CENTERS FOR DISEASE CONTROL AND PREVENTION
Moderator: Chris Motsek
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2:00 pm EDT

Operator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. At the end of today's presentation, we will conduct a question and answer session. To ask a question please press star one. Today's conference is being recorded.

If you have any objections, you may disconnect at this time. I would now like to turn the meeting over to Mr. Chris Motsek with the CDC - Deputy Lead for the State Coordination Task Force. Sir, you may begin.

Chris Motsek: Thank you. Good afternoon, good morning, good evening, depending on your time zone. This is Chris Motsek, the State Coordination Task Force Deputy. Welcome to Sustaining the Zika Response in 2017 Blood Safety National Webinar.

Invited participants include state health officers, state, local, and territorial preparedness directors, epidemiologists, laboratory staff, and anyone who participates in Zika-related activities within their jurisdictions, and other staff with Zika-related expertise. We are aware that the invite has been shared with your constituents or other appropriate parties of interest. However, if you represent the media or press we, are going to ask that you please disconnect at this time.

Today's discussion has been structured for public health participation. The intent of today's webinar is to provide a blood safety overview presentation on the following Zika preparedness and response activities. A functional two-way

discussion will follow. Following this webinar, one remaining session will follow this afternoon - that is the medical investigations team, which is scheduled from 3:30 to 4:30 Eastern Daylight Time.

Please keep in mind we will continue to update our guidance as we learn more through research. After today's question and answer segment - if you have additional questions, please feel free to email us at preparedness@CDC.gov. That's preparedness@CDC.gov.

Today Koo Chung will be the subject matter expert representing the Blood Safety Task Force. Koo is a health scientist with the Blood, Organ, and Other Tissues Safety Office within the Division of Healthcare Quality Promotion. He's been with the BOOTS office for six years and has been working on the Zika response Blood Safety Task Force since June 2016. Koo.

Koo Chung: Good morning, good afternoon. Again, my name's Koo Chung with the Blood Safety Task Force, and today we'll be discussing a little of information about the Blood Safety Task Force and our response in 2017. Next slide.

So again, I'll be discussing a little bit of Zika virus background. I'll probably move through these slides pretty quickly. But once we get to the bulk of the blood safety content - which is the background on blood organ and tissue collection screening as well as blood donor screening - we'll take a deeper dive there. And at the end we'll also have a Q and A session.

Joined with us today during the Q and A session are a representative from Roche and Grifols who are the IMD holders for Zika. Next slide.
So again, a little background on Zika virus. Next slide. Okay. So you know - as we know, Zika's spread primarily through *aegypti* and *albopictus*. Many people infected with Zika won't develop any symptoms or have very mild

symptoms. And Zika is particularly important during pregnancy because of its cause of microcephaly and other severe brain defects. Next slide.

So before 2015, Zika outbreaks occurred in Africa, Southeast Asia, and the Pacific Islands. And currently, outbreaks are occurring in many other countries and territories. This map you see to the right - the URL will take you to this map - is an interactive, is a new interactive map of areas at risk for Zika virus.

You can scroll your mouse over these areas and more information will be available about that country. I highly recommend that you guys visit this new map. It's pretty good. Next slide. So this is Zika virus in the US as of March 2017. Again, the URL at the bottom. This map is updated on a weekly basis at that web address and includes information about the number of Zika virus diseases reported by state. The darker colors obviously meaning more cases than the lighter colored ones.

I'd like to point your attention to the Puerto Rico map; the Puerto Rico island which is dashed. There is widespread - which includes a widespread local vector-borne transmission. And if you look at the very tip of Florida as well as the southern tip of Texas you'll see a hashed little area. These are limited local vector-borne transmissions that are occurring in the continental United States. Next slide.

So as we know Zika is spread through mosquito bites. And you know, the most important bullet on this slide is that Zika may be spread through blood transfusions. And there have been reported cases of blood transfusion transmitted Zika virus through platelet transfusions in Brazil. Next slide.

Again, some more information about the mosquitoes. You know, important to note here are that they live in and live in and around homes, as well as they're aggressive day and night time biters, which is different from other mosquito vectors. Next slide. These two maps represent the estimated ranges for *albopictus* and *aegypti*. *Aegypti* being in blue and *albopictu*s in green. So these maps have been updated from a variety of sources that CDC collects.

