

**FDA Virtual Town Hall Series - Immediately in Effect
Guidance on Coronavirus (COVID-19) Diagnostic Tests
Moderator: Irene Aihie**

**May 20, 2020
12:15 pm ET**

Coordinator: Welcome and thank you for standing by. I would like to inform all participants that your lines have been placed on a listen-only mode until the question and answer session of today's call. Today's call is being recorded. If anyone has any objections, you may disconnect at this time. I would now like to turn the call over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello. I'm Irene Aihie of CDRH's Office of Communication and Education. Welcome to the FDA's ninth in a series of virtual townhall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today, Timothy Stenzel, Director of the Office of In Vitro Diagnostic and Radiological Health in the Office of Product Evaluation and Quality; (Sara Brenner, Associate Director for Medical Affairs; and Toby Lowe, Associate Director of the Office of In vitro Diagnostics and Radiological health in the Office of Product Evaluation and Quality. All from CDRH will provide a brief update.

Following opening remarks, we will open the line for your questions related to today's discussion. Now, I give you Timothy.

Timothy Stenzel: Thank you, Irene, and hello everyone. Welcome again to our virtual town hall today. We want to welcome Toby Lowe. She will be a regular speaker participant going forward. There is lots of folks behind the scene that have been providing assistance from the agency during this pandemic. Toby's one of those.

She's, among many other things, one of her roles is to keep the Frequently Asked Questions page updated. She writes a lot of the text that goes into it and she's a tremendous resource to have on this call when there are particular questions that perhaps I am not up to speed up on as well as she is. I'd rather you hear from the expert.

The other folks that are somewhat unsung heroes potentially are if you sent us an email at our templates email address, you've probably encountered (Yvonne) and she's a superstar as well.

All right. Let's get started. There was press last week about the Abbott ID NOW test and I wanted to briefly explain what has gone on with that press release and what we are doing with the Abbott ID NOW test.

Weeks ago, we updated the instructions for use to remove VTM due to potential delusional effects that may have impacted the sensitivity of the Abbott ID NOW Test. More recently, we have seen reports and we have preliminary data, that's now public, that suggests there may be a decrease in sensitivity at the very low end with the Abbott ID NOW. And we just wanted to make that publicly known.

We've worked collaboratively with Abbott to adjust as we go along here and we're in the process of updating the instructions for use and the intended use limitations to convert a negative result with the Abbott ID NOW to a presumed negative result.

And what this means is that if there are clinical features, indications that suggest that the negative result from an Abbott ID NOW test may not be a true negative. That the agency recommends reflex to another molecular test for confirmation of that negative.

We are looking at all sorts of helpful diagnostics and tests during this pandemic. The agency believes that as long as certain minimal thresholds for sensitivity for a diagnostic test are achieved that they may play a role and that there are different roles potentially for different diagnostics.

Point of care diagnostics. For example, that detect either the protein antigen or are, in fact, nucleic acids, if they return a result very quickly, could play a role in this pandemic, an important role. Especially if that positive result can be relied upon that is the specificity is very high.

And so as long as the minimal threshold for a point of care direct detection test is at least sensitivity of 80 percent. We believe that knowing this and knowing the true performance of such a point of care test and knowing that it may be less sensitive than a central ab molecular test is important but also can play a role in triaging patients who are suspected of having COVID-19.

So, Abbott has agreed to perform a number of post-market studies and also initiate a new one which we're negotiating what those end points will be for that study. If we are able to determine that sensitivity of the assay in controlled trial circumstances is at least 80 percent, we feel like that test has a

valuable place going forward in this pandemic. So, that pretty much covers that topic.

We've built up a number of questions, some of which we try to address on the weekly CDC calls which was I not able to get to all of the answers on Monday. So, I wanted to go through some of those topics now.

So, let me just go through some of those questions and give you the best answers that I can.

So, there's a lot of questions on serology tests. We have a question on whether or not there's a recommendation to use IgG, IgM, IgA combined test or total test. The agency really doesn't have a position on which of these isotypes is most important.

We will evaluate and authorize tests that if performed minimally expected performance criteria as set forth in the templates for serology. And we make sure that those performance characteristics are known, and users of these tests can make their own decision as far as that goes.

