

**Virtual Town Hall #69
September 08, 2021**

Moderator: Joseph Tartal

Joseph Tartal: Hello, and thank you for joining us today. I'm Joseph Tartal, Deputy Director in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. I'll be moderating today's program. Welcome to another virtual town hall meeting for SARS-CoV-2 test developers. This is meeting number 69 in our continuing series in which we'll discuss and answer your questions about diagnostic tests in the fight against COVID. Please note that we have switched to a biweekly schedule. The next town hall will take place on Wednesday September 22nd.

Our panelists for today's program are Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health, or OIR, in CDRH's Office of Product Evaluation and Quality. And Dr. Kristian Roth, also from OIR.

We'll begin with opening remarks from our panelists and then we'll answer your emailed questions about COVID test development and validation and finally open the line to live questions. To ask your questions, please select the Raise Hand icon at the bottom of your screen. When you're called on, please identify yourself and ask your question promptly. Also, please note, we are not able to discuss specific submissions that are under review. Now I'll hand over the program to Tim.

Tim Stenzel: Well thank you and welcome again to this week's edition of the town hall. We note, unfortunately, that COVID infections are very prevalent in the US today as they are in many parts of the world. I do want to remind those that have been inquiring through perhaps the pre-EUA process about OUS, or outside the US, studies for SARS, since there are plenty of patients, positive patients in the US, and as I've said before-- we said before that we really want you to start your studies in the US where possible and especially for point of care and home diagnostic tests.

And that only if you run into hurdles about getting enough positive patients you reach out to us and find ways that you can perhaps go outside the US. Regarding panel tests which we'll talk about a little bit more later, in the US right now there's hardly any flu circulating. And there may be parts of the world where there's more flu and obviously for panel tests, it may be easier in some cases to get positives outside the US, so that's still one caveat.

I do want to re-review the priorities which remain intact and they're primarily for diagnostic tests that are high volume central lab tests as well as point of care in home. For serology, the highest priority tests are quantitative tests that are traceable to the international WHO standard as well as neutralizing antibody serology tests. As we move forward, particularly for the antigen submissions, we are moving towards-- we've noted that in many cases, the relative priorities of antigen submissions, at this time at least, is relatively equivalent.

So we are moving, and I've directed the team to move, to making sure that first in for these tests that are in this category of being roughly equivalent, that generally we will review them on a first come, first serve basis, a first in, would likely get-- we endeavor to get comments back or other feedback back or potentially authorizations first.

I also want to go back to panels and I think there are some questions that we received ahead of the call about panels but in particular antigen panels. So we've gotten a number of inquiries about non-SARS viruses and how to get them such as flu A B which is not circulating very much in the US, which is a good thing for patients but challenge for developers.

For antigen tests in particular and for all home diagnostic assays, we do recommend fresh samples. Banked or even contrived samples for non-SARS viruses are going to be-- are not something that we recommend. There are, at least in the point of care in central lab, there are a number of flu AB or RSV assays that are fully authorized that can be used to assess patients for them.

So if you are developing a panel assay where it's challenging because, especially for antigen, we're going to recommend that you have fresh samples. We recommend that you consider a ways of getting your SARS analytes authorized and somehow blocking the signal or not identifying the signal for any other analytes you might have on that panel for which you don't have available fresh samples to validate the assay. And, let's see, more into that a little bit later.

One other item we wish to note is that for kit developers that are implementing changes to their EUA authorized devices, when you implement a change prior to EUA authorization of that change, that's only going to be relevant to high complexity labs. So other labs or home situations, whether that be moderately complex or point of care or home, are not going to be able to be implemented prior to authorization.

So reading from the COVID test policy guidance as well as FAQs, "Unless and until an EUA is issued that authorizes additional testing environments for a specific test under CLIA, use of that test is limited to laboratories certified to perform high complexity testing and including testing at the point of care when the site is covered by the laboratory's CLIA certificate for high complexity testing." End quote.

So again, for implementation of modifications, those can be implemented prior to EUA authorization in a high complexity environment. And with that, I think we have covered the introductory remarks and we'll go to the questions that we received prior to the call and have prepared answers. And Kris and I will tag team.

So the first question is, we received a question noting that the first COVID vaccine has received full approval status and asking when tests will begin receiving full clearance. Further, the question asked whether-- the questioner asked whether once one is cleared if the EUA test will no longer be able to be used. Of course, we've responded to this question or type of question on this call many, many times over.

