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

Moderator: Irene Aihie
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Coordinator: Good afternoon and thank you for standing by. As a reminder, today's conference is being recorded. If you have any objections you may disconnect at this time. Your lines are on a listen-only mode until the question-and-answer session of today's conference. At that time you may press star followed by the number 1 to ask a question. Please unmute your phones and state your first and last name when prompted. It is now my pleasure to turn the conference 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 fourth in a series of virtual town hall meetings to help answer technical questions about the development and validation for tests for SARS-CoV-2 during the public health emergency.

Today Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in CDRH's Office of Product Evaluation and Quality will provide a brief update. Following his remarks we will open the line for your questions related to today's discussion. Now, I give you Timothy.

Timothy Stenzel: Good day. Welcome again to this town hall. Thanks to everyone involved in

responding to this pandemic. We are in this together and together we will see our way through it. We at the FDA as everyone else in our field are keenly interested in doing what we can to accelerate a return to normalcy.

I've witnessed amazing collaborations and sacrifices today to get to where we are today. And I know that additional collaborations and sacrifices will need to be made to get all the way through. So thank you so much for what has been done so far and thank you in advance for everything else that's going to happen.

My hat also goes off to the great staff here at the FDA. Our template email address, for example, has seen tens of thousands of emails to date and our backlog however of unresponded emails is incredibly small. Still, we are adding staff to even more quickly address questions.

Okay. Moving into updates. Yesterday we authorized five new EUAs including two serology essays, chem-bio and ortho-clinical. We also this week have authorized our first saliva EUA. I will address saliva in more detail in just a few moments.

Next, I would like to move into key safety messages. This may be as required a regular part of this town hall going forward. First up and these are going to be addressed in various ways either by manufacturers or on our FAQ page. We've heard about safety issues relating to the use of Guanidine containing transport media such as the prime store NPM with the Hologic Panther System. We advise against use of this transfer media as it can produce potentially toxic gas.

Second, for use and for specific about the Abbott ID Now Test. Abbott will be updating its labeling and instructions to remove the use of VTM with this test. The test works as intended with a direct simple use. Customers will be notified to not use VTM.

So we've heard of issues with VTM and appears to be primarily a delusional issue that reduces the sensitivity of the essay.

I will address potential issues like these going forward and how you can notify the FDA. Of course, you can always notify the manufacturer when you experience problems.

Okay. As I just mentioned we do want to hear about potential issues with test. Please use the online FDA MedWatch System. You can simply Google MedWatch (M-E-D-W-A-T-C-H). It's an easy online report. You will review these issues in a timely manner and address them as soon as we can.

Second, home collection. While we look forward to authorizing the first home collection we have not done so yet. I think there may be some media reports otherwise. But to date we have not authorized home collection but we do think that it's going to happen very soon in a number of different situations.

Home testing. Likewise, we have not authorized a home test and there may be some confusion out there. We look forward to authorizing the first home test and are actively working as with home collection with a number of developers.

Saliva. Saliva remains a very interesting sample type. Obviously relatively easy to collect. Doesn't require any use of a swab which is sometimes in short supply. To date we've only authorized one saliva collection device for use with this specific test. The performance was quite excellent and we were pleased to see that excellent performance and the comparison between either Nasopharyngeal and Oropharyngeal swabs and the saliva.

This was used at (Rikers) where they have a particular selection device for the

use in a health care setting under observation. As well as the (unintelligible) coupled to thermal fisher ATPCR reagent. So this is somewhat of a hybrid authorization.

To date we have seen otherwise quite variable results with saliva. We don't know exactly why. This could be a sample stability issue. But we clearly see that at least in one case this works. Whether this is a combination of particular devices or it's resulting from the use of a device that may stabilize the viral learning immediately. We do not - you had known yet.

But we look forward to authorizing additional saliva collection options for developers. So if you are interested in saliva we do want to see those as EUA submission. This is a new sample type and we want to make sure that we address the variables seen in some devices and some uses and can assure that quality results are achieved.

Serology. So we continue to seer problematic claims and uses of serology tests particularly those that have been listed on our FAQ page under Pathway D. These devices are only for high complexity labs. They are not to be used with moderate complexity labs or in point of care near patient settings nor in a home.

None of these have been - that are currently listed on our Web site have been authorized by the FDA except the three serology essays that I previously mentioned. We are looking for ways to additionally make this very transparent to as many people as possible.

