimen to a test that has been already validated for nasal specimens. In terms of the regulatory approach, is

this your own EUA that you're - that you are the EUA holder and you'll need to add saliva, or are you a laboratory that is looking to add saliva testing to a commercial test kit?

Todd Lewis: We were going to use somebody else's EUA but we can do it as an LDT too. I mean we could poke around that way. But and if you can marry the two and just do a verification in the - I guess of the LDT. Yes.

Toby Lowe: So - right, so if you're - if you're looking to add saliva as a specimen type to an EUA authorization, we would just ask that you submit - the EUA holder should submit a supplemental EUA request including the validation that we recommend in the template for saliva. And then that could be added provided that the data supports it. It could be added to the authorization.

For a lab looking to add saliva as a specimen type to another entity's authorized test, we would also hope that you would use the FDA recommendations for validation that are in the template. We have indicated in our guidance and there's also the HHS LDT statement, that we would not expect to see an EUA request for that modification.

But we would expect it to be done - for the saliva collection to be done with a legally marketed saliva collection device. The collection device otherwise would need to come in for authorization if it's not one that is already authorized.

Todd Lewis: Right. Okay. And it doesn't have to be standalone, it can be part of another test kit?

Toby Lowe: Can you clarify that?

Todd Lewis: So some test kits have that in the collection device built into that EUA and some collection devices have an EUA just as standalone.

Toby Lowe: Right. So if there is…

Todd Lewis: As a matter…

Toby Lowe: …a collection device that is included in - within an EUA for an assay, then that collection device is only authorized for use with that assay. In order for a collection device to be more broadly legally marketed it has to have that standalone authorization.

Todd Lewis: Okay. All right. That answers it. Thank you.

Toby Lowe: Great.

Coordinator: Our next question comes from (Roberta Badsen). Your line is open.

(Roberta Badsen): Hi, yes. My question is - my name is (Roberta Badsen). I'm from Tempest Labs. Just a question about if you have a test authorized under EUA and you do receive a false positive are you required to report that via the MDR process?

Toby Lowe: We would expect false positives to be reported both to the EUA holder, it sounds like you are the EUA holder…

(Roberta Badsen): Yes.

Toby Lowe: …and to FDA.

(Roberta Badsen): Okay.

Toby Lowe: So you could send that into the - through the MDR process or through the EUA reporting mailbox that should be on your letter of authorization.

(Roberta Badsen): Thank you very much.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Elaine Allen). Your line is open.

(Elaine Allen): Hi. This is (Elaine Allen). I'm calling from Agilent. I'd like to first appeal to everyone, all the listeners, for their patience because today is my second day in the environment of developing tests for the COVID. So my questions are very basic. May I ask, and I have a few, what is the average approval time from submission for an EUA to final approval?

Toby Lowe: I don't believe we have ever judged - that we've been giving out at the moment. We do have some information on our FAQs that talks about the time for review and generally it is - it does vary based on the quality of the submission as well as where the submission falls in our priorities.

(Elaine Allen): Okay. That's great. And does that - does the approval time perhaps, is it affected if it's a serology testing or antigen testing type EUA?

Toby Lowe: We do have different teams that are working on serology, antigen and molecular tests. So they are each - they each have their own queues of tests that they're working through.

(Elaine Allen): Okay. So it depends on them. Now the minimum test requirement says 30 positive and 30 negative for clinical data. Is that still the acceptable sample size for EUA approval?

Toby Lowe: So the recommendations for validation are in the templates on our website and those are - all of the current recommendations are in there.

(Elaine Allen): Okay. Templates. Okay. So then…

Toby Lowe: I think generally we do - we do try so that we can get through as many callers as possible, we do try to ask callers to limit themselves to one question. So I would ask that you maybe pick your next top question and then we'll move onto the next caller.

(Elaine Allen): Thank you very much. I appreciate it. Like I said, I appreciate your patience. And this is my last question. Is the agency still utilizing enforcement discretion for promotion and sales of EU products up to 15 days prior to the submission of the EUA or could we preview our intention to our customers more than 15 days in advance? For example, coming soon, so that our customers know we're working on this important project? Or how far in advance can we do that?

Toby Lowe: So the policy that we have in place is regarding, excuse me, does indicate that you can notify FDA once you have completed validation and you are intending to begin to offer your test. So once you have notified FDA you - under that policy, you would then begin offering your test. And within 15 days - and this is for a molecular test, within 15 days you would submit your EUA request. For a serology test it would be within ten business days.

(Elaine Allen): So it is the 15 days prior to submission? Am I understanding that correctly?

Toby Lowe: Once you have notified - once you have completed validation and notified FDA we expect to see an EUA request within ten or 15 days depending on the kind…

(Elaine Allen): Okay.

Toby Lowe: The type of test.

(Elaine Allen): Okay. So promotional materials, can we promote it prior to the 15 days?

Toby Lowe: The test should not be offered for use prior to completing validation and notifying FDA.

(Elaine Allen): Okay. Okay, great. Great. Thank you. And thank you all for your patience for my multiple questions.

Toby Lowe: Thank you.