There's a question about where you can find information. On the slide presentation today, we've given all of the important FDA links including where you can find serology guidance, where you can find NCI testing results, where you can find the calculator for serology tests.

So, we do provide an NPV, or Negative Predictive Value, and Positive Predictive Value calculator on our serology performance page. There's a link to that calculator. You can either look at the performance with one test or if you use the two-test strategy on a second serology test that is different from the first it can potentially have a good impact on increasing the positive

predictive value and we provide a calculator there that does theoretical considerations for a two-test strategy.

The NCI documentation is also on that serology performance page. The FDA guidance documents are present on one of those pages. I forget which one. We also provide the link in the slide doc today for the Frequently Asked Questions page.

The next question has to do with point of care rapid serology IgM, IgG letter of protest. They are saying they notified us, but it's not been reviewed by the agency and the agency hasn't made an authorization decision. The question has to do with the CLIA complexity. In those situations where the agency hasn't reviewed, those are automatically in a high complexity category. The high complexity lab does have a point of care station. They can use these tests within their high complexity CLIA lab.

When we make an authorization for a moderately complex and/or CLIA wave we will make that information known in the authorization and also clearly post that information on our FDA website links where we designate either H for high complexity, M for moderate complexity or W for CLIA waved.

In those cases where a test has been designated the CLIA wave, it can be used in the point of care in your patient setting as long as that setting is covered by a CLIA certificate.

Next question has to do with LDTs as developed by a lab using the serology RUO kit. The labs are allowed to develop LDTs for serology and notify us and not require any EUA authorization although we're happy to review EUA submission for authorization in that setting as well.

There's a question about the recently authorized direct antigen test. Again, this is a point of care lateral flow rapid test that detects SARS-CoV-2 protein. They are wanting to know how reliable it is? How do the results compare to PCR? Are there any thoughts about whether it is able to significantly wrap up testing?

The performance as evaluated in the EUA authorization is listed in our EUA authorization page in the instructions for use, within a link for that product. So, you can look at how it compares to PCR and again, our minimum criteria for any diagnostic test such as this is at least 80 percent sensitivity which that test was able to achieve.

They had a minimum of 30 positive results on actual patient samples. So, we were able to authorize the test based on that. We also had preliminary information on direct swab results and, again, we were able to detect four out of five positives. They are continuing to do a study. They had authorization post-market to be able to do that.

As soon as that study is complete, we'll update package insert with the performance on direct swabs. And as long as that achieves 80 percent or more sensitivity relative to a high sensitivity PCR test, that sample type will be able to remain with that test.

Moving on, we had a number of questions about saliva and home collection. We did update our molecular and direct antigen templates with saliva. We have recommended studies for going ahead and validating and determining performance for saliva in those templates. We have obviously authorized (Rutgers) for both physician or clinician observed saliva collection as well as now home collection.

Saliva is an interesting sample type. It's obviously something that doesn't require a swab. It's easy for a patient to do themselves. So, that is an interesting sample type. We continue to see some variable performance using saliva. I can point you to now posted publication of the United Health Group Gates Funded Study.

Looking at oral secretion. Where there was a variable comparative performance when you look at cycle threshold on a PCR assay. There was basically no correlation between oral fluid and an MP swab as the gold standard comparative for that study.

It doesn't mean that saliva isn't a potentially good substitute for detection of the virus. It just means that there is potential variables that we don't yet understand. And as long as overall performance is good, saliva, we believe, is an adequate substrate to perform testing on.

All right. Let's see. There's a question about whether self-collected nasal swabs are adequate if unobserved? And yes, we have authorized, in fact, now more than one home collection of nasal swabs and we believe that does not need to be observed to get adequate performance.

The next question has to do with testing strategy. One of those is if there is an EUA approved antigen test, where does that fit into the testing strategy? We think that there is a role for this. I forgot to mention that the direct antigen tests do have the opportunity to be produced in great numbers in the quantities of millions of tests.

So, there is the opportunity to make more testing available using a direct antigen test than perhaps other direct tests for the virus. However, its

performance limitations would be remembered as far as the sensitivity relative to a central lab molecular result.