Next on serology. Serology specificity is highly important as there are potential uses of the result of this testing we inform important decisions and specificity, in particular, is important.

False positives might lead somebody to believe that they are immune when they are not. Therefore there are significant risks in interpreting the results of the serology test.

We are looking for ways to additionally highlight these concerns and stay tuned.

I will just point out that even with a test that is highly specific if the prevalence of immune persons in a population is relatively low and we don't know the exact number right now or the percent of our population. Then the setting of an incredibly low prevalence even a very specific test can have a number of false positives and the positive predictive value is relatively low.

So again we will look for ways to further educate and inform all concerns about these issues so stay tuned.

Next I wanted to address some previous questions from last week and try to provide some more general clarity.

One question we had, have we authorized any tests molecular or serology for use with a deceased person? No, we haven't. Manufacturers should seek such authorization if they are going to address claims.

And that clear lab as I said last week they can validate this sample type if they so choose as long as it’s already a previously authorized for general use sample type. So we would also say that probably a nucleic acid test is collected soon after passing would be better than a serology. Obviously post mortem blood tests are challenging.

If there are samples - serology types sample - plasma serum it's available

immediately prior to death that was draw clinically, that may be a good sample type to use for such serology testing.

Next question was, will the FDA review quantitative serology tests? Yes, we will. Can we follow Pathway D? I would ask that you come and talk to us if you wish to follow Pathway D and you have a quantitative test claim.

Next question, are labs developing their own serology tests required to validate isotype? Through Pathway D labs simply can notify us once they have validated their serology test and a submission is not required. We do recommend that you do validate isotype if you are claiming and reporting results by isotype.

Next question is, can third party reviewers review EUAs? Unfortunately, no. Right now that is not a pathway that we are allowing and we would ask that EUAs come in through the FDA.

And finally, there was a question about what to do with serology tests that were authorized to allow through Pathway C or D prior to notification? You can reach out again to our templates email address.

Also I would like to make aware - all aware of our FDA fraud line or fraud email. If you have concerns about fraud or misrepresentation you can email us at FDA-COVIDBOVID-19-FRAUDULENT-PRODUCTS@FDA.HHS.GOV and that will - an email address will be in the transcript to follow.

Okay. At this point I have completed my preliminary remarks and I would ask to turn this over to Dr. Sara Brenner for some remarks and comments by her before we open the lines for questions and answers. Thank you.

Dr. Sara Brenner: Great. Thanks Timothy. I just wanted to follow up on a thread that was opened last week on collaboration with stakeholder communities. And I think those who did reach out who voiced questions on the line last week and then followed up with emails I have been able to have conversations with quite a few folks and brainstorm on how we can take a whole of the community approach to expanding testing and improving the quality of testing.

So I just wanted to again welcome folks to reach out whether you are from a university, academic medical center or laboratory or test developer. We're being very creative in terms of looking at ways that we can work together on this. Timothy mentioned in improving test quality, expanding our testing capacity across the U.S and also report and track the results that are coming forth.

So that's sort of a second topic under that umbrella that I wanted to mention that we're looking at quite intensively now and that is how to track data that has been reported from tests that are being performed at a both molecularly and increasingly serological so that we can gain a better understanding of prevalence of the disease and its clinical course over time in specific regions.

And I would envision that as sort of three different tiers of diagnostics. Data one, at the national level that's used by decision-makers who are making broad sweeping national decisions.

The second, level of granularity at the state or local level that will help local decision-makers.

And then a hyper-local or even individual clinician and patient-level set of information that includes things like comorbidities, other specific Electronic Health Record components for each patient that can help us better understand

how accurate the testing was and follow the patient's clinical course through time.

So we would be asking for your input, thoughts and collaboration on those aspects that help us harmonize data and use it clinically as well as understand from an epidemiological standpoint how the course of the pandemic is progressing and how that can inform good science-based and evidence-based decision making at every level.

The last topic that I want to mention which I think was mentioned before in these town halls is a community engagement strategy around manufacturing, makers and folks who are trying to contribute in different ways to supply - to address supply chain shortages.

One topic that we've been spending a lot of time on here in our office is 3D printed Naospharyngeal swabs. So that's just one example of a type of a product in the IDD pipeline that folks are trying to get creative around manufacturing or creating for local use.