Coordinator: I would like to remind participants that to ask a question please press star 1 and record your name clearly when prompted. To withdraw your question you may press star 2. Our next question comes from (Win Lee Chou). Your line is open.

(Win Lee Chou): Thank you. Yes. This is a follow up with an earlier question. I just want to clarify it. And so for the standalone device such as the approved home collection kit, the saliva as well as the swabs, so you are - I already have a in-house EUA assay for LDT assay. And what I need to do if I want to do home collection, I can just buy the standalone kit and that's it? There's not any additional test whatsoever, right?

Toby Lowe: So we have indicated that we do expect tests for home collection to be authorized prior to being used for home collection. So we would expect you to submit an EUA request for that. Excuse me. If you are looking to use one of the authorized home collection kits which I believe the standalone home collection kits are only for nasal swabs at this point.

I believe that we have collection devices authorized for saliva, but not home collection kits. And so if you do want to use one of the authorized home collection kits you - the first step would be to reach out to that company to partner with them.

And then they would be able to give you a right of reference to the data that you'll need to submit to FDA for your EUA request.

(Win Lee Chou): Okay. So yes, I just wanted to clarify. So as far as I know there is a one, home collection swab, the nasal swab kit testing approved, right? Standalone kit. So then there's a saliva collection solution. They have to pick up an EUA, the standalone as well, or maybe I got it wrong? So even with that…

Toby Lowe: So there are several standalone home collection kits that have been authorized for nasal swabs.

(Win Lee Chou): Okay.

Toby Lowe: And there are no…

(Win Lee Chou): For saliva. Yes.

Toby Lowe: …home collection kits authorized for saliva. There are…

(Win Lee Chou): Okay.

Toby Lowe: …I believe three EUAs for saliva collection devices but they…

(Win Lee Chou): Okay.

Toby Lowe: …can only be used for home collection when they are part of an authorized home collection kit. They are not…

(Win Lee Chou): Got it.

Toby Lowe: …a home collection kit on their own.

(Win Lee Chou): Got it. So for the standalone, those swabs, those kits, standalone, if I use the standalone together with my test, do I still need to submit some EUA for FDA or I'm okay?

Toby Lowe: We have indicated that we expect to see EUAs at this stage, for all tests, excuse me, all tests that are intended for use with home collection specimens.

(Win Lee Chou): You will use a standalone device. So you still in - need to see the EUA application for that. Right?

Toby Lowe: That's correct. And if there's a specific situation and a specific collection kit that you would like to get input on, you can send an email to the email address…

(Win Lee Chou): Okay.

Toby Lowe: …and we can clarify.

(Win Lee Chou): Okay, great. Thank you very much.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Justin Binding). Your line is open.

(Justin Binding): Hi. Can you hear me?

Toby Lowe: Yes.

(Justin Binding): Okay. My name is (Justin Binding). I come from a smaller medical center. And we're seeing about using our current PCR instrument in these kits. We're currently working with the manufacturer that has an assay that is EUA - that has the EUA approval, and the software has EUA approval but the - but it doesn't have the emergency use authorization for the software with that instrument.

We're trying to - we're working with them to see if - about adapting it and developing a lab developed test. But I saw on the FDA site that you're currently seeing about only approving emergency use authorizations for like at home kits and collection kits and other ones that would be more widely distributed.

Are we still able to receive the emergency use authorization or would we have to go through CLIA and our accrediting agency for a lab developed test?

Toby Lowe: We have indicated that we are not - that we are declining to review EUA requests for LDTs at this time. But what I would encourage you to do if

you're working with the manufacturer of the test kit, is I would recommend that you work with them to possibly collaborate with them on the validation and have them submit a supplemental EUA request to add the components that you're interested in using, to their EUA as that would also help other labs that may want to use the same combination…

(Justin Binding): Okay.

Toby Lowe: …of components with that test kit. And then the EUA holder could update their authorization.

(Justin Binding): Okay. So that - that would - could still see approval if the manufacturer actually also submits it just to amend their current EUA?

Toby Lowe: That's correct.

(Justin Binding): Okay. All right. Thank you so much.

Toby Lowe: Sure.

Coordinator: Our next question comes from (Lindsay Miles). Your line is open.

(Lindsay Miles): Hi. I have a question about manufacturing the viral transport medium. We are following all CDC guidelines for the sterility checks A and B. But my question is do we actually have to perform or is there a requirement that we validate or verify that sterility check? Or if we're following CDC guidelines are we covered? If we are required to validate, how do we approach that?

Toby Lowe: You know, I have not looked at that guidance in a little while. I believe that we, for notification under the policy that we've put out, that we would just

expect you to confirm that you are following the protocol and have validated that. And that you have internally validated that the VTM is sterile.

(Lindsay Miles): And so my question though is what does that mean? Because the CDC guidelines don't have a method validation process. So we are completely following their guidelines but, you know, we're just wanting to make sure that we have everything covered but there's not really any guidelines for a method validation for the sterility check that we are following, per their guidelines.

Toby Lowe: Sure. Let me just see if I can find this very quickly. Otherwise, I would ask you to send the question in so that we can make sure that we are able to get you the right information there.