And these maps represent our best estimate of the potential range of *aegypti* and *albopictus*. These maps are not meant to represent risk for the spread of disease. Again at the bottom of the page is where you can find these maps on our website. Next slide.

So Zika clinically - the clinical presentations of Zika like we - I mentioned earlier - are usually very mild. But some of the most common symptoms are fever, rash, arthritis, conjunctivitis, and other symptoms such as muscle pain and headache have also been reported. Fatalities are incredibly rare, and severe diseases also are pretty uncommon. Next slide.

So, other modes of transmission; obviously it's been heavily reported that Zika can be transmitted sexually but - as I mentioned previously - through blood transfusions as well. It's possible for transmission through breast milk and organ and tissue transplantation as well. Next slide.

So now I'm going to go into a little more detail about blood, organ, and tissue collection and screening. Next slide. So we'll begin with a little bit of background into blood, organs, and tissues. Not everybody's incredibly familiar with these products. So for blood - blood can be collected in two separate ways - either as whole blood or as apheresis.

Whole blood is what you would think of when you go to a blood center and, you know, you donate a pint of blood. Apheresis is where they collect a specific component of your blood and return the rest of it to your body. This - the whole blood can then be spun down into separate product types as well, for example, red cells, platelets, and plasma. Whereas, for example, in apheresis, we specifically only collect red cells, or platelets, or plasma and return the other components back to the body.

Screening for blood has been conducted for - well - for hepatitis B and C, HIV, HTLV, Syphilis, West Nile virus, and now Zika. Next. So human cells, tissues, cellular, and tissue-based products - or HCT/Ps are products such are corneas, bone, skin, heart valves, HPCs, reproductive tissues, and others. Generally, we just call these tissues - just to make it a little bit easier. And very similarly to blood, screening for these products are hepatitis B and C, HIV, HTLV, Syphilis, CMV, chlamydia, and gonorrhea.

And of note, Zika is not included for screening in tissue. Currently there are no screening assays available for screening or testing tissue products. Solid organs are products such as kidneys, hearts, livers, and so on and so forth. Next slide.

So specifically related to blood safety, there have been no reported Zika virus transfusion-transmitted cases in the United States. But, as I previously stated, there have been probable Zika virus transmission cases in Brazil. The US FDA issued industry guidance in February 2016 and revised these guidance in August 2016.

The revised guidance states that blood collection centers in all states and US territories should perform Zika screening on all donations using a screening test authorized for use under an FDA investigational new drug - or IND

application, or with a licensed test when it's available; or use an FDA-approved-pathogen-reduction device for plasma and certain platelet products. You can find detailed, the full guidance, at the links below. Next slide.

So this is a screenshots of our blood and tissue safety website. Here we have some very basic information about what we know about Zika virus and about blood screening and Zika. And at the top of the page you see two grey boxes: blood and tissue collection centers and areas at risk.

The Blood and Tissue Collection Centers box will lead you to a page where there are links to several guidances and other information related to and useful for blood and tissue centers. And the Areas at Risk page takes you to a page where we designate, for the purposes of blood and tissue safety intervention, areas at risk for Zika virus. That website, the web address is provided below. Next slide.

So again, once you click that Areas at Risk button, it takes you to this page. So the areas listed under Areas of Active Transmission in the US can defer from those issued for travel guidances because of additional concerns about potential risk for blood and tissue safety. So if you look about halfway down that page, there's Areas of Active Transmission in the United States.

And then just below that, you'll find the following are areas of active transmission of Zika virus in the continental United States for the purposes of blood and tissue safety intervention. And under that, we list Miami-Dade County and Cameron County in Texas as areas of potential active transmission for the purposes of blood and tissue safety. You can find this website directly at that link posted below. Next slide.

So where we showed you the map previously for the continental United States with the color gradient depicting the intensity or the number of cases by state, just under that map is this table that defines local laboratory-confirmed symptomatic disease cases and presumptive viremic donors reported to ArboNET by states and territories. This is also updated on a weekly basis, and this is updated as of March 22, 2017.

As we can see, symptomatic disease cases in the United States have reached 5,158 cases, whereas presumptive viremic donors in the United States have reached 43. We break these down by state as well. So you can see that Florida has reported 26 cases of presumptive viremic blood donors, whereas they have reported 1,109 symptomatic disease cases. Again, you can find this table at the web link below. Next slide.