So if you have those sort of thoughts, ideas or capacities that you are trying to build up and you are looking to engage with FDA for guidance and direction please go ahead and reach out to us.

So I'll stop there and turn it back over.

Timothy Stenzel: Thanks Sara. Okay. We can open it up for questions and answers.

Coordinator: Thank you sir. At this time if you would like to ask a question or if you do have any comments, please unmute your phones and state your first and last name when prompted by pressing star 1. Again that is star 1 for any questions or

comments...

((Crosstalk))

Coordinator: Our first question comes from (Grant Metler). You may go ahead, sir.

Brant: Thank you. That's Brant (B-R-A-N-T). Mr. Stenzel, yesterday a CNN report by Elizabeth Cohen as senior reporter said that I quote, "On March 16 the FDA loosened its standards and allowed companies to sell antibody tests without submitting any evidence that they worked." I hope that you can dispel that myth. But the article also talked about testing the products and I presume that's a serology product. Now I have previously enquired of the FDA about the Voluntary Submission Program which you mentioned last week. The response to my query was, here is a release form send 125 test kits. My question is, will you also publish the protocol - the testing protocol and how exactly the test kits are going to be tested? Thank you.

Timothy Stenzel: Thank you Brant. So to address your first question or comment, we through Pathway D we allowed test developers who had validated their test for the intended purpose reporting our IGM and IGG and or IGG or other serology endpoints that they could follow this pathway to certify to us and notify us that they had validated their test and that they could then receive confirmation from us and could market it in the U.S.

The requirement for this pathway is that these tests be validated properly and also that they attach the limitations - there is forming limitations and that these claims could not include sole use for diagnosis.

So there is obviously a standard here that must be adhered to. If that standard is not followed, if a developer has been transparent with us that would result in

potential consequences.

So the other important feature is that the formal EUA process is also to be followed - I mean it also can be followed and that is a fully EUA authorization pathway and for FDA EUA authorization.

In addition, the Pathway D notify develop - notification for developers they intend - these are intended for high complexity labs in that environment high complexity labs can assess whether or not these tests on their own their performance can be verified. So we believe that with all these controls that we can ensure that only accurate results are reported back to clinicians and patients.

Second, the Voluntary Testing Program that has been mentioned in multiple forums now by multiple officials is active and we invite all developers who have an appropriate device to come in.

If you have specific questions about testing protocols, those individual developers as they consider whether or not they want to be a part of this program can enquire for more detail.

At a high level we are trying to determine whether the results that come from these tests with patient samples can be relied upon and can have a level of accuracy that indicates that these are fit for use in the United States.

We also are looking at an alternate pathway for EUA authorization when participants have participated in the program and more details to follow. Thanks so much.

Coordinator: And thank you. As a reminder that is star 1 if you would like to ask a question. Please limit all questions to one question. Thank you. Our next question comes

from Alice Jones. You may go ahead.

Alice Jones: Good afternoon. Thank you. I wanted to ask a question about the requirement for the sterile scissors that's noted in several of the manufacturer's answers and or CDC Web site? So obviously I think the concern there is bacterial degradation of the RNA from a nonsterile cutting implement if you will. However, there is bacterial inherent in the sample collection process. So my question is truly the impact of using nonsterile scissors to cut the swab to be able to place it into the transport media.

Timothy Stenzel: Sure. So some media has obviously has inhibitors of growth of unintended organisms. Also overgrowth of unintended organisms can degrade the sample. So I would advise that where possible to follow the instructions as indicated and to the best of your ability. I think Id o realize that we are in real-world situations here and I would just ask you do your best to follow those instructions.

Alice Jones: Okay. Thank you very much.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. And our next question comes from (Peggy Magloplin). You may go ahead.

(Peggy Magloplin): Good morning or good afternoon. I actually have two questions. One for Dr. Stenzel and one for Sara. Dr. Stenzel, can you speak to the state allowances in regards to testing as opposed to the FDA allowances because that is very confusing for the general public. And Sara, you had mentioned if folks are working on activities that could assist in tracking et cetera to reach out to you, could you be more specific as to whom and what email should be used for that? Thank you.

Timothy Stenzel: Sara, do you want to start and I will finish?

