Virginia Department of Health
Tele-Press Conference on Serology Testing Efforts in Virginia
Moderator: Marian Hunter
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10:30 AM

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

Marian Hunter: Thank you. Good morning everyone and thank you for joining our call today. My name is Marian Hunter and I'm a public relations coordinator for the Virginia Department of Health Office of Communications. Today we are joined by the Virginia Department of Health Office of Epidemiology Public Health Physician Specialist, Dr. David H. Trump, MD, MPH, MPA.

Our subject matter expert will give a PowerPoint presentation on serology testing in Virginia, followed by a question and answer session. Today's call is being moderated by an operator so when we get to the Q&A portion of the call please follow their instructions to ask a question. Now I would like to welcome Dr. Trump to share an update on serology testing in Virginia.

Dr. David Trump: Thank you very much. Good morning everyone. I'm Dr. Dave Trump and to get it on the record, I am not related. Just a brief background, I am a career public health physician, over 30 years of practice in public health and preventive medicine first with the US Navy and then after my retirement, I served the Virginia Department of Health as a health director for the Peninsula Health District Newport News up to Williamsburg.

Then as state epidemiologist and then finally as a Chief Deputy Commissioner for Public Health and Preparedness before retiring in 2016. I returned to work with the Health Department here in the Office of Epidemiology at the end of April.

The briefing this morning is on antibody testing for COVID-19 in Virginia. And we'll do some brief background on antibody testing - what it is, what are some of the limitations, what are some of the roles, and then talk briefly about the antibody test results that the Virginia Department of Health had received to date. And then spend a fair amount of time talking about the Virginia Coronavirus serology project and followed by some other antibody testing projects that the Health Department is undertaking over the next several months.

Just briefly, antibodies are our immune system's response to an infection, whether it be a virus or a bacteria. The immune system makes these proteins that in this case will bind to the COVID-19 virus. Through their binding if they bind in the right spots and tightly enough, they'll keep the virus from getting into cells.

And also if they coat the virus enough it makes it easier for other immune cells to come in and sort of deal with the invader. This is something that happens during any infection. It's not immediate and as a result, antibodies are not reliably detected through testing until about two to three weeks after the onset of any infection.

Antibody testing - the other more general term is serology testing, is of use in COVID-19 but there are limitations. First, when we talk about antibodies we're really looking for indirect evidence of a past infection. It's not the test

that we use to diagnose a current infection.

For that, we need the viral test, the PCR test done on a nasal swab sample. Also right now, we don't know some things about the antibody testing. We think we know some, you know, what's likely to happen based on our history with all other infectious diseases, but we don't have the evidence to be confident that the antibodies that our tests are now detecting, do protect against reinfection.

How long that protection would last? We know they have antibody protection often weighing or weakened over time. And then we also don't know that if you get reinfected after you've had an initial infection and have antibodies if those antibodies will help the illness be milder.

And probably more importantly, we don't know if you're reinfected would you be as contagious again and likely to spread the virus to others. So there are lots of questions and lots of people who are looking for answers to those questions and will know more over the next several months. But those are the current limitations on antibody tests and how we need to think about them.

One thing we do know about any test is they're not perfect and we do have to think about which test to use. Currently, the Food & Drug Administration as approved 16 antibody tests under emergency use authorization for use in the United States. And they have a range of performance and test performance uses terms called sensitivity and specificity. And sensitivity is how good the test is at binding a new infection; the specificity is how good the test is as - at calling a negative a true negative.

In this example the infographic on this will be able to see - talks about what happens if we assume that 5% of the population have had the COVID-19

infection and we test 100 of them with a test that has 90% sensitivity and 95% specificity.

That 95% is an A in most grade books but we find that if we apply that test in 100 people we'll find the five out of the 100 who had the COVID-19 infection and the test will tell us that there are another five that are positive. So one in every two positive results is what we call a false positive and that's a big reason why we can't guarantee that a positive test result means that you actually have the antibodies and actually have protection against COVID-19.

Now we take a different test, now a test that is 99% specific, we can get that false positive rate down to one in every five to six positives. It's still not zero, but it's better than if we had chosen the test with 95% specificity. Tests aren't perfect and we also have to think about who we test. On the left, if you see the infographic, is that same example where 5% of the population we think had the infection and are testing finding, you know, five positives and one person most likely who is false positive.