The FDA has granted full marketing authorization for the first COVID 19 molecular test back in March. That was the Biofire Respiratory 2.1 Panel which included the SARS-CoV-2 virus on that panel. It was granted marketing authorization using the De Novo pre-market path-- review pathway. So the grant and all subsequent molecular, essentially all subsequent molecular submissions, can then be 510(k). Or, serology and antigen tests we haven't yet authorized a full authorization for those, so those first authorizations will be a grant through the De Novo review pathway.

And further, that this authorization of the Biofire does not impact the EUAs for any other tests. We're not pulling those EUAs from the market. We have no intention of doing that. We will continue to authorize tests through the EUA pathway and tests authorized under EUAs can be used. More full

authorizations will occur as developers submit them to the FDA and our team is able to grant or clear those submissions.

However, since test EUAs are still being accepted, reviewed, and authorized, they will continue to receive higher priority than full authorizations, though. And this should be for obvious reasons. That we're still looking to expand testing capability and converting an EUA to a full authorization as usual and not expanding testing and pulls our reviewers away from EUA authorizations. So we are prioritizing -- still prioritizing EUA authorizations. However, some have already come in and we anticipate authorizing more.

Next question. Are there tests being developed to follow through on the viral loads and associate them with disease activity of COVID 19 such as long hauler patients? Of course. I don't believe that universally the long haulers still shed virus. And as far as viral load tests, which would be fully quantitative tests, if such test is something that the developer wishes to pursue, that would involve the use of calibrators linked to the international WHO standard.

However, while we're open to considering such submissions, it does remain unclear to us what the clinical usefulness of such viral load assays would be. Certainly see lots of research potential for so many doing purely research and wanting to try to figure out if viral loads mean anything. We continue to monitor the literature. We also continue to monitor the CDC recommendations, other professional and lab associations and to date, they appear to uniformly discourage the use of viral loads in patient management.

As far as long hauler patients go, there's likely a need to identify these patients upfront if possible or to assist in their diagnosis. We do know that there are publications that a patient who has -- suspected of long hauler disease and didn't have a diagnostic test performed when they may have been exposed and develop an infection because non symptomatic-- asymptomatic individuals can suffer from long hauler. Or some may have been symptomatic and simply didn't get-- and had a mild disease and simply didn't get a diagnostic test.

So there are publications and clinicians can do their best to use serology tests to identify whether those patients have, in fact, been previously exposed to SARS. That may come in handy. And there are, we know, a number of developers who are looking at other biomarkers to try to assess risk and potentially diagnose a long hauler in addition to other clinical hallmarks of that disease. And so we do remain open to those submissions and discussions with developers for that.

But we have not, other than for IL 6 which predicts potential for ventilation, we've authorized three IL 6 assays, other than that, we have not authorized any other sort of immune response assays for use in patients who suffer from more severe consequences of the virus and/or long hauler.

Moving to the next question. Given that no flu samples have been available during the last flu season and there's no currently circulating-- not much circulating flu as far as I can tell based on the CDC flu report when I checked this morning, is it possible to use contrived swab samples to prepare for an EUA submission for a rapid lateral flow test for SARS-CoV-2, flu A, and flu B antigens... in order to obtain a claim for flu A and B swab samples, the swabs will be spiked with VTM samples and blinded for testing at the testing site?

So we do not recommend this for a number of reasons. One is we actually don't recommend VTM for lateral flow use for SARS or really any other virus. We've just seen so-- for under an EUA, we've just seen so many challenges with VTM and VTM has been-- some sample types for some assays have needed to be pulled back because of false positives with VTM. And then the other thing is because there are cleared, fully authorized flu A, flu B, RSV, and other viruses that are available to use, we are not recommending the use of contrived samples for flu A and flu B and that would be especially for antigen tests.

And so again, we mentioned at the opening that if you want to have a panel test and you're not seeing active disease for some of your targets, if you can find a way to do the validation for the targets where you do find fresh samples for antigen tests that would be awesome as long as those results aren't reported out to the clinicians and/or the patients if that's possible.

OK. Kris, I think over to you for the next question in response.

Kristian Roth: OK, thank you, Tim. The next question is, is the FDA considering EUA submissions for saliva-based multiplexed flu, COVID molecular tests? And if so, is that home collection permitted and which template should we follow? So the data supporting flu testing using a saliva sample is limited. Also, there are no clear devices or EU tests -- EUA tests -- which are authorized for the detection of flu in a select sample.