Another question about what tests can be used for screening of asymptomatic individuals and return to work decisions. Can an EUA diagnostic test be used? So, on our Frequently Asked Questions page, we do address the testing of asymptomatic individuals and currently all our EUAs authorizations are prescription and so as long as the physician or clinician has ordered a test and it happens to be on a patient without symptoms, as long as an EUA authorized test is used that is okay by us.

We don't know the performance in the asymptomatic population. There are a number of developers who we're working with and who are interested in this and then if a developer of a kit would like to claim or a lab would like to claim performance characteristics around asymptomatic individuals, we would ask that they approach us with study designs so that we can work with them and we can find a way to authorize such tests.

I'm just looking through the questions to see what we can address now. I think that covers the vast majority of the questions that we had previously received. There was one question about the hologic EUA application for TMA as you probably have noted we did authorize that test. So, those labs that are interested in that can see all the information on our EUA authorization website.

So, with that, I think we can open it up for questions and answers. Thank you.

Coordinator: Thank you. We will now begin our question and answer session. If you'd like to ask a question, please press *1. Please unmute your phone and record your name slowly and clearly when prompted. Your name is required to introduce

your question. Again, that's *1 if you'd like to ask a question. Our first question comes from (Karen Richards). Your line is open.

(Karen Richards): Hi. Thank you. So, thinking ahead post EUA, for providing FDA cleared serology test to the market, I imagine that FDA has or will be receiving many pre-submission requests. To streamline the process, will FDA be issuing any guidance on the requirements for 510(k) submissions and allow for serology tests to be submitted as 510(k)s as opposed to requiring a first product to be submitted as a de novo application?

Timothy Stenzel: The first application for serology or direct antigen or a molecular test for SARS-CoV-2 detection or detection of antibodies directed at that will defacto be a de novo application. And then we will, as we have in the past for something novel, we will write a document that's called a special controls document that outlines the considerations that allow for the down classification to a 510(k) for all subsequent.

The special controls document just outlines those expectations for development and validation and other factors that mitigate the risks and allow all subsequent submissions to be 510(k). That's the expected pathway for all . We certainly welcome anyone who wants to come forward, any developers who want to come forward now and get the first one being a de novo grant and subsequent 510(k) clearances.

As far as what will be required for that, it's going to be largely the same that we would for any other serology directed at a respiratory virus or a direct detection technology for a respiratory virus. And we'll work with anyone with that through the pre-submission two-step process.

Coordinator: Thank you. Our next question comes from (Allyssa Holmartz). Your line is open.

(Allyssa Holmartz): Thank you. Thank you for these events. We really appreciate it. So, my question is, as a manufacturer of a rapid antigen detection assay, can we use (code1) SARS-CoV-2 assay as a comparative method to demonstrate equivalence?

Timothy Stenzel: As of now, we're asking that developers compare it to a high sensitivity molecular assay. That's because the threshold that we've set for SARS-CoV detention is 80 percent relative to a molecular test.

(Allyssa Holmartz): Okay. Thank you so much.

Coordinator: Thank you. Our next question comes from Dan Schultz. Your line is open.

Dan Schultz: Hi, Tim. This is Dan Schultz with Greenleaf Health. How are you?

Timothy Stenzel: Good.

Dan Schultz: Good. So, question is, have you guys given any thought or have any thoughts about tests for cell-mediated immunity for COVID?

Timothy Stenzel: I haven't but that doesn't mean that our expert teams hasn't. So, if you have some ideas or thoughts, address to our templates email address which should be posted on the slides for this meeting.

Dan Schultz: So basically, do sort of a pre-EUA, is that what that would look like?

Timothy Stenzel: Yes. I think that's the best so that you understand what our thinking is. We understand your technology and how the validation might best be demonstrated.

Dan Schultz: Great. Okay. Thanks a lot. Appreciate it.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. And as a reminder, if you'd like to ask a question, please press *1. Please also limit yourself to just one question. Our next question comes from (William Lamparder). Your line is open.

(William Lamparder): Yes. I have a question in regards to certain test kits being approved. It's been a few months since they submitted application for the Zhejiang Orient Gene Biotech company from AYTU bioscience and I was wondering why or when that will be approved and also, they have another test kit, Biolitics. They're both over 95 percent accuracy and they're also approved by the FDA in other countries as well. I'm just wondering what's the hold up?

