Introduction and Dr. Shah's background

Hello everyone. My name is Doctor Richard Horowitz and I'm the co-host of the Doctor Talk Healing Lyme Summit 2.0. My great pleasure today to introduce to you, Doctor Jyotsna Shah.

Doctor Shah is head of Hijinx laboratory. So we've been using for she. I think it's over 30 years. At this point. We've been using AI genetics. And I'm so happy to have you on.

Just not today to discuss the AI genetics testing for Lyme for tick-borne, relapsing fever, for bbca, for Bartonella, for all the tick borne disorders.

So thank you for joining us today. Thank you for inviting me. Yes. Of course. So tell me, just how did you get involved? I mean, I know you have you have a PhD from Harvard.

You discovered the. Fish? No, I don't have a PhD from Harvard. My PhD was from Nairobi University. And I came to do fellowship at Harvard. I was the fellowship at Harvard.

Got it. Okay. But then you came to the United States. Your initial interest was in malaria. Is that what I've understood before? And then you kind of moved over a bit.

Of malaria, basically tropical medicine. So I had done my PhD on sister surmises, and when I came here, I was involved in filariasis and, then into malaria, TB, all infectious disease, kind of got into that.

And then the choice was, do I go into genetics or do I continue with infectious disease? And while I was doing my fellowship at Harvard, you know, you know, Lyme disease was being talked about.

It was pretty new. And they had just found it in Nantucket in white mice. And so we would hear about these studies that epidemiology department was doing in Nantucket Island, which was close to Boston and that they were finding these, Borrelia in these white footed mouse and that was causing disease.

It was becoming quite popular. And they started having ticks and trying to infect ticks. Infect, mice with that and try and start growing cultures and things like, because there was a big, animal house, that hardwood had in tropical medicine where they would grow different things with different small animals in which they will harvest different kind of parasites, filler related worms and things like that.

So I'd heard bit about it and it sounded interesting. And then when I started work, then I decided to go into industry and not into academia for a very simple reason.

I did not want to spend my weekends writing grant applications. I was seeing everybody there seven days a week and I said, no, this is not what I want.

I want a regular life. Friday, two days off because I had a daughter that I wanted to spend time with. So I went into industry and I was thrown into all kinds of infectious disease, and being asked to look into pneumocystis, which I really didn't know at the time what it was.

So I had to go research about it. And I developed a whole set of probes. And this is where I started fluorescent to inside to hybridization, because there was no other way of doing analysis of what I was finding in terms of designing probes.

So that was the beginning of fish fluorescence insight or hybridization. And that technique proved to be very, very useful for Pneumocystis. And that is how I further went into, busy.

I ended the Fisher assay. And after that, while I was there, there was, one of the scientists came from Billy Budd of his lab as it happened. And we used to share the office.

So we would talk about things. And his whole family was infected with Lyme in Long Island. And so this kind of got, you know, I got interested in that.

And then when the opportunity came, I would have gone to Stanford or worked on, tick borne disease. I decided to join agent X and start working on tick borne disease.

And I'm still here. And after all these years. And I, you know, I don't think people know, but, you know, you and I go back quite a bit because when I first discovered Bbca in the Hudson Valley back in the 1990s, we sent the ticks to I.

Gen-X. You had discovered them right in the Texas, had Rhode Island with Tom Mather's lab. And it was ultimately the fish testing. Right. That was confirmed by New York State actually, early on, that it was a reliable test.

And that was, of course, my first experience with a patient in a wheelchair for five years who couldn't walk with Bbca out of the wheelchair with Matt Brown, etc..

Mac so, I mean, you and I go back actually quite a while using fish testing and helping Hygin X, right. Using a genetic testing to get to the bottom of what was causing the illness in our patients.

Early Lyme research and development of FISH testing

Well, I the credit goes to you because you gave us the samples to work on the BCI, you taught at the BCA and then we started working on the fish assay, and eventually we managed to get, that as approved.

But not only that, that put us in the you know, what is the BCA started that project. And I think to this day, fish is one of the tests that everybody loves because it was designed at the genus level.

So it detects species that we wouldn't find otherwise. And, you know, two things that I would here. One was from Doctor Phil, and he would say that every other test would fail, but fish would come back positive in a patient is treated just like you.

The patient gets better. So you guys had the experience. And I think with all your help, we were able to, you know, push with the fish and get New York approval because you had talked to them in this meeting about their desire.

And, you know, one time when, we had a meeting at, at one of our meetings, I think the epidemiologist from New York state came to wait and see. Your results are wrong.

There is nothing like this because, some other lab had found that none of the ticks were positive for what we are saying. But the following year, he came back and I said that I apologize.

That was really nice of him. But you will correct. What you found is what I am finding as well. So that kind of helped us to, you know, say what we are doing has so many.

Right? And, you know, this is the way science advances, right? I mean, we question things, we do experiments. And, you know, you've been a part of the front lines, in my practice.

I mean, I would never have been able to help the 13,000 plus people I have helped if it wasn't for I genetics lab. So I want to thank you. And of course, Nick, who passed.

I mean, you guys have really been the front runners and and what's exciting for us, you just got FDA approval, which is groundbreaking, right? For getting the Immuno Blad approved for even home testing.

Tell people about that. A bit. Okay, so what we have done is so we always believe there's, you know, that the standard two tier testing wasn't the best way to go about testing for Lyme disease, because the markers were missing that we knew were critical.

And we always had shown that that they were important by PCR, by, you know, based on the clinical histories that you were treating patients with, and they would get better.

When we reported out those results. So we said, if we are going to get the FDA approval, we really need to get the right test approved and it doesn't matter what it takes.