Our recommendations are to establish an EUA claim for flu. We recommend using the molecular EUA template which notes testing banked positive samples. Unfortunately, some of these samples are not available in saliva. So in lieu of that, we do recommend a paired sample clinical study design establishing performance of a saliva sample compared to nasopharyngeal swab samples. To support a flu claim for saliva, this should be done prospectively.

Furthermore, validation using fresh, prospectively collected positive samples will likely be challenging as incidents of flu infections remain low. So this is really a data driven question and I think the suggestion here is that the data is still kind of evolving for flu in saliva. The second part is home collection and that is something that is likely possible. We do have a number of home collection kits and that specific question can be answered either via the inbox or if you have a reviewer for your test. Back to you, Tim. Thanks.

Tim Stenzel: Oh. Thanks, Kris. The next question actually is also a saliva-based question. My question is in regards to the validation of saliva based SARS-CoV-2 test for an EUA. Given the rapidly expanding body of evidence that testing of saliva specimens for SARS-CoV-2 is just as sensitive and often more accurate than nasal swab specimen, does the FDA have any plans to consider saliva comparator assays for validation of new point of care diagnostic tests?

The requirement to collect two specimens for each patient at a point of care setting is a critical barrier for validation of saliva-based assays. Given the importance of approval for saliva-based diagnostics to help facilitate testing compliance among young people, is the FDA considering a shift to allow highly sensitive saliva-based comparator assays to validate a point of care test?

So, in our view, based on the data and the review of literature, we would not agree with the assessment of this person who sent in this question as far as saliva being a better sample type than nasal or one of the nasal swabs. Saliva, in our view, remains a very challenging sample type. Obviously it's challenging

because we don't know whether flu A B or other respiratory viruses are able to be detected as accurately or accurately enough to be utilized in an assay.

So we do currently still recommend that new tests utilize-- they want to use a live saliva sample validated in a clinical study compared to a paired NP swab using a highly sensitive molecular test as a comparative method. OK, Kris. Over to you. On part 3, I wasn't sure about the PPA. Kris, you just go with what you know to be correct. A great response for the next question OK?

Kristian Roth: Thank you. So this question is a-- looks like we have four part here so we'll try to address them. In order-- this is concerning the use of the Biofire Respiratory Panel 2.1 or the RP 2.1 as an appropriate comparative method for anterior nasal swab claims. It was previously stated that this would be an acceptable comparator for anterior nasal swab-- sorry, acceptable to compare anterior nasal swab performance candidate assay to nasopharyngeal swab or performance with Biofire 2.1. This is ultimately to support an anterior nasal swab claim for the candidate test.

So it was also stated that using the Biofire 2.1 as a comparative method, there may be additional information requested to ensure your SARS-CoV test has been validated with samples having low viral load. And this is again in reference to that particular test returning a CP value, which is not equivalent to a CT value. Just to bring folks up to speed. OK.

So going to the first part of the question, can we elaborate on what additional information would be required to demonstrate that the clinical study includes low viral load samples? So we do recommend providing a sufficient number of low positives. And this is all covered in the template. And these low positives should be characterized by a highly sensitive RT PCR EUA test which outputs a CT score. For EUA, we have accepted study data that uses a combination of comparative methods and I believe that's answering the second part of the question. Sorry, I get ahead of myself. The second part of the question is, would it be acceptable, at the completion of the clinical study, to test only positive samples with an EUA authorized SARS-CoV-2 test that report CTs?

And again, we have accepted a variety or multiple comparative methods to establish performance. So that's something that could be open. I would suggest again discussing with us first. There are details here, which may matter. So I think generally, yes. But please let us know exactly what you want to do.

The second question is, if developing a multianalyte test using the Biofire RP 2.1 as the comparative method, is it difficult to show information required to demonstrate that samples with low viral load were tested for other targets such as influenza and RSV? So I would say that the pre-selection of archived positive samples should represent a range of viral load or CT values including low positive samples. We expect that the viral load of flu and RSV samples be reasonably distributed throughout the measuring range of the comparative method.

So let's move on to question-- or subpart three. If establishing performance for an anterior nasal swab by comparing to a paired Biofire 2.1 NP swab result, what are the performance expectations? So again, this is covered in the template. And I believe that you should definitely check with the template. But I think we're looking for a PTA of greater than 90% and an NPA of greater than 95% in comparison to an FDA cleared molecular test.

Let's move on to number 4. Would it be acceptable to instead establish anterior nasal swab claims by comparing nasal swab performance on the candidate test to nasal swab results with the Biofire 2.1? This

also goes on and says, provided that an LOD equivalency study for nasal and NP swabs is conducted for the Biofire.