Timothy Stenzel: Are these serology tests?

(William Lamparder): Yes.

Timothy Stenzel: Okay.

(William Lamparder): Sorry.

Timothy Stenzel: So, we've obviously updated our guidance on serology tests recently and...

(William Lamparder): Yes. I...

Timothy Stenzel: ...put into place processes and procedures. So, you should expect that in the very near future that decisions will be rolling off and that we'll make those decisions public. You know, the original, let's see, March 16th guidance allowed tests of this sort if they met the criteria that was set forth in the guidance to notify us.

(William Lamparder): Yes.

Timothy Stenzel: We would post that notification and to be legally marketed. We're meeting the public health need at that time.

(William Lamparder): Okay.

Timothy Stenzel: And now the update is for us to review those applications and make decisions. So, we're now focused on that. So, you should see a lot of progress in the near future.

(William Lamparder): Okay. Because I know they did a review by a private party, I believe it was, and to meet your guidelines and everything and they proved that it was almost 100 percent accurate with the Zhejiang Orient test.

Timothy Stenzel: Okay.

(William Lamparder): And then these other tests from Biolitics in Singapore are excellent as well. Yes. I just know a lot of people are wondering what's going on?

Timothy Stenzel: Yes. No. I can understand that. Like I said, you will be getting to see a lot of decisions going forward...

(William Lamparder): How long do you think it will take for them to - I mean, it's been, what, a month or two now.

Timothy Stenzel: So, if it's a specific test or tests, if you send us an email with the templates email address, we will try to give you as much information we can. If it's considered confidential information that may be...

(William Lamparder): Oh, I'm sorry. I almost forgot one other thing. The AYTU Bioscience, they're working with (Sire Cyanide) and (Sterling Medical) on the (Helight). I don't know if you heard of that, the (Helight) Products where it kills the virus inside your body. They submitted for a patent and FDA approval. I don't know if you can even say anything about that or have any info on that?

Timothy Stenzel: Yes. That would not be in our office. Not be in the IVD Office. So, again, if you send an email to the templates email address, we can potentially direct you to somebody that might be able to answer some questions about that.
Thank you.

(William Lamparder): Great. Thank you so much for your time. Take care.

Coordinator: Thank you. Our next question comes from (Polinee). Your line is open.

(Polinee): Thank you very much for all the good work the agency is doing. The question is with respect to direct antigen test. Now, I think with (Quidel) has essentially a point of care, the lateral flow approach, is there value in thinking about having this test done in central labs and highly automated machines and especially in this case, the results would take only a few hours but it's still the logistics of blood sample or in this case, nasal sample or saliva going into the central lab and coming back would be a days' result but you can do population level testing.

So, what are your views Dr. (Stenzel)?

Timothy Stenzel: Are you talking about the (Quidel) Rapid Direct Antigen Test) for SARS-CoV-2?

(Polinee): Correct, doctor. That's actually on the level floor. Do you think there's any value in having these tests done in a not necessarily (Quidel)? Like, if you were to develop an antigen test in highly automated because these are all (unintelligible)-based principals and you could do it in a central laboratory in micro (unintelligible) fashion. Would that be any value in doing that?

Timothy Stenzel: Certainly, you know, performances adequate. We welcome all assistance in this pandemic. The public health need isn't just for me or our office to figure out. I'm just thinking through the benefits of such technology. There may be higher throughput potentially. There may be lower costs.

But there is the trade-off on sensitivity most likely. It's unlikely that it would be as sensitive as a central lab molecular test. So that's the trade-off. So, I wouldn't say no. And if it's something that you want or others want to develop, we would be interested in having a conversation with you.

((Crosstalk))

Tim: Yeah, I appreciate it. Performance characteristics would be just like the direct anagen test, and I would think that a large part of that template would apply.

Man: Thank you very much.

Tim: You're welcome.

Coordinator: Thank you. Our next question comes from (Eric Konick). Your line is open.