But if we assume that only 1% of the population had COVID-19 infection, apply that same test, we'll now find that one person who was infected in the past but will still have one false positive, and we're back to 50% of the test results are potentially false positives. And the challenge is we can't tell Patient A that their test is a true positive or a false positive. Right now that is the unknown of any antibody test results.

So there are limitations to antibody testing for COVID-19 right now, but they do have value. One is in clinical care where a physician, as part of working up a patient who is presenting with COVID-19-like symptoms, they want to do the PCR testing and an antibody test especially if that person is coming into care late in the illness when the PCR test may not be picking up the virus and

the antibody test would help make a diagnosis.

The doctor could also use an antibody test if they're looking at someone who has a new health condition or has a change in their existing condition and they give a history that they've had fever, cough or other symptoms that could have been a COVID-19 infection a month ago.

They can use an antibody test to help make a diagnosis in that patient, to help their decisions about patients and how the current condition should be managed. They also use antibody testing to look for individuals through the service plan (unintelligible) for therapeutic antibodies, people who've had infections in the past and whose antibodies could be used to treat a currently infected person. There are also roles for antibody testing in public health as part of our investigating cases.

We now call a confirmed case anybody that has a positive PCR or a viral test, but we can use an antibody test to classify someone as a probable case as long as they also have either a history of the clinical symptoms of a COVID-19 infection or they were in the setting where they had a high likelihood of being exposed like in a nursing home outbreak. The other place (unintelligible) antibody test is one with PCR tests who look at an outbreak such as in a long term care facility or workplace, to understand the true - full impact of the COVID-19.

And then finally there's a role for using the antibody tests for this purpose of zero prevalence assessments and that's what we would test a defined sample of the population, to get an estimate of those who have antibodies and hopefully an indicator of those who have had a past infection, including those who may have had symptoms, but more importantly, those who either had no symptoms or maybe had a very mild illness and never required or came in to

get a PCR test.

So what do we know about that background rate of infection in Virginia or that zero prevalence, how many people have been infected and either diagnosed with a PCR test or had an asymptomatic or a mildly symptomatic illness? And really now, we don't know.

To date, VDH has received 50,000, over 50,000 antibody test results really in the last five weeks. What we're reporting on here are all those that have received approval for use by the Food and Drug Administration. And of those 50,000 tests, 5-1/2% are positive.

Now some of those are among people that we already know are confirmed cases, people who've had a PCR test that's positive, and also have an antibody test that's positive. Others are individuals who have been classified as a probable case and they all - and either based on clinical symptoms, exposure setting with the antibody test results. And so we take those cases out of the mix, we get a number of about 2-1/2% positivity among those who were not cases, those who have not been counted yet as cases here in Virginia.

That's probably the best guesstimate right now about what the background rate of infection may be in Virginia. But as you'll recall, we don't know whether half of those are false positives or maybe 15% or 20% are false positive. And that leads us to the Virginia Coronavirus Serology Project.

That is a statewide project whose purpose is to really get an estimate about what percent of the adult population have antibodies to the virus that causes COVID-19. As that indicator of people who have had either previous infection and were symptomatic, or were asymptomatic.

And to get an estimate that is for Virginia overall which is also an estimate of other differences among the five health plan regions here in our state. The Virginia Coronavirus Serology Project will be enrolling 5000 adults statewide, 1000 uses to help plan in regions. The sample size, that number is required to get an estimate that's relatively precise, plus or minus 1% if we make an assumption that we're testing in a setting where about 2% of the population will have some evidence of past infection.

The project is doing this through enrolling adults who are seeking care in - or laboratory services in health systems' existing locations or outpatient clinics and lab collections. We have enrollment quotas that - so that we are seeking representation of the region's population by some broad age categories and also race/ethnicity categories. Within each of the regions, the locations that are being chosen are going to provide some diversity by geography and by the populations served regionally.

The project involves getting some central participation, having the individuals complete a short questionnaire and then have their blood sample collected. So the blood samples will be sent to a single laboratory that is running an FDA authorized test that is reported to be 100% sensitive and 99.6% specific.

That timeline is for enrollment in (unintelligible) through mid-July. We actually have begun enrollment this week. It's very initial and we'll have that increased enrollment over the next several weeks. And the goal is to have, at least the preliminary reports, no later than July 31st to inform decision making that will occur over the next - into the fall of this year.