So for tissue safety, currently tissue screening is not available outside of research settings. Tissue donors are screened for Zika factors. Tissue donors are screened for Zika - for risk factors for Zika virus using questions that include residence in and travel to areas of active transmission. You can find more recommendations regarding recommendations for living donors and for non-heart beating/cadaveric donors in FDA's March 2016 guidance. You can find the full guidance at the link below. You can also find this information on our website. Next slide.

So for organ safety -no Zika guidance has been issued by the Health Resources and Services Administration, or HRSA, who oversees organs. But the Organ Procurement and Transplantation Network, or OPTN, issued a statement on Zika virus in July 2016. You can find details about that July 2016 statement at the address, at the web address below. For questions specifically related to organ safety, please contact our functional box at eocevent281@CDC.gov. Next slide.

So, now we're going to dive a little bit deeper into blood donor screening. Next slide. So this - so FDA authorized two INDs, or investigational new drug applications, for screening donated blood. The first being Roche Molecular Systems, also known as the cobas Zika test. It was authorized for use on March 30, 2016, and it began with screening donations in Puerto Rico, and now includes continental United States as well. The 'cobas Zika test'- I just simply call it the Roche test - is for individual donation testing only.

The Grifols Diagnostic Solutions, Inc has the Procleix Zika virus assay test. This was authorized for use on June 20, 2016. Focusing on Southern United States, which now also includes all donations from CONUS as well, . The Grifols test uses a combination of pools: 16 donations in a pool and individual donation testing. However, pool screening was discontinued as of December 11, 2016. Next slide.

We're going to get into a little bit more about the testing algorithms for the cobas or Roche assay. So here I've created a little flow through, a flow diagram, to help describe the cobas Zika test. So when a donor comes in to donate, a sample is collected and that sample is then screened using the cobas Zika test.

If that cobas Zika test is reactive, that same sample that is collected is repeated on cobas twice as well as a simulated mini-pool, where that sample is diluted one to six and re-run on the Zika cobas test. Simultaneously, that sample is shipped to BSRI, or Blood System Research Institute in San Francisco, where confirmatory testing is performed.

The confirmatory testing includes the CDC Trioplex NAT assay as well as the CDC MAC-ELISA, which includes IgM and IgG serology. Next slide.

So for the first follow up, which a sample is collected, usually within two weeks of the index donation, the sample is collected. The cobas Zika test is re-run. But in this scenario, during the first follow-up, the repeat cobas Zika test times two as well as the simulated mini-pool are not performed. However, the sample is shipped to BSRI for confirmatory testing using the CDC Trioplex as well as the CDC MAC-ELISA. Next slide.

So on second follow up, samples are collected within two to eight weeks after the index donation. Again similarly, once the sample is collected, the cobas Zika test is performed. A repeat cobas times two and the simulated mini-pool are not performed, however that sample is shipped to BSRI for confirmatory testing - again the CDC Trioplex and the MAC-ELISA. Next slide.

So these are examples of how this cobas Zika test might look for a donor. So for example, let's start with donor number one, which was tested at lab A. The cobas Zika repeat tests were nonreactive. These are all assuming that these were - the index donation was reactive.

So, let's say donor one sample was collected. The index donation tested reactive for cobas Zika. It's then the repeat tests are performed, and those are nonreactive on both repeats. The simulated mini-pool is also non-reactive, and the CDC Trioplex, or the alternative NAT is also non-reactive; and the Zika MAC-ELISA, IgM, and IgG also - are also nonreactive. In that scenario, so, donor number one would be considered a false positive according to the testing algorithm.

So let's move down the list a little bit and look at, for example, donor number three. So again, this donor tested index reactive at lab C. The repeat tests

were both reactive. The simulated mini-pool was also reactive. The alternative NAT was reactive; IgM was equivocal and IgG was positive.

In this scenario, we would consider donor number three a confirmed positive Zika donor. So through the rest of this table, all of the bold donors are donors where these would be considered confirmed positive donations. Next slide.

This map represents testing laboratories in the United States that are currently using the cobas Zika test. As you can see, it's widely distributed across the United States. And all of the ones that you see on the right hand side that say - the purple stars rather - the ones that say on or before 11/18, all of these blood centers are now using the cobas Zika test within their blood centers. Next slide.