(Eric Konick): All right. Tim, Toby, thank you for hosting us, and thank you for everything you're doing during this pandemic. My question is related to unobserved at-home collection for RT-PCR assays and specifically related to dry swabs and how to obtain positive samples.

So, I think as you're probably aware, at least in the Seattle area, we're seeing a huge decrease in the number of positive patients, so actually getting positive samples is challenging, especially for, you know, at-home collection, so would the agency accept dry swabs that have been collected from negative – SARS-Co-V-2 negative participants that are spiked VTM or UTM as a positive sample?

Tim: So are you an IVD kit developer or a lab?

(Eric Konick): Oh, I'm sorry. University of Washington.

Tim: Oh.

(Eric Konick): So academic medical center.

Tim: Yeah, so I understand, and it's nice to hear that the prevalence of acute COVID-19 is relatively low in the Seattle, Washington area. Below 2 percent was the last numbers I saw, so I can certainly understand the challenges of that. There are some innovative things that we can do that might be able to help you in those areas where incidence is lower. I'm not sure what I can say publicly right now, but we are working to address that very topic. So, again, your name is – is this (Alex), or who is this?

(Eric Konick): This is (Eric Konick).

Tim: (Eric). I'm sorry I didn't catch your name.

(Eric Konick): Oh, no worries.

Tim: And we know each other, so you're welcome to email me directly or email our template's email address and ask about this, but I have some thoughts that could help you and potentially others, and we want to make that – I just don't know what can be publicly shared at this time.

The dry swabs and home collection of dry swabs is very interesting, and we are working in collaboration with others to make this available, and Toby may know a little bit more about what we can share right now publicly, and Toby – I'm not sure. I've reached the limit of what I know I can publicly talk about, but, Toby, do you have anything to add.

Toby: Yeah, we'd love to talk to you about the specific that you're looking to do and see if we can take at that and see what we can work out with you. We do have some information on the FAQ about validation material, but it will really be dependent on your specific situation and, you know, what you're looking to validate, whether you're validating your assay as a whole or if you're validating home collection, and we may have some – you know, we do have some stability study data that you can leverage for home collection, and then we would need to see, you know, what other data you already have and how that can all be used.

Tim: I believe – and this is ringing a bell now. I believe what is the – sort of the only piece that might be missing from this is validation of resuspension of a

dry swab with your particular assay or assays that you want to use with this, but much of the rest of the work has already been accomplished, and rights are allowed to the previous data that Toby mentioned about stability. So I think there's a pretty clear pathway that is least burdensome here and pretty efficient.

I think, if I remember correctly, we just want to make sure from the dry swab you have a good method of resuspending and it performs well in your hands, and at that point, coming off the swab in that situation, I don't believe actual patient positives – individual, you know, positive patients aren't needed for that, but let's double-check on that, okay?

(Eric Konick): Great. Thank you for your help.

Toby: And you can email either of us directly, or if you have a lead reviewer that you're working with, we can work with you on that.

(Eric Konick): Great. Thank you.

Toby: Yes.

Coordinator: Thank you. And as a reminder, please limit yourself to just one question. If you do need to withdraw your question, please press "star" 2.

Our next question comes from (Brant Mitler). Your line is open.

(Brant Mitler): Yeah, hi, Tim. I want to ask you about the serology Ig – G (IgM) lateral flow devices. What specifically are you looking at in terms of the specific methodology and data that allows you to provide a moderate complexity designation? And I'm not asking about going to the, you know, CMS CLIA

website. I'm asking for the specific elements that you-all are looking at that allowed that designation of moderate complexity. Thank you.

Tim: Okay. Yeah, so in order to get the moderately complex designation, it does need to be EUA-authorized. That is an assessment that is done by the team in regards whether it requires highly trained technologists to perform that testing. For example, a rapid lateral flow serology test in almost all cases would be amenable to a moderately-complex environment.

Whether or not it then also qualifies for waived status being status or, you know, sort of point-of-care does require different amounts of information, but as far as the moderately complex, it does not, in and of itself, require user studies or anything like that, because it's being performed within a lab environment that does have lab-trained professionals.