Dr. Sara Brenner: Sure. Yes. So you can just email me sara (S-A-R-A).brenner B as in Blue - R-E-N-N-E-R@FDA.HHS.GOV and I look forward to answering any of your questions related to that going into more detail.

Timothy Stenzel: And (Peggy), you can call me Timothy. Yes, as far as state allowances go so we have allowed states to authorize LDT tests for labs within their state jurisdiction. This is limited to LDTs in high complexity laboratories. One such program is obviously well-established sort of program is New York State which has been reviewing LDTs for a number of years prior to - for labs in their state. So they are well experienced.

We have not specified how states decide how to authorize these high complexity LDT developed tests. We do leave that to the state.

Labs within those states are still allowed to come into the FDA for EUA authorization. There are certain situations where those are required such as home testing or home collection. Also the particular devices that might be used such as saliva collection we would - and new sample types that haven't been authorized prior to the FDA- previously by the FDA or where we see a broad generalized applicability of our sample type we would ask that they come in as well.

And we are also - I'm very open to working closely with each and every state that wants to do this and support their programs in any way we can to address any questions that we can.

So hopefully that further clarifies and potential issues there.

Coordinator: Thank you. And our next question comes from (Shawn Dowen). You may go ahead.

(Shawn Dowen): Hello. Could you please tell me what is the FDA's preferred coding language? What is the common medical oriented language (COMOL) as it were for medical devices or biomedical diagnostic devices?

Timothy Stenzel: (Shawn), I'm not sure I understand your question.

(Shawn Dowen): Should I be coding in C, THP, Python, Rubi, SQL?

Timothy Stenzel: Oh. Okay. Okay. Software coding. I don't believe we have a preferred method. We have a very experienced software review team and we are just looking for, you know, great software to be able to - and working with great software developers to address concerns. But to my knowledge we don't have a preferred platform.

(Shawn Dowen): In that case...

((Crosstalk))

Dr. Sara Brenner: (Shawn), this is Sara. If you want to follow up with me I can help route that question. One of the related interests that we have is data sharing and open EPIs and that sort of thing. So I would be happy to route that question if you want to reach out after the call.

(Shawn Dowen): Okay. What is your contact information, Sara?

Dr. Sara Brenner: It was as previously given my name sara.brenner@fda.hss.gov.

(Shawn Dowen): Okay. Thank you very much miss and to you too Timothy. Got it.

Coordinator: Thank you. And our next question comes from (John Norris). You may go ahead, sir.

(John Norris): Thank you. Hi Timothy and Sara. I'm a former Albert family member specializing in health policy and management and my course is sometimes assessed FDA health policy. In recent years actually since 1987 I have been an advocate around the world for fully-at-home infectious disease testing similar to devices used currently at home for diabetics to assess their blood sugar level.

Yesterday - excuse me, I published an open letter to the President advocating Fully-At-Home massive testing in the Coronavirus case. Excuse me. I intend to write you a letter today assessing or criticizing and supporting various aspects of current FDA policy related to fully-at-home testing. And I'm just saying this today because I hope you will take the letter in the spirit it's intended. Thank you.

Timothy Stenzel: Absolutely. We welcome all input and we take it all seriously. We are very interested in home collection and in home testing. And we are working with multiple parties and hope to authorize the first ones very, very shortly. So stay tuned.

Next question?

Coordinator: And our next question comes from (Shelly Fair). You may go ahead.

(Shelly Fair): Good afternoon and thank you for taking my call. I have a question in regards to quality systems and the quality program expected between an IDE and an

emergency use authorization. So the emergency use authorization guidance states that a quality system or parts of the quality system can be waived by FDA. However, IDE states that for a medical device development you should be following A20.30. So I just like clarity on do we need if we have a product in IDE study right now but the intent is to bring it forward as a emergency use authorization do we need to follow all of A20.30 or is there flexibility with the manufacturing especially when it coming through an academic institution?

Timothy Stenzel: Okay. Good question. I want to just repeat the question back. You want to know what are the IDE requirements when considering the EUA situation.

(Shelly Fair): That's correct because in some ways it seems as though to get a product or using a product with a IDE or brigaded IDE it's more stringent to follow all of A20.30 versus well, there could be complete flexibility or whatever level of flexibility when it's emergency use authorization. I would just like clarity as to what happens if we have a manufacturer that cannot follow all of A20.30 but still we would like to move the product forward to an emergency use situation.