Next, we're going to get into a little bit more with the Grifols donor screening assay. Next slide. So this - for an index donation very similarly - a donor comes in to donate, a sample is collected, and the Procleix Zika virus assay is performed.

At the same time, that's a sample that was collected would be repeated for/on the Procleix Zika virus assay either twice or in triplicate. That sample would then be shipped to BSRI or Wadsworth depending on the collection agency, and confirmatory testing will be performed on that sample as well.

So, confirmatory testing under the Procleix assay is the CDC Trioplex on red cells, the CDC MAC-ELISA - IgM and IgG. And, if IgM positive on the MAC-ELISA, neutralizing antibody testing is also performed. And lastly, the CDC Trioplex assay is also performed on plasma.

So the difference here is that, you know, some blood centers will only do the Procleix Zika virus assay in duplicate, and some will do it in triplicate, and that just depends on the blood center that the donor donated at. Okay. Next slide.

So, the first follow-up is collected approximately seven days after the index donation. And once that sample is collected, the Procleix Zika assay is run again, but the repeat assays are not performed on follow-ups. Instead, that sample is then shipped to BSRI or Wadsworth, and confirmatory testing is performed. So that would be again the CDC Trioplex on red cells and plasma, as well as the MAC-ELISA and, again if IgM positive, neutralizing antibodies testing will also be performed. Next slide.

Additional follow ups for the Procleix assays is a little bit different from the Roche, so approximately every week until the donor is Zika nonreactive, and IgM positive confirmed or neutralizing antibody and/or IgG seroconversion, or NAT and serology results are nonreactive. So for additional follow ups for the Hologic/the Grifols assay, again, the repeats are not performed. But the confirmatory testing is performed, and samples are collected every week until these criteria are met. Next slide.

So here are examples - are what test results would look like for the Grifols assay. And again, all of these donors are donors that were index positive for or reactive for the Zika assay. So for example, donor one was reactive on the Zika assay as well as alt NAT or Trioplex assay reactive, serology nonreactive., and on follow-up was either Procleix, alt NAT, and/or serology nonreactive.

In this scenario, this donor, because of the alternatives NATs reactive result, would be considered a confirmed positive. Moving down the list a little bit,

let's look at number 3. So in this scenario, it was index Zika virus assay reactive, alt NAT nonreactive, serology nonreactive, and follow-up samples were all nonreactive. So the only reactive result that we have was that index donation. In this scenario, we would consider this donor a false positive.

And again, let's go through one more here. Let's look at donor number six. So donor number six was reactive on the index donation for the IND assay, nonreactive on the alternative NAT, and serology - for some reason - was missing on this donor. However, the follow-up sample was reactive for either the Zika assay, the alternative NAT, and/or the serology. In this scenario, this blood donor would be reactive. Again, the bold ones are confirmed positives and the non-bolded ones are false positives. Next slide.

So these are all of the testing sites that are currently using the Grifols assay and when they were on-boarded. So please take a look at this list. And there may be - so other states may be sending - or other blood centers may be sending their samples to any one of these blood centers or testing laboratories for Zika screening. Next slide.

So here's some key messages that I wanted to convey to you guys before we move into the question and answers. So blood donor screening is now occurring nationwide through these two assays. State health departments and blood centers or blood banks should be - should ensure that procedures are in place for sharing information regardless. I'm sorry regarding positive blood donors.

Good examples of blood centers in - and states that have been working very closely together are, for example: Florida Department of Health has a very good relationship with OneBlood, one of the largest collectors in Florida, and Texas has a really great relationship with Gulf Coast Regional Blood Center.

So if you wanted to reach out to Florida and/or Texas to see how they've developed their relationship with the blood centers, please let me know and I can share out my contacts within the state health departments to get you guys connected.

Blood donation screening may help public health identify new areas of transmission. So this is why we think that conveying or having strong communication with state health department is important, so that the states have all of the information necessary to make determinations like this.

Next. Presumptive viremic donors should be reported to ArboNET, and with our folks in Fort Collins we've updated the ArboNET instructions for reporting blood donors. And this updated instruction was distributed by CSTE. If you have not received these updated instructions, please feel free to reach out to us at that email address, eocevent281@CDC.gov.