So it is generally acceptable to perform an anterior nasal swab to anterior nasal swab comparison for EUA. However, in this case, only a nasal swab claim will be granted. We recommend further validation for other respiratory sample claims. So I believe the intended use for the Biofire perhaps does not include anterior nasal swabs so I would suggest that this person, again, write up a detailed proposal explaining exactly what they would do and the justification and we can consider that going forward. But typically, we want to see an EUA test used on label as part of the comparative method. OK. Thank you for hanging in there for that one.

And it looks like I will take the next one as well. Has the center, CDRH, issued any specific guidance or suggestions on seeking 510(k) clearance for COVID assays currently under EUA? And is the Biofire De Novo clearance the appropriate predicate for a COVID 19 assay?

So we are currently working on a transition plan for devices offered under EUA. This is included in the center's guidance priority list for fiscal year '21. Since Biofire was granted at De Novo, they are currently the only legally marketed predicate for 510(k) submission. This is, of course, until subsequent tests are cleared through the 510(k) pathway.

FDA recommends that if you intend to pursue the 510(k) pathway, that you submit a pre-submission to discuss your proposed validation strategies and comparator method for review. If you are proposing an intended use which is different from the Biofire respiratory panel 2.1, then further discussion is recommended.

And moving on to the last question. This company is working on a prescription at home molecular SARS-CoV-2 and influenza test. And the question is, does the readout displayed to the home user need to distinguish between influenza A and influenza B, or could the readout simply say whether the sample is positive or negative for influenza?

And this is a question that is quite thoroughly discussed. And we do recommend that influenza A and influenza B are differentiated as a test result. And this is based on external opinion and discussions with flu experts and has consistently been recommended for previously cleared 510(k) flu tests. And with that, I believe we are done with the pre-submitted questions and perhaps move on to the next phase.

Tim Stenzel: Yes let's open it up for a live questions please.

Joseph Tartal: OK. Thank you both for all of that. And thank you again for your emailed questions so please, make sure if you want to email questions to do so before the next town hall which will take place in two weeks. So now we'll switch to the live questions. And as I stated earlier, when I call on your name, please promptly ask your question. And as a reminder, we cannot answer any questions as they relate to specific device submissions. So with that, the first question that I'm going to go to is from Anthony. So Anthony, please ask your question. First you'll need to unmute. OK, Anthony. I'll move on to Autumn. So, Autumn. Please ask your first question.

Autumn: Hi, can you hear me?

Joseph Tartal: Yes.

Autumn: Perfect. Wonderful. First and foremost, thank you very much for facilitating these calls. I realize how much of a burden they are to support them week on and week out and it continues to be an invaluable vehicle for us to ask questions as manufacturers so thank you. My company had submitted an EUA earlier this year which was granted authorization for a product on the condition that we perform a prospective clinical study post authorization.

Since submitting our EUA, we've introduced a dual target design that ultimately we plan to submit for authorization as an improved assay design. But understanding Dr. Stenzel's comment from earlier in today's call clarifying that modifications can be implemented prior to authorization for laboratories performing high complexity tests and to utilize the least burdensome approach, will the FDA consider allowing us to conduct the study for the improved dual target design rather than for the currently authorized single target design to support the change to the original authorization and avoid conducting the prospective study twice?

Tim Stenzel: Yeah. I think that's a useful question to ask our reviewers. A little bit too detailed for me to get into what test and what was the post-market study and what was the timeline for that. Obviously, if our reviewers had asked for a post-market study, it was to confirm something so that the test that's currently on market is known to be functional – so - and getting accurate results. So, but I think that's a question specifically to the lead reviewer for your first authorization. And to-- if you submitted a pre EUA or you're preparing an EUA for the second test that you include the reviewer that might be assigned to that. But I think we're going to want to know a lot more details before we give you specific advice. I don't want to say no without knowing those details that we obviously want to be as flexible as possible in our determination. OK?

Autumn: Understood. Thank you very much.

Joseph Tartal: Thank you, Autumn for your question. Next up, Michael. Please ask your question.

Tim Stenzel: Callers should unmute. We are not able to unmute callers. So if you can unmute and star six may work. That usually works on Zoom if you're just on the phone or your local mute.

Joseph Tartal: OK. With that we'll move on to Patrick.

Patrick: Can you hear me?

Joseph Tartal: Yes.