That's the project VDH has entered into agreements with the University of Virginia for the project management. Dr. Eric Houpt who is a professor of infectious disease with UVA, is the project leader. UVA will be going to

laboratory testing and also will be responsible for enrollment for the Northwest region. The other enrollment locations or partners are in (unintelligible) northern regions (unintelligible) healthcare and Eastern, ECU for central and (unintelligible) clinic for the southwest.

There's no single way to do a serology project of this magnitude. But we do feel this is a result for what we've invested here in Virginia has some strength. We are seeking to be representative by age group and race/ethnicities again statewide and at the regional level.

By using the outpatient clinic setting we're approaching individuals who have already made the choice to leave their home, to be out and about and they have also gone through whatever healthcare, health screening is in place or needs to be in place for that setting, to make sure that the, you know, the risk of an individual having COVID-19 was low.

We've also been able to partner with the site's existing clinical studies staff who are experienced with approaching working with individuals for the sort of enrollment and also the existing blood draw services at those facilities. One potential limitation but qualified as the strength of this project, is we are most likely going to have higher participation of individuals with chronic health conditions because we are seeking people who are in a healthcare setting.

The strength is that this is a population of people with diabetes, with chronic heart disease, pulmonary conditions who if they do become infected, are going to more likely - are more likely to have a severe illness, more likely to require hospitalization and also more likely to have complications from their infection.

And we really need to know for communication with the public and also for

healthcare planning, what percent of that at-risk population still has had no experience with COVID-19 so we have better information on planning for the next several months.

There are definitely some weaknesses with this approach. We are unlikely to enroll enough people from each specific health district or county, for example, to have reliable estimates of what the experience has been at that local level. Because we are in healthcare settings we will represent its (unintelligible) and ensure the members served in the current project is not enrolling any children.

So that leads us to, you know, some other work that the Virginia Department of Health is doing with regards to antibody testing with serology. The Health Department is analyzing, you know, deciding how to best present those antibody tests that have been reported to date so that those can be available publicly on the COVID-19 dashboard.

And then the Health Department is also working to add capacity for antibody testing in the future. I mentioned, you know, that we're going to not necessarily have a picture of what's going on at the local level plus the statewide project.

So there will be - their capacity, so there will be opportunities to do smaller studies involving maybe 200 or 300 individuals at the community level whether that be a community of color or otherwise underrepresented population or a particular rural community, to get a better picture of what has been going on with COVID-19 in that community.

We're also looking at adding capacity so we have antibody testing as a pool for outbreak investigation and potential management of populations in settings like long term care. We're exploring opportunities to do a child and infant

serology project probably in one - just one region of the state. And then it all, as part of that, working with the Division of Consolidated Laboratory Services to support their addition to the antibody testing capability.

Just to put this in context, in the serology work that I described, it is important work for the long term response in Virginia, to our long term understanding of COVID-19 and for having the tools to best, you know, inform you and the public about, you know, what is happening with this infection among the people of Virginia.

It's important that it's not the urgent part. The focus of the work on serology projects is in addition to what is the important emergent work of finding current infections of COVID-19, identifying those individuals through PCR testing and expanding that ability for testing and in particular, expanding the ability for contact tracing and being able to advise individuals to minimize the spread of the infection from one person to the other.

So after that, having heard about the limitations and, you know, potential uses of an antibody test, what do we do with a positive antibody test? What is the recommendation for someone who has been tested for whatever reason, and has a positive antibody test? Right now the recommendations are to continue to follow all of the general recommendations already in place - use of a mask, social distancing, avoiding crowding conditions both in general and then also in workplaces.

Antibody testing positive results direct no change in the actions. If someone presents with symptoms it could be due to COVID-19 again we don't know if antibodies are a guarantee against the infection. So they would need to take measures to limit their infections and other PCR testing may be necessary.

The healthcare worker who is antibody positive should have no change in what they're doing in their clinical practice with the use of personal protective equipment, for healthcare workers and first responders. A positive antibody test should not be used to make decisions without living conditions for people residing in, being related to any congregation setting, whether it be a long term care facility, a school, a dormitory or recreational facility.

And then also a positive antibody test is not used to make decisions about whether a person should or should not return to work. And those are the currently published CDC guidelines for COVID-19 antibody testing. With that, I thank you for your time and we'll open up for questions briefly.

Marian Hunter: Before we begin the question and answer portion of today's call, I want to remind you that our call is focused on serology testing. For questions regarding other topics or if our subject matter expert is unable to answer your question today, please direct them to the Virginia Joint Information Center at COVID19JIC@vdem.virginia.gov. We will have a copy of this PowerPoint presentation along with the MP3 audio and transcript, posted on the VDH Web site. We are now ready to begin the question and answer portion of today's call.