Again, tissue donor screening is not currently included under any of these INDs, so just keep that in mind. And state health departments and tissue banks should strengthen communication regarding Zika virus in tissue donations. Even though, in the absence of screening - in the event that screening does become available, I think it would be a really good idea for states and tissue banks to be beginning to develop this - these relationships - now so that there's a smoother transition in the future.

And very lastly, all of this information that we just discussed are available on our website. And more specifically, there is an investigational toolkit for transfusion transmitted infections at our website that could be very helpful for states that may have to do transfusion transmitted investigation. Next slide.

So that's the end of our presentation, and I think we could go ahead and open it up for questions. And again we do have a representative from both Roche and Grifols on the line with us to help answer specific questions regarding their assays.

Operator: At this time, if you would like to ask a question please press star 1. Please unmute your phone and record your first and last name clearly when prompted. Your name is required to introduce your question.

To withdraw your question, you may press star 2. Once again, at this time if you would like to ask a question please press star 1. One moment please for our first question. Our first question is from (Ben Chan). Your line is open.

(Ben Chan): Thanks for taking my question. I'm wondering if you can comment or are knowledgeable about whether or not there's a plan to update the tissue and solid organ transplant guidelines around Zika?

You know, right now it's, I believe it's just, if there's been any travel in the last six months, you defer the donation. But it seems like there's a role for, you know - again, I know that's there's no (turnability)to test tissue or solid organs for Zika. But it seems like there may be a role for clinical decision making here around the risks and the benefits, and whether or not there may be a possibility to test the donor - the donor's blood for example, for - you know, PCR antibodies as a way to try and stratify risk; to have these clinical conversations and decisions around the risks and the benefits of solid organ donation.

Koo Chung: Sure (Ben) thanks for that question. So I'm, this is Koo by the way, so I'm going to go ahead and try and dissect this question a little bit. So first I'm going to start with the tissue screen - the tissue guidance.

So the tissue guidance, which was provided by FDA - and I believe the guidance you're talking about is the latest one that they have which is from March 2016 - and related to that, I can't speak to FDA about when they may update that guidance. But you know, you could definitely reach out to FDA to ask that question. But we don't know any information about when they may be updating that guidance.

And point taken. We do understand that there could be some value in, maybe - you know, the blood screening - using the blood screening assays for the purposes of tissue screening. But again that's not currently available. As far as organ, a solid organ screening, that's actually under the purview of HRSA. And I would recommend that you reach out to HRSA related to screening of solid organs. I hope that answered your question, (Ben).

(Ben Chan): Yes, thank you. I was just wondering if you had any updated information on that, but it sounds like I need to reach out to those organizations individually. So thank you.

Koo Chung: Yes.

Operator: I'm currently showing no further questions. I would like to remind participants if you would like to ask a question at this time to please press star 1.

((Crosstalk))

Man: Can't read that.

Chris Motsek: We have a question coming from a (Debbie Freeman). It says when confirmatory testing is done, at BSRI in California or Wadsworth in New York, do they report those confirmatory results back to the state of Oregon? If so, what is the turnaround time on this?

Koo Chung: Sure. (Debbie) thanks for that question. This is Koo again. And so again, I'm going to repeat that question. When confirmatory testing is done at BSRI in California or Wadsworth in New York, do they report those confirmatory results back to the state of origin?

So Wadsworth and/or BSRI should report those and will report those results - the confirmatory results --back to the blood center. The blood center should then report that back to the state. Now every state has different laws for how reporting is done within their state, so we would have to defer to the states themselves. But that information is most definitely reaching the blood center.

The second part of that question for (Debbie) was - if so, what is the turnaround time on this? That varies widely but I've, generally speaking, have seen results come back within 2 to 3 weeks for the confirmatory testing, but again, that does vary. That's on average from the top of my memory what I can think about how long it takes for results to get back. Maybe our folks from Grifols or Roche could also potentially have input on that?

Lisa Pate: Yes, this is Lisa Pate from Roche. And so, the results are reported back to the testing laboratories which also report them to the blood centers. And I believe the testing laboratories in most states are the entity obligated to report reactive results to the state testing labs.

But because Zika is different and because, you know, time is sort of, of the essence - if you think you may have a vector concern or vector problem in a

location, we actually ask the blood testing laboratories to notify us within 24 hours. If there is a reactive donation, and we then report that information to both CDC and FDA who are, you know, very interested in monitoring the situation - and they may reach out to you.