Timothy Stenzel: So we work on a high, you know, even prior to this emergency with a number of different entities that have significant risk devices that they require IDEs and, you know, that from academic institutions to RND organizations and obviously not just fully compliant IDT manufacturers. So we found a way to work with all. The primary concern for which they require an IDE are is there are significant risks involved and are those risks mitigated in any way.

So, you know, for those devices in this case with limited test where there might be significant risks and you can come to us through our templates email address - ERA templates email address and we will discuss with you whether or not an IDE may be required.

But for tests I could be wrong but I'm not sure that we've had a situation where that's been addressed. But - so you may have specific considerations that are specific to your development or intended development that maybe is best handled offline. But overall we want to do the right thing in regard to significant risk situations.

Coordinator: Thank you. And our next question comes from (Hanna Fish), you may go ahead.

(Hanna Fish): Hi. Thank you. I think this might have been addressed in an earlier question but I just wanted to get clarification with regard to the voluntary program with the NR agency review of the serologic test (unintelligible). Can you now elaborate on what that review process is and how that information is going to be made available to the public and what we can expect as far as review of complexity of those tests?

Timothy Stenzel: Sure. This is primarily intended for rapid serological tests. It is an interagency program that's designed to do testing with actual patient samples.

Voluntary program, we have yet to decide on how this - the result of this may be formally made public. We will, you know, situations work with individual developers on that.

The sort of regulatory review of any data that may come out of this is going to reside with the FDA. So if a sponsor would like to - test developer would like for the test results from this interagency collaboration to be used for a formal submission to the FDA that is going to be entirely possible and we'll work with - the FDA will work with those individual developers to determine how that would happen.

We are working on further announcing how that potential pathway so stay tuned that should be forthcoming in the not too distant future.

Coordinator: Thank you. And our next question comes from (Elizabeth Ora). You may go ahead.

(Elizabeth Ora): Hi. I was wondering, is there a process to remove tests authorized via EUA from the market if they are found to be ineffective or dangerous?

Timothy Stenzel: So there is a way to do that. We are fully are willing to deny an EUA authorization if on your review we cannot establish that there will be accurate testing. And if we determine that a test in the market is not performing I mentioned earlier the MedWatch we will first and foremost reach out to a developer and initiate conversation. And we will together try to find the best way forward to ensure that there is accurate testing available.

At the beginning at the top of the call I mentioned an update about the Abbott ID Now, this exact pathway was followed. We had a conversation with the developer and together we decided, you know, we make decisions together on collaborative beyond on the best pathway forward. So that is our traditional way of handling these sorts of situations. We always first want to engage the developer to understand what the performance issues might be to try to understand what the root causes if there are in these performance issues. What the solution to those issues might be and what is the best way to address that as quickly as possible so that - for the benefit of the public health.

Hopefully, that addressed your question.

Coordinator: Thank you. And our next question comes from (Paul Barto). You may go ahead, sir.

(Paul Barto): Yes. Good afternoon. This is (Paul Barto) calling in from McKesson. Thank you for taking my call. Really, it's kind of a two-part question. So the first part is, I'm interested to understand how the FDA is considering a long term authorization for serology tests. So really once emergency use authorization is listed and the 510K rules are applied.

And the second question is, for these serology tests, are you anticipating them to be used in a professional environment with point of care designation so with the equivalence of a clear waiver?

Timothy Stenzel: Yes. Yes. That was a great question. So first of all the long term authorization, so I do not personally foresee this emergency declaration going away any time soon or we are talking at least years. Where a potential market situation may occur is if a developer comes in for full FDA authorization whether that's De Novo or some other pathway and gets authorized. The EUA law allows for other similar devices to no longer be covered by the UA. This is only done very carefully though because we always want to assure there is plenty availability of test in the market as perhaps, you know, a single manufacturer though performance may be excellent we want to address market access to everyone to ensure that adequate volumes and number of tests can still be performed.

So those decisions are made extremely carefully and the benefit risk of what we do is always addressed and we always air on the side of ensuring adequate availability of testing.

Second is, the use of serology tests in the professional environment i.e your patient testing point of care came to a clear waiver. We have the ability to when we authorize an EUA or a test that's amenable for use in these settings to sole deem it through language in the authorization. CMS has generously agreed to

allow this process to occur. We are under the (unintelligible) any authorized test. We have provided a designation - a letter designation H for High, M for Moderate and W for Clear Waived or deemed clear waived in this case other than high complexity. And we are very open to reviewing tests for this.