Patrick: OK, good. I may be in the wrong spot but I am not a developer. I'm a semi-retired customer service consultant. I have two grandchildren that live at home. 5 and 11. I have a wife that's 59. Works as a medical assistant. I work with scouts with 60 youth in my group. And also, my church has 120 members.

We are having problems. It seems like there are only 3 over the counter home COVID tests available that have emergency use authorization. And they're not available. I can't find them anywhere. My question is I'm concerned about availability. Is there-- are there other tests coming soon that can get approval?

Because this is, right now, lead times are like at the end of October and I've got two kids in school and I'm an elderly person with pre-existing conditions. I really need to know their status.

Tim Stenzel: So, yeah. Thank you for calling. And we in fact have authorized 13 at home tests. I believe at least seven varieties of them are cleared or authorized for over the counter. We're very well aware with the Delta surge that the manufacturers are struggling to keep up with the demand. And the US government is funding an increase in the production of those tests in order to try to alleviate this issue.

On the other hand, we have authorized over 60, it might be over 70, home collection devices. So there's a variety of sources for those home collection through various entities as well as online sellers that are authorized to do that. So always double check. Make sure they're authorized. And many are over the counter collection devices. So no prescription is needed. The turnaround time is obviously a little bit longer than a test that you can perform at home and that should be taken into account.

But I certainly know of individuals who have purchased those home collection devices where they're reasonably affordable and have a stash at home. So the other option that you have is to look at any of the national providers of testing services or local providers of testing services and they may have some options for you as well. So the national reference labs, the biggest among them are Labcorp and Quest. There are other excellent reference labs out there. And they each have home testing available as well. So you may want to check them out. It's a home collection device. Amazon has a home collection device and I apologize to the manufacturers on the call. I don't have a complete list, but the complete list of home collection devices and home tests is on the FDA website and we continue to highly prioritize tests that come in for submission for the home environment, whether it's a home test for the diagnosis of SARS or home collection for the diagnosis of SARS.

So either in the home antigen or molecular tests, or for collection, it's usually a molecular test. And those remain our highest priority. And when we receive a submission that is complete and provides the evidence that we know the tests would be accurate. We have unfortunately had to deny authorization for tests that were clearly not accurate. Or perhaps in some cases where we had evidence that we could not trust the data that they submitted.

And as soon as these home submissions come in and they look good, they are the very highest priorities for us to review. And overall, we now are approaching 410 test authorizations by the FDA. So there are various ways to get it but I certainly understand the current situation and it's unfortunate. And at least from the FDA perspective, by authorizing accurate tests as fast as we can, we are going to continue to do our part.

Patrick: Thank you.

Joseph Tartal: Our next question is from Tianyang. So please unmute your phone and ask your question.

Tianyang: Oh, OK. Thank you could you hear me?

Joseph Tartal: Yes.

Tianyang: Great. And thank you. My question is when FDA authorizes a new OTC test kit will the manufacturing volume and supply capacity be considered as an important part because we noticed that

BD and Access Bio the newest approved test kits are not in the market after its approval. So just wonder if the volume and the supply capacity will be considered.

Tim Stenzel: Yeah, I can't speak to any specific test but yes. I mean, we're not going to spend a lot of time on a very low manufactured test. And having been on the other end, on the test developer side, and the ability to ramp up production is sometimes a challenge. So it does take time. You're not going to necessarily want to ramp up production until you get an EUA authorization.

And also, the distributors that you might use including online and retail stores that might want to sell your test are going to want to know that your test is EUA authorized before making room on their shelves for that. So there are unfortunately real world challenges subsequent to an EUA authorization that the FDA has no control over.

Tianyang: OK. Thank you.

Joseph Tartal: Our next question will be from Sahil. Sahil, if you can unmute your mic and ask your question.

Sahil: Can you hear me?

Joseph Tartal: Yes.

Sahil: OK. So, hi. My name is Sahil. I was just wondering if you have any updates on therapeutics because a lot of hospitals are running out of therapeutics and so I just wondered if there were any upcoming EUAs or any more therapeutics you can approve using Emergency Use Authorization?

Tim Stenzel: So we're part of the device center and this call is largely focused on COVID tests and authorization of COVID tests. The centers that would authorize therapeutics and/or vaccines would either be vaccines are authorized by the Center for Biologics. And many of the therapeutics that are authorized by the Center for Drugs, so you may be able to reach out to them to inquire as to their-- that you ask your question of them.

Sanil: OK. Thank you.