So, there's kind of a different pathway for Zika than there is for HIV or HCV, for example, where intervening, you know, with a mosquito isn't really the problem. So you may get information sooner than later. We try to do that. It's worked very well in Florida and Texas as well, and we hope that it will also serve other states as, you know, as cases pop up during the spring and summer.

Operator: And we have a question on the line from (Leah Colton). Your line is open.

(Leah Colton): Hi, my question regards the number of presumptive viremic donors that have been identified in the United States. First of all, do we have an estimate for the denominator for that value? And second of all, of those 40- however many - those were for the total United States that were identified, have they all been confirmed in the manner that you described?

Koo Chung: So this is Koo again. So you're speaking of the presumptives. So of the 43 what is the denominator for the 43, and also, if these 43 have been confirmed using the processes that I've laid out today?

(Leah Colton): That's correct.

Koo Chung: Okay, so to your first question, what is the denominator of these 43? That's kind of difficult to answer, but every blood center in the United States should be screening their blood for Zika virus. So these numbers should vary to the line - vary closely with what's - numbers of - total number of transfusions that

have been reported in, for example, the National Blood Collection and Utilization Survey that's been reported through by CDC.

To your second question, have these presumptive viremic blood donors been, I guess, vetted through these algorithms? That's also a pretty difficult question to answer, but generally speaking -yes. There are some states that are using the test results - the results that are provided by the INDs - to help make their determination as to whether a donor is viremic, and whether that is a confirmed positive. But there are also other states that are using their own laboratory screening and collecting their own samples to make that determination as well.

(Leah Colton): Thank you.

Koo Chung: Sure. There was also a question again from (Debbie Freeman) again. She asks, is that reported via the AABB Biovigilance Network within the 24-hour period? So I guess it's important for me to separate this here.

The AABB Biovigilance Network is separate from the ArboNET reporting and from other reporting that's being done by Roche and Hologic as well as CDC. AABB has asked their blood centers to participate in this, their biovigilance Zika network. But I believe that is a voluntary reporting system. So I can't speak too much to that. Thank you again for the question (Debbie).

Operator: I'm currently showing no further questions on the phone line. I would like to remind participants if you would like to ask a question to press star one. All right and we do have another question. One moment please. Our question is from (Wendy Webbly), your line is open.

(Wendy Webbly): Hi, I have a question regarding some results we received today. They're a little bit different than the original results that we had been receiving. Before we would receive the reactive, and these particular results came in as NAT positive.

Is it still just the screening test or, when they come back as NAT positive, have they been vetted and we're not seeing all of the vetting like we used to?

Koo Chung: Hi, this is Koo Chung again. So I think I just got this question from Ms. (Baker) as well via email, and I was going to try and reach out to her after our call today. But can you - so you're saying that previously you were receiving these notices and they were using the terminology reactive but now they're using the word NAT positive? Is that...

(Wendy Webbly): Yes.

Koo Chung: ...okay. So I guess - it could be, and I'm not sure which testing platform is being used that you're speaking of, but generally speaking the word reactive is used when we're talking about the IND NAT; and if we're talking about PCR - or they said NAT positive - is what they said?

(Wendy Webbly): Mm-hmm.

Koo Chung: That could potentially be referring to the CDC Trioplex NAT assay - that's being run as a confirmatory, part of the confirmatory algorithm. I'll also ask Roche and/or Hologic - if they have any questions or any comments about that.

Lisa Pate: As you said this is - oh this is Lisa Pate from Roche -- as you said to our test results from cobas are reported as reactive. And I believe you're right that the

NAT confirmatory or the NAT done at BSRI is reported as positive, or negative, or in some cases equivocal.

So I can't interpret the information that the person asking the question is asking without sort of knowing, where is, where in the process this donation is. It's a reasonable thing to try to reach out to whoever sent you that result and ask for clarification from them to make sure that everybody's using the same words to mean the same thing.

((Crosstalk))

Steve Thomas: Lisa, hi. And this Steve Thomas from Grifols, and I just wanted to confirm that that is how we report as well. We do report our Procleix result as reactive, or nonreactive, and the alternative NATs are usually positive or negative.

Koo Chung: This is Koo again. And I think I'll reach out to I think to Ms. Baker specifically to round out that question later this afternoon. Thanks for that.