Tests that come solely through the notification process of Pathway D are not available for this deeming. We can only deem when we are able to review and authorize the test through one of the existing for an EUA authorization pathway.

So hopefully I addressed your questions.

Coordinator: Thank you. And our next question comes from (Steve Sjkags). You may go ahead, sir. (Steve Stags), your line is open.

(Steven Stags): Hi. Good afternoon. Sorry about that.

Timothy Stenzel: Hi Steve. How are you?

(Steve Skags): Good. Thank you very much for this. I appreciate your taking the time to answer these questions. I had a follow up from last week that I haven't seen in the FAQs or I just missed it. We spoke about the co-validation effort being made that was happening with some or was planning to happen with some partnerships that the FDA was forging for serology tests particularly I think under policy D. I have not been able to find anything else out about that and I was curious if that was either still in the works setting it up or if I have just missed it.

Timothy Stemnzel: No. We have not made any formal announcements. We have reached out to all developers that have or should have - to all developers that have notified us

through Pathway D to invite them in to be participants in this. We have begun receiving test kits from at least some of these developers and we believe testing will begin in the very near future. And as soon as we can find a way to report results either through an EUA authorization or other means we will make that available. We also are working on a way to let the community know more about the details of this program.

But for now, we invite developers who want to be a part of this to send us an email at CDRH-EUA-TEMPLATES email address and we will connect you with the program and you can get all the details from them directly.

Coordinator: Thank you. And our next question comes from (unintelligible). You may go ahead, sir.

Man 1: Thank you for taking my question. Is the FDA or any other government agency providing a reference style for serology testing or maybe (unintelligible) development materials that can be used so what is the FDA or government doing to help serology essay developers in this particular case?

Timothy Stenzel: So to my knowledge such panels are not yet available. We have engaged with multiple parties to try to stimulate the development of these panels. We know that several commercial entities are looking into collecting patient specimens in the effort to address this need. We - as soon as such material is available for test development, validation and verification we will endeavor to make that publicly known on our FAQ page. But at the moment I believe they are still in development.

Coordinator: Thank you. And our next question comes from (Kassim Aleikum). You may go ahead, sir.

(Kassim Aleikum): Yes. Hi. Thank you for giving me the opportunity of asking the question. I believe my question was just answered while (Paul) raised the question of the active 510k and the pathway for the point of care testing.

Timothy Stenzel: Okay. Any follow up questions.

(Kassim Aleikum): All right. Thank you. A follow-up question, yes, I was just discussing about this with our templates as well. When a company is filing for a serology E way under the section C what type of clinical performance study is required and is an IRB approval required for the clinical study if the specimens taken are retrospective study?

Timothy Stenzel: So we are working on templates for serology and we hope to make them available as soon as possible. You can - if you are interested in what our thoughts are about serology development and validation you can email us at the template email address and we can provide you with a draft document that we are working on or that we have already worked on. And also address any direct questions or follow up questions you have about that.

I'm sorry, what was the second part of your question?

(Kassim Aleikum): Is an IRB approval required when doing a clinical performance study?

Timothy Stenzel: So an interesting question. So I don't know that this is entirely within the FDA purview. First of all, I would address any questions with your IRB about whether IRB is required or, you know, if you are using residual de-identified clinical specimens whether a waiver of consent is required from your IRB. I think those your best - questions best handled by local IRBs.

I would say that traditionally when a commercial test developer develops a test

and is going to use such leftover patient material that getting an IRB authorization for the use in development of commercial products is at the very least wise.

(Kassim Aleikum): Okay. Thank you.

Coordinator: Thank you. And our next question comes from (Susan Sharp). You may go ahead.

(Susan Sharp): Sara and Timothy thanks both of you and your team at the FDA for everything you are doing to help us navigate through this crisis. Sara, this question is for you about the 3D printed swabs. Has the FDA decided for these swabs if they are going to be need to be made under GMP and have biocompatibility studies done before they are being able to be used in the population? Thank you.