Coordinator: Thank you. At this time if you would like to ask a question, please ensure that your phone is unmuted, press star 1 and record your name clearly when prompted. Again, that is star 1 if you'd like to ask a question. One moment, while we wait for questions to come in. One moment for the first question. Our first question is from (Alan Suderman). You may go ahead.

(Alan Suderman): Yes. Hi, Dr. Trump. Are other - do you know of any other states doing a similar serology project? Or are we the only one you know about? And I'm sorry, I had one other question. Could you - if someone has tested positive

would testing them again like multiple times to make sure it's not a false positive, would that have any, you know, is that something you've considered?

Dr. David Trump: They're both very good questions. There are several other places that have already reported on zero prevalence assessments that they have done. Santa Clara County and Los Angeles County in California obviously; Indiana State; and New York has done several surveys. Some of those are - I think only one of those has been reported in a medical journal online, in the Los Angeles study. The others, there are news reports about those.

So there are other efforts and I'm sure there are other efforts going on now that are sort of in the stage we are, of being planned or implemented. And the New York ones are probably - are informative. The most recent one they tested over 8000 individuals and found differences by bureau. These reports were 40% positive rates among the people they tested in the box compared to a lower number in Staten Island. I think it was 20% overall.

These tests - the approaches have been different. Some have used Facebook advertisements to recruit people, others have gone to grocery stores or other shopping locations and included people who were interested. The most recent New York City project worked trying to identify high-risk populations, underserved populations, work through local churches. Again, as I mentioned earlier, there are different ways to do this, but that, you know, those are some examples of the work that's underway.

The Centers for Disease Control is also doing some more focused work and I know the NIH has announced a study that they're doing mainly working at children through some connections they have with those patients nationwide. So that was number one.

And number two, there are ways to get a better true positive result and what you mentioned, testing a sample twice is one of those. We have not made a final decision, but I suspect that when we get to the end of the project we will retest the positives to see with another assay, different laboratory, different test, to see how those two tests agree.

And that is a very common approach to working with antibodies, you know, for many infectious diseases - with HIV infections, you know, name an example where you do a screening antibody test and then other tests once you get back to make a decision about, you know, what is the true infectious status of the individual. Again, thank you for the question.

Coordinator: Thank you. The next question is from (Luann Rice). You may go ahead. (Luann), your line is open. Can you make sure your mute is off?

(Luann Rice): Oh. I'm sorry. I was muted. I have two questions. One is whether the participants will get the results of the testing. And the other is you had mentioned that you have results for 50,000 from the antibody test. And I think you had said the percentage positive was in the 2% range. Is that across all of the health regions or are you seeing a different rate already in the different health regions?

Dr. David Trump: Remind me of the first question. I've already forgotten. I'm sorry.

(Luann Rice): I'm sorry. The first one was really unrelated. It was whether those who participate in this study will get the results...

((Crosstalk))

Dr. David Trump: Yes. The individuals have the option to, you know, opt-in to get results. We

expect most of them will be interested in those results. And they'll be mailed to the individuals probably two to four weeks after the sample has been collected. We're going to be having them sent from the different sites to the single lab UVA once a week.

And it will be run in batches so it's not an immediate test. But yes, they'll get the results if they are interested in them and definitely will get an explanation about what a positive test result or a negative test result means and what the public health recommendations are for your actions as a result of that information.

And then as I mentioned, you know, it really has been over the last - really the last four weeks that the state has gotten this influx of antibody test results and that's - the analysis is underway, again to figure out what they're telling us and then also how to best present them. So I do not have the information right now about how the rates are varying by state or by any other information, age group or anything like that. You know, when we're ready to present Madam Chair, it probably will be through the COVID-19 dashboard. But I don't know what that timeline is at present. It's a work in progress.

Coordinator: Thank you. At this time there are no further questions. As a reminder, if you'd like to ask a question, please press star followed by 1. One moment to see if we have any further questions. There are no further questions at this time.

Marian Hunter: Okay. I want to thank you all for joining our call today. As a reminder, there will be a digital copy and transcript of the call along with the PowerPoint presentation posted on the VDH Web page that will be under the VDH COVID Web page on the media room tab. Thank you again for joining our call.

Coordinator: Thank you. That does conclude today's conference. Thank you all for participating. You may now disconnect.

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