I think we have another question in the chat box from (Shelby). What is the percentage of true positive viremic blood donors among those that screen positive on initial screening? (Shelby) thank you very much for that question. And I think this one - I'm going to let Roche and Grifols tackle this question.

Lisa Pate: Okay. So this is Lisa Pate from Roche. So I'm not sure. There are kind of two ways to answer the question. One would be the overall specificity of the assay, which the data's not yet been reviewed by the FDA, but we've reported it in public forum that our specificity is 99.997%.

With respect to the specific, you know, how many of the reactives have been confirmed with alternate NATs and or IgM? I believe it's - I want to say - it's

about two thirds of them have been. There's some in process and we're, you know, there's a number that are still being followed up, so I don't know that exact number.

Be mindful of the fact that those - our assay as well as Grifols - is very much, you know, considerably more sensitive than the alternative NATs that are being used to try to confirm them. So, you know, often we have to wait for IgG - or rather IgM results to come back before we can confirm. But I hope that answers your question.

Steve Thomas: Hi, this is Steve Thomas again from Hologic. So for our sensitivity - it is at 99.997 and for us we have 19 confirmed reactives out of a total of 108, which is about .18% - or 18%, sorry.

Koo Chung: (Shelby) I hope that answers you question and thank you for that Lisa and (Tom) - and Steve.

Lisa Pate: Sure, you're welcome.

Koo Chung: So if we don't have any other questions on the line operator, I was wondering if maybe Roche and or Grifols may want to speak of their assays in a little more detail. Or if they have anything else they wanted to add to our conversation today.

Lisa Pate: I think, this is Dr. Pate again from Roche, I think that you covered sort of the algorithm or the - under the IND for testing - and what's used to confirm it really well. There's not a lot of other specifics about the assay that I can say.

One is, one point would be that it's run on our cobas 68 or 8800 system which is our newest analyzer. But other details? There's nothing really, I think, that

would probably be germane at this moment. Although, one thing I will say is, I did say that we had - we tried to - we ask our blood laboratories to report to us within 24 hours and then I report to CDC. And it is personal. It's me that does it - reports to CDC and FDA - and then CDC reaches out to state public health.

In Florida and Texas, though, we have included in our list state health authorities that want to be notified kind of at the same time or soon after CDC. And we're willing to try to do that if you have a particular concern. You know, if you're in a state that happens to be, you think, at high risk for Zika cases in the coming months - if you want to reach out to me - it's lisa.pate@roche.com.

I can, you know - we can have a conversation and see how we might be able to help you kind of get the information even faster than if you have to wait for CDC to call you. Which probably doesn't take very long anyway. You know, our goal is really to facilitate the public health response to Zika, and we want to work with you, you know, as much as we can.

Steve Thomas: Hi, and this is Steve Thomas again from Grifols - and not a whole lot of additional information. Just that the Zika virus assay is run on the Panther system and we also do get our reporting of initial reactives within 24 hours, and we also do our reporting to FDA, CDC, and AEDB regularly on reactives and total testing done. And if there's any additional questions that you have regarding our specific IND assay please feel free to contact us at Grifols.

Chris Motsek: Brandon are you seeing any more questions in the queue?

Operator: I'm showing no further questions at this time.

Chris Motsek: Well Koo, we just want to thank you for the information and the questions and answers. I just want to remind everyone - our audience out there - that the

transcript and audio recording is going to be posted to the Zika webpage on a rolling basis. We're shooting to try to get it out about seven days after this event, but if it a little bit later just bear with us, and it will be on the webpage.

This is a great resource and/or tool if you're not able to attend every session. So please, you know, share with who you think could benefit from this information. Also we do have one more sustainment strategy discussion this afternoon. It's in approximately 40 minutes, so we hope you call into that as well.

The link to access the previous webinars will also be provided to our awardees in the Division of State and Local Readiness during the Friday Update, and also to - our partners from our State Coordination Task Force partner share functional mailbox.

I just want to say thank you again for participating in today's webinar. Just as a reminder, please, if you do have more questions, just send it to preparedness@CDC.gov. That's preparedness@CDC.gov. Everybody have a great afternoon, evening, or morning - wherever you are. Thank you very much and we hope to hear from you and - in about 40 minutes. Thank you.

Operator: Thank you for participating in today's conference. All lines may disconnect at this time.

END