(Lindsay Miles): Okay, thanks. I appreciate it.

Toby Lowe: Yes. I'm not seeing this in my very quick review of the information and I don't want to take too much time on the call. So of you could send that into the mailbox so we can get you an answer to that.

(Lindsay Miles): Okay. And one - I'm sorry, one quick follow up question to that. So I know you mentioned that it's just to validate that the VTM is actually sterile. So kind of what - how I interpret that is that the sterility check is the validation that the VTM is sterile - is a sterile medium.

Toby Lowe: That's correct.

(Lindsay Miles): Great. And I'll follow up with sending to the mailbox that - that's how we're interpreting it but we just want to make sure that we're following all guidelines and protocols that you guys have.

Toby Lowe: Great. And Kris, did you want to weigh in at all on this one?

Dr. Kris Roth: Yes. Just briefly, you know, sterility is a statistical evaluation. Right? So it's just a matter of how long and how much of the VTM you test. So I think that's perhaps why we're not having a kind of a concrete recommendation in that notification guidance because it's not - I think there's multiple ways that it could be done.

And so as Toby mentioned, I think, you know, if you have a protocol in mind I think we'd be glad to comment on it. We have done that in the past. But just keep in mind, I think there are, you know, multiple ways to take a look at sterility.

(Lindsay Miles): Okay. We'll send in the question and a follow up to the mailbox. Thank you.

Toby Lowe: Great. Thank you. And thanks, Kris.

Coordinator: Our next question comes from Julianna. Your line is open.

Julianna Chen: Hi Dr. Lowe. My name is Julianna Chen and I'm with Hologic. Thank you with - like so much, for taking my call. We do have a question that we would like your help to clarify. We're starting to see like many individuals face published travel requirements for travelers entering their states. And then these requirement are written in a way that they need to be a SARS-CoV-2 PCR test.

Our test is one of the few non-PCR nucleic acid based amplified tests so it's one of the NAATs. And just poses a challenge for the travelers as they would still need to quarantine with a negative result from our test. And we've been seeing similar use of the term PCR used in places for descriptors for like

amplified technologies instead of NAAT, or molecular IVD being used in like many programs for return to work and return to school at the local level.

So we are hoping FDA could help us with two things - one being that if you could help us update the FAQs to recommend to policy developers that they could use generic descriptors such as NAAT or molecular IVD when possible, so these tests are not solely based on PCR technology. And that we will not get - the other non-PCR test will not get excluded.

And then that will help to educate the public health and policy officials at the state and then at the local level, about the distinctions in between those two types of tests.

Toby Lowe: Absolutely.

Julianna Chen: And then another one - sorry, being that if we could have FDA look at the letter to clinical labs and HCP about antigen tests, if FDA could help clarify that NAAT or molecular tests may be used to test antigen negatives instead of just PCRs but - or (RTPCR) as recommended, that would be really great for us. Thank you.

Toby Lowe: Thank you for that. That's an important clarification. And I know that we do try to use molecular as a more general term typically. But absolutely, we do refer to PCR tests at times when molecular may be more appropriate. If you have specific recommendations where you see information is put out and you think that we should change some of our wording, you can definitely send that in.

If you can send that in to the mailbox in writing with your recommended edits that is incredibly helpful for us. And we will definitely take a look at that.

Julianna Chen: Thank you so much. My leadership actually already followed up with you and I will definitely send another email to the template address as well. Thank you so much.

Toby Lowe: Great.

Julianna Chen: And we really appreciate your help. Thanks.

Coordinator: Our next question comes from (Bruce Emanuel). Your line is open.

(Bruce Emanuel): Hi. My name is (Bruce Emanuel) and I have a really simple question. Do you have approved any EUAs for the CRISPR based of this COVID test?

Toby Lowe: I'm sorry. I'm having a little trouble hearing you. Can you repeat your question?

(Bruce Emanuel): Yes. Sorry. My name is (Bruce Emanuel) and I have a simple question. Do you have approved any EUA for CRISPR based testing?

Toby Lowe: Yes. I believe that there are tests authorized with that technology and yes, I believe - it looks like there are two. You can actually search on our - on the EUA page by the attributes of the test. And CRISPR is listed for two of them.

(Bruce Emanuel): So by any chance will it be able to find also how long it took for them to get the approval?

Toby Lowe: We - only list the authorization dates, not the dates that the EUA requests were received by FDA.

(Bruce Emanuel): Thank you. I appreciate you.

Toby Lowe: Sure.

Coordinator: I show no further questions in queue. I would now like to turn the call back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Today's presentation and transcript will be made available on the CDRH Learn Web page at www.FDA.gov/Training/CDRHLearn, by Thursday, November 12th. If you have additional questions about today's presentation please email CDRH-EUA-Templates@FDA.HHS.gov.

As always, we appreciate your feedback. Following the conclusion of today's live presentation, please complete a short 13 question survey about your FDA CDRH virtual town hall experience.

The survey can be found at www.FDA.gov/CDRHWebinar immediately following the conclusion of today's live discussion. Again, thank you for participating and this concludes today's discussion.

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