Dr. Sara Brenner: Yes. Great question. And I think the answer that we're coming to is, yes. Yes for GMP sterilization and biocompatibility. We are actually working on an internal document to address other concerns with regards to the 3D printed swabs but that one is one that I think we are coming close to settling on.

(Susan Sharp): And will that information be up on the FAQ when those decisions are made?

Dr. Sara Brenner: I'm not if it' will be FAQs or how we will communicate that but certainly we will find channels. If you want to shoot me an email just so I can make sure to follow up with you specifically as soon as we're ready to release information I can do that.

(Susan Sharp): Thank you so much.

Dr. Sara Brenner: You bet.

Coordinator: Thank you. And our next question comes from (Maryanna Pegner). You may go ahead.

(Maryanna Pegner): Good morning and thank you for holding these town halls. My question is related to the availability of a template document. The one available for manufacturers on the FAQ page right now refers specifically to a molecular method. Are there other templates, other developments and when might we be able to see them?

Timothy Stenzel: So great question. We are finalizing templates for serology at this moment and we'll put them on our Web site as soon as possible. In the interim, you can shoot us an email ar cdrh-EUA-templates and you can get a draft recommended validation protocol.

Coordinator: Thank you. And our next question comes from (Jane Aya). You may go ahead.

(Jane Aya): Hi. Thank you so much. My question is for Dr. Brenner again related to the 3D printed Nasopharyngeal swabs. I'm wondering if there are any published FDA guidance or standards documents that are relevant specifically to the design and manufacturing of Nasopharyngeal swabs.

Dr. Sara Brenner: Yes. That's a great question and that's sort of what we are working on now. We are doing sort of a scientific structuring of what our recommendations would look like and the different to consider that will then go through policy, regulatory and legal review. So in terms of guidelines we do not have any that are public-facing yet at this point and we are aware that there are several different scenarios by which a 3D printed Nasopharyngeal swab, for example, might be created including the entities who are involved in the designing of more of the software side, those who are actually in the manufacturing world

either in a small way for local distribution or distribution with another institution. And then potentially commercial entities who would be producing at high volumes and distributing. So each of those entities will have some responsibility.

But on the design side that you asked about we are trying to figure out what the role of us and our collaborators and partners for example through the MOU with NIH and VA and American Mates would be with regards to helping to vet the designs themselves. So stay tuned for information forthcoming on that. And if you would like to email me directly please do and we can keep you looped in as that conversation evolves.

Coordinator: Thank you. Our next question comes from (Harry Davity). You may go ahead, sir.

(Harry Davity): Thank you Timothy and Sara for all the work you guys are doing. My question has been answered. Thank you.

Timothy Stenzel: You're welcome.

Coordinator: Thank you. And our next question comes from (Jennifer Stockmann). You may go ahead.

(Jennifer Stockmann): Hi. Thank you. I have a question about your initial remarks regarding potential safety concerns with the prime store tube as well as the use on the Hologic Panther System. I was wondering if you could provide more elaboration on there as well as is there any documented guidance with regard to this product and additionally what the findings were?

Timothy Stenzel: Yes. So we're going to update our FAQ page with a warning. It turns out that

there us bleach used in the process in the Hologic Panther System and bleach in combination with Guanidine can produce cyanide gas.

(Jennifer Stockmann): And then is that interaction specifically between that product and that test only?

Timothy Stenzel: That is the only one that we are currently aware of. We are looking across all authorized manufacturers to see if we need to update that. So that's our existing up to date knowledge as of today.

(Jennifer Stockmann): Thank you.

Coordinator: Thank you. And our last question comes from (Brianna Hawkins). You may go ahead.

(Brianna Hawkins): Hi. Thank you for taking my call and my question. My question is do you anticipate having a template specific for rapid imaging detection test i.e lateral flow essays or detection of virus?

Timothy Stenzel: Yes. That's a great question. So we're spending a lot of time right now on working with developers of serology test and that's the current wave of new development. We see that rapid imaging direct detection lateral flow rather point of care type tests are going to be coming soon and we've already begun working on to find a lead on developing the template for that category of tests.

Coordinator: And thank you. I would now like to turn the conference 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 Monday, April 20. 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 town hall experience. The survey can be found at fda.gov/cdrhwebinar immediately following the conclusion of today's live discussion.

Again thank you for participating. This concludes today's discussion.

Coordinator: Thank you for participating on today's conference call. You may go ahead and disconnect at this time.

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