Toby: Yeah. I was going to add that, a couple of the things that we look at to get to moderate is whether it is automated sample-prepped and analysis and the hands-on time for the user, so we would want very little hands-on time for the user to get to moderate, and there is some information on our website about CLIA categorizations and sort of this scoring that we use for the level of complexity. You know, that's for normal times, but we do look at the same type of criteria for an EUA as well.

(Brant Mitler): Toby, what website is that, or is that just the CLIA categorization website?

Toby: Yeah, it's on FDA's website – the best advice, if you Google FDA CLIA, it probably will be the first or second link. The title of the page is, CLIA Categorization.

(Brant Mitler): Yeah. Well, my...

Tim: Good points.

(Brant Mitler): Is there anything, for example, just...

Tim: There is a form that we follow and we score, and there's the information on the website for that. We do follow that even in an emergency situation.

(Brant Mitler): Well, just to follow up, is it specifically – for example, is one aspect that you have to have an external positive and negative control provided?

Toby: No. I don't that's a specific criterion.

(Brant Mitler): Thank you.

Tim: Yeah, so particularly those external controls for serology right now would be challenging. So, yeah, we would love to see them – folks who do the testing and buy the kits would love to see those controls come with the kit, but we are working through a real-world situation in authorizing on tests right now.

(Brant Mitler): Thank you.

Coordinator: Our next question comes from (Larry Lines). Your line's open.

(Larry Lines): Hey there. I just had a question – I'm no professional or anything, but I've been following along with a local USA company in Utah called Co-Diagnostics, and they were talking about having a dual serology and PCR test, and those tests really interest me because, like I said, I'm no professional, but I've been reading up a lot.

And most of the tests seem to be having some of their false results due to the primer dimers in the RT PCR chain reaction process, and that is a big part – they have, you know, intellectual property on their co-primers which eliminates that. They also are working with an oil lab DNA with their co-primers to try to work for a saliva test, which I haven't heard much about.

They submitted that mid-April. I'm just really curious. That's a local company. It's a little small. I'm worried they may be overlooked because of small, but from the research I've done, their intellectual property and could really help, so I would just love to hear back from that.

Tim: So, yeah, there is information that might be considered confidential. The...

(Larry Lines): That's what I worried about. You know, I'm local. I'm right by Utah, and I know dozens of people who can't get tests, and, you know, I'm with no media, and I just worry about my friends and family where these good tests may be being held up, you know, the spit tests which have these co-primers which would reduce a lot of these primer dimers which is a very predominant cause of these false positives in these RT PCR chain reaction.

And I'm just worried that some of this whole business confidentiality is really overtaking the safety of these tests. As long as – you know, they've been bragging this new test could be serology and RT PCR and that could be the gold standard for our company.

Toby: I think...

((Crosstalk))

Tim: So yeah...

Toby: Go ahead, Tim.

Tim: No. No. You go ahead.

Toby: So the confidentiality that Tim's mentioning is not holding up any reviews. We just are not able to provide any information about any specific companies that may or may not be seeking EUA until that is public, so we just can't share any of those details on these calls, but we are definitely open to any new technologies or improvements on existing technologies, and we encourage all of those companies to come talk to us.

(Larry Lions): Is there any movement on their oil DNA lab saliva test using co-primer technology to reduce false positives?

Toby: Again, we can't comment about any specific companies or...

(Larry Lines): You comment on (AYGU) a second ago which is confusing to me.

Toby: No, I don't think we commented anything specific to that company or test driver.

(Larry Lines): I understand. You know, I don't want to take up any more time. I feel like you guys won't answer my question specifically. Thank you very much.

Coordinator: Thank you very much.

Tim: Let me just – hold on. Let me just complete the loop on this. Toby was right. We welcome all developers. If - we do not speak specifically about any

developers that haven't given us permission to speak or we haven't taken public action.

However, we do work with those developers, and we are working very closely, and if there's any innovative technologies that will assist us, we've authorized now over 100 tests, and that represents tens of millions of testing opportunities...

(Larry Lines): May I say one thing?

Tim: Yeah.

(Larry Lines): Over those hundreds of tests, I do believe it's about 40 or 50 percent coming from the same four or five companies, and that's just what worries me. You know, seeing such a pandemic and you have a small company that has the potential to grow, I just do worry it may be overshadowed. For the good of the community just based off of, you know, large corporate greed and – that is my main point.