Joseph Tartal: In fact, you can reach out to the Division of Drug Information, DDI. They answer any of those type of questions including the COVID therapeutic questions. With that, our next question is from Irazone. So I'm going to unmute you so please unmute your microphone and ask your question.

OK. We'll move on to our next person. Greg S. So Greg please unmute your microphone and go from there.

OK. Move on to Jack. Jack Fang. Jack?

Jack Fang: Hi can you hear me?

Joseph Tartal: Yes, we can hear you.

Jack Fang: All right. So as FDA claimed for many times that antigen home-- sorry can you hear me?

Joseph Tartal: Yes.

Jack Fang: Yes, got it. So antigen home test is the priority. So may I ask, how big is the team working on the EUA antigen home test?

Tim Stenzel: It's a sizable team. And they and they are currently prioritizing home tests and point of care tests and I meet with them weekly, if not more. Well, I meet with that specific team weekly to go over their entire submission list and prioritize their reviews. And then we also meet daily as a full team and management team and the home team can ask me any questions on any topic. So that we can move quickly.

As I mentioned earlier, and sort of the reverse of what I said, so if a submission comes in and it's complete and our reviewers don't have to ask any questions, it gets high priority. But the reverse is also true that if a test-- if a submission is not fully complete and we have questions, it is going to not be as high priority as tests that are complete and that we can-- and all the information is there and in a manner at which we can understand how the validation was done and can move forward on those authorizations.

It's incredibly rare for all of this-- for any of the submissions to be fully complete. So even on the highest priority test submissions, there is a fair bit of back and forth. And we're entirely dependent, once we've asked the question, on how fast that developer gets back to us. So the recommendation that we would have is that make sure that your submissions are complete, they're well done, that they generally follow our recommendation. That if for some reason our recommendations are not followed, that will entertain questions on our part.

Some of those potentially could be mitigated if there's good written justification for their changes. But the workload is still high. We're still getting more than 100 EUAs a month this far into the pandemic. And as I mentioned at the top of the call, for a large number of the submissions now, they are roughly at the same level of priority. And we are moving to direct at least for the antigen team to move to a first in, first out. So those that have been waiting longest for comments or a decision will hopefully hear first.

Jack Fang: All right. Thank you.

Joseph Tartal: And with that we have one more hand raised remember if you want to ask a question, please raise your hand. We'll go to Greg S. and try again.

OK. We will try again with Arazone.

Tim Stenzel: Please unmute your line if you wish to speak. We will designate you as the next caller and call your name. If you haven't tried star 6 on your phone if you're calling in by phone try that. If you're connecting through the internet there is a mute button on the internet that you can use. Unmute yourself and speak. But you are shown as needed right now and we cannot unfortunately hear you or give you the permission to unmute.

There you go. Oh, Arazone you were unmute for a second and then you're muted again.

Joseph Tartal: So please unmute yourself if you want to ask the question. Also, Greg S when I do unmute you, it is telling me that you're using an older version of Zoom. So it's not allowing you-- that may not be allowing you to unmute as well.

Tim Stenzel: But that may be the situation. That's a good reminder at the top of the call and maybe in the email to be sure you have a current version of Zoom. And if you're not able to get through due to technical issues, you always have the email address for the upcoming town hall to ask your questions ahead of time. But we also have the EUA template email address, and you can send us an email question there and we'll endeavor to get back to you as soon as possible.

Joseph Tartal: And with that, it doesn't look like we have any other additional questions than those two that are trying to come in. So we'll give everyone one last chance. Please raise your hand if you have an additional question and you're available to unmute and ask that question. OK. Sounds like we have no additional takers. As was previously mentioned, if you do have a question, feel free to email us that question ahead of time and we'll meet again in another two weeks.

So thank you, everyone. We greatly appreciate your participation. We greatly appreciate the expertise of both Tim and Kristian. Today's presentation transcript will be available at CDRH Learn. Please visit CDRH Learn at www.fda.gov/Training/CDRHLearn. Note that we've updated the title of this section to make it easier to navigate. You'll now find the recordings in the subsection titled Coronavirus COVID 19 Test Development and Validation Virtual Town Hall Series.

For additional questions about today's presentation and topics, please send an email to CDRHEUAtemplates@fda.hhs.gov. As we continue to hold these virtual town halls, we appreciate your feedback about the program series. So please complete a brief survey which you may find at www.fda.gov/CDRHWebinar. Finally, as a reminder, we are switching to a biweekly format. So please join us for the next webinar on September 22. This concludes today's town hall. Thank you.

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