You know, I do believe in their technology very soundly. You can speak to the stock price, which I have no interest into it as well. I just want to get good tests, you know, made in America out to my friends and family, and, you know, I just worry. I have a lot of elderly family, but, again, thank you for your time. I understand if you can't get any more into detail. I do not want to take up one more minute of your time. Thank you.

Tim: Okay. Let's move to the next question please.

Coordinator: Thank you. Our next question comes from Ms. (Zimmer). Your line is open.

(Ms. Zimmer): Hi. Thanks. My question is about the re – authorizations that you have about home testing and the criteria that people would need to meet to get at-home testing or it seems like right now the FDA is considering that we just limit to something like known exposures, and I was just wondering what your thoughts were on that as we talk about this symptomatic testing and return-to-work style testing.

Tim: I missed – I heard – I just want to confirm the question. The FDA is authorizing symptomatic, and you said something else?

(Ms. Zimmer): Yeah. The most recent authorizations for at-home testing have included guidelines for how individuals can qualify and that's saying that people need to have symptoms or they need to have a known exposure.

Tim: Uh-huh. Toby, do you know the details on that? I thought we were authorizing with those suspected of having COVID-19.

Toby: Right. They are authorizing pretty much the same indication of the other tests that we're authorizing, so suspected of – I might not get the language exactly right, but I believe it's suspected of COVID-19 by a health-care provider, and so the home collection tests are the same indication, and those – basically, that assessment is being done for most of them by a questionnaire.

And so those questions on the questionnaire are intended to get to whether or not they're suspected of COVID-19, so in most cases that is whether they're symptomatic or have known exposure, which, you know, could be a variety of aspects to get to known exposure.

(Ms. Zimmer): Gotcha. And I guess I was just wondering....

Tim: And we say on our FAQ page – I just want to add something that we say in our FAQ page that – that a physician-ordered or clinician-ordered test or whatever order is allowed by an individual state, as long as that order is placed that testing can be performed on asymptomatic individuals. We are on our FAQ stating that very criteria.

(Ms. Zimmer): Thank you, and I guess I was wondering if you were considering evolving that thought going forward or if that's something that you're pretty set on.

Tim: Evolving to clearly allowing it for asymptomatic individuals?

Tim: So we're very open to working with developers to achieve that ability to put that in the intended use, but right now the actual performance of tests on asymptomatic – you know, the sensitivity specificity in the setting of an asymptomatic individual, that's an evolving science, and we don't know exactly what the true performance characteristic are in that population.

So the appropriate validations would need to be done in order to show that testing's safe in that environment for that specific claim that a developer would make. But in the intervening period – and we're working with developers on this. In the intervening period, we are not objecting to use of testing in that situations. Using legally-authorized test, we can do that.

(Ms. Zimmer): Thank you.

Tim: Uh-huh.

Coordinator: Thank you. Our next question comes from (Bahla). Your line is open.

(Bahla): Hi. My question is about rapid anagen tests for home use by consumers, and you mentioned earlier in your monologue that you see value in a home-use test because it can be scaled to the millions and expand testing capacity.

So for such a home use, let's say, over-the-counter test, do you see the minimum performance requirements similar to what you had said before where you want 80 percent sensitivity versus a molecular test, and the associated specificity, which you didn't put a number on, but would be great to know.

Tim: Yeah. So I think I was mentioning a point-of-care testing, not specifically a home testing or home collection. The same performance expectations would be there in those environments. We've obviously authorized, you know, several home collection opportunities, both swabs and saliva.

And we look forward to more, and – but if a test is actually performed in the home, there are user studies, there are usability studies making sure their actions are correct, making sure that such a home user can get an accurate result. But the performance expectations are the same. For a direct-detection technology that would be 80 percent relative to a high sensitivity molecular assay.

And for serology it would be the same. It would be a minimum overall sensitivity of 90 percent and overall specificity minimum of at least 95 percent. It's sometimes a little bit more challenging to achieve those with an in-home test. However, we still want that test to be accurate even though it's in-home, so it does require a developer to carefully develop their test instructions so that performance at that level can be achieved, but yeah.

(Bahla): Of course. And as a quick follow-up, if the home test – if the usability studies are done to prove that in the hands of a lay-user we can achieve 80 percent sensitivity relative to a molecular test and, let's say, 95 specificity in this case for a rapid anagen test, would that test then be considered for home use, and would that still need a prescription to be delivered to the consumer.

Tim: So we are open to over-the-counter sale, so that's a great dialogue to have, and you can reach out through the template's email address. We mention lay-user, it's typically in the setting of a health-care setting, point-of-care setting, and a consumer home situation is a little bit different, and so the studies would be a little bit different, because you're using somebody in those studies – in that validation to prove accuracy that a patient in the home can get an accurate result relative to a clinician or a nurse in a CLIA-waived environment getting accurate results.

Those are two levels of backgrounds or training, and, therefore, different levels of evidence are required to show accuracy in those two settings. Of course, absolutely, but it's great to know that FDA is open to over-the-counter tests. Thank you.

Tim: Oh, yeah. Absolutely.

Coordinator: Thank you. Our next question comes from (Christy Burgeson). The line is open.

(Christie Burgeson): Hi, Tim Stenzel. We thank you so much for having these Townhalls. My question actually goes along really well with the one just asked. I was going to say now that home collection without observation is an option I was wondering if the prescription-only status was being forced to protect the supply of if consideration was given to waiving that requirement.

Tim: So – I'll take a stab at this. You know, the current tests are being authorized through Rx only, prescription, and that allows us some degree of mitigation of risks. When a clinician or an order – health-care professional order isn't plausible, the risks of false negatives or false positives for whatever kind of tests are mitigated when a health-care provider is involved and ordering and interpreting and explaining and determining, say, medical decisions being made off that testing. So we're totally open to different options.

Under the streamline EUA where we really required very minimal validation to rapidly expand testing, that was one of the mitigations we looked into. So if a developer wants to look into a different situation where a health-care provider is not involved that – we just want to look at how we mitigate any potential risks, and so that would be highly dependent on your technology.

These use – they use an interpretation the clear – when you have, you know, we understand their test results, it's clear to somebody what we would do with those results and how it impacts your healthcare.

So that's a great conversation to have, and it's going to depend a lot on the specifics, so reach out to the template's email address for that.

(Christie Burgeson:) Thank you.

Coordinator: Thank you. Our last question comes from (Mark). Your line is open. (Mark), your line is open. Our last question comes from (Sara Clark). Your line is open.

(Sara Clark): Hi, Tim. Thank you for taking my last question. It's my understanding that FDA will be issuing some guidance on VTM in the near future but currently

doesn't have anything out. I was wondering how a manufacturer who does not have a 510-K can get the product on the market as soon as possible.

Tim: Yeah. This is clearly an unmet need, providing VTM, and we've been taking inquiries at the template's email address and addressing them as (quickly as possible), and we are considering ways in which we can make this more broadly applicable, and I really can't say anything else at this point, other than to stay tuned, because this is a hot topic, and we hope to provide additional information in the not-to-distant future.

(Sara Clark): Okay. Thank you. I appreciate your time.

Tim: You're welcome. All right. That was the last question, I think. I want to follow up on a conversation that happened earlier on this call, and that is I do want to emphasize that we do work with all developers and all developers are treated fairly and equally, and we make decisions as fast as we can.

Our decisions are sometimes complicated, and they're all aimed at providing products that consumers and clinicians and health-care systems can rely on, and we're very open to new ideas.

I think as clearly expressed today and all previous Townhalls and some of the innovative approaches we have taken in this pandemic from looking at ways to really expand authorization for home collection and being open to home testing and open to over-the-counter, and so I just want to emphasize that.

There was a caller who mentioned a specific company, and it's publicly known that we have authorized tests already on April 3rd from Co-Diagnostics, and everybody gets a fair shake with us. That's absolutely how we roll. So with that, Irene, I turn it over to you.

Irene Aihie: Thank you, Tim. Thank you. This is Irene Aihie, and 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 Wednesday, May 27. 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 presentation, please complete a short 13-question survey about your FDA CDRH virtual Townhall 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.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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