So what we decided to do was be a CDC was also very helpful. Helpful because they have these panels that they provide on whoever is doing research. So you start out with one simple panel, then you go into this next one and the final one.

So you really look at about I would say 400 or more than 400 samples, to develop your test. So we started doing that when we had full confidence in the immunology and, you know, had done enough by then and we started testing and that is all started appearing really good.

We were on Sensor Green, and if we were outstanding. So then we said, well, I think we have got what really makes sense. So let's apply to FDA for the test.

So we did apply and we cleared the IgG test. It is the most sensitive test on the market. It detects multiple all the species that we currently know of in the US and also in Europe and Australia.

And, you know, it's a test that if we find something new we can add on. And of course, we would have to get approval from FDA for the additional markers.

But that's something that's possible. So and the other question was there was this two tier idea up to now that you had to do a two tier test to get specificity.

That was the main reason. But by doing that, you were losing sensitivity. And we said, no, why can't we do a test that is a single test, not a two tier test.

A patient can do and get the right answer. So we have been working on it and that is what was cleared for G and I g m. This is really interesting. And I think as a physician you can you know, enlighten us on this.

Our very understanding is that I converts to IgG. That's the standard procedure. So when we are looking at patient samples, when we first got the results and we compared them with what was expected, we said the results make a lot of sense because early disease.

Well, most of them were AGM. Then you will see G and M together and then you will see more GS. And that is exactly what we are seeing in the late stage Lyme arthritis.

So how would you classified stage three. So most of them in our hands were turning out to be ignored. AGM, whereas other test that we use as a compact comparator really did was not picking up IgG as well.

But they were getting more AGM and to us that didn't make sense. We said, well, I think our results are perfect. So we just went ahead and submitted that and they came back.

Sorry your sensitivity and third stage is low. We are not going to accept that. Can you improve? I said we cannot improve it. The test it is. This is the way it is.

But if you look at G and them together, they're all positive in G because they have converted. And that is where they did not accept our argument. They said you have to we have to go by what is out there.

And we you know, it's a competitor. So you don't match. Yes. Well, you know, in my world though, the AGM and I you know, this there was research done years ago at the University of California, Davis, showing that in the mouse model, right when Briley invades the lymph nodes, it would get rid of the part of the lymph nodes that makes basically IgG and leaves IgG.

And what we were seeing in our patients and we we replicated this and basically published it a few years ago. We got up to a 45% rate of CDC positive exam blots in our chronic Lyme patients, not IgG.

And our assumption at this point was because the immune system was being affected just as it was in the mouse model. And that's why we weren't seeing as much IgG, but ultimately because the immuno blot is recombinant DNA, right?

The beauty is we don't have to worry about a false 31 band on a Western blot because of viral immunity or Epstein-Barr. Right. When we see any of the Borrelia specific bands on an immuno blot, 23 USB, c 31 Usb-a 30 for us, B 39 very specific 8393 I know in the right clinical setting, whether it's AGM or IG, as long as it's fitting the clinical picture and we've ruled out other diseases.

We are dealing with chronic Lyme, but it is true. I do see much more IgG than IgG in our chronic Lyme patients because of the way the immune system has been affected.

That is true. We do see that and that, you know, that it happens even today, that that's not what I'm seeing.

FDA approval of Lyme immunoblot testing

We do CGM, but what I'm trying to make a point is that, you know, I believe when we were able to show very clearly that exam is being picked up by the AGM, blotting IgG is being picked up by the IDG blot, where we saw all the samples for only Lyme arthritis.

I'm talking about. I'm not talking about any other form that I believe the results were correct, that they were really IgG and not AGM as well. Were mostly IGA, very little AGM.

The difference was when these tests were done by other groups that they use year two and still one. What they use is total IgG and AGM total antibodies.

So the idea of on is DNA and there are some antigens to which antibodies are present for a much longer time in M form. And that is why they were getting positives.

And when we were being very strictly AGM, we were missing some of them. That was vaccination. But the results that we presented as AGM specific were correct, but were not acceptable to them.

So that's something we are working on because we really believe that test is very useful. IgG I think is the best one because we are able to include 31 and 34 in them and or 93, as you say, 39.

2331 and we also have the IgG, CDC bands in there, but we don't read them and we provide the results both ways. But in our hands, it showed that that was wasn't were necessary to call it positive.

The I Genesis criteria was working very well. And that is what's approved as well. Right. So the point is people now have access. They have access to your test at home, right, for diagnosis.

And and I think that's really one of the breakthroughs. And you know, when we do an agent X panel, when someone comes to me for the first time, my standard is usually I'm going to get an IgG mg immuno blot for Lyme, I'm getting an IPA, mg immuno blot for Bbca.

I'm get an exam, I give me no blood for Bartonella, I'm going to get a babka fish and a Bart fish if I usually do that, and occasionally tick-borne relapsing fever on the rest.

I find that I'm able to pick up really the vast majority of these infections in people. And although sometimes the fish can be negative initially because the bugs are hiding, ultimately I would say the fish testing has been amazing.

And picking up the BS here, because some of our patients are immunosuppressed, they don't make antibodies. The fish is the only way to pick it up and you know, I had invited you and Nick years ago to China.

We got a call from the Chinese government. I mean, this was an amazing experience. I'll tell people about. It was like 15 years ago. I was in France lecturing to infectious disease doctors in French, of all things.

And I got a call from the Chinese government. They thought they were discovering Berbizier, you know, an epidemic. Fortunately, they asked me to come over.

I wasn't sure if it was real. And it turned out it was. They paid for our flights, and I invited you and Nick to come along with fish testing. We all met in China and proved, in fact, that it was the busiest that they were seeing.

And I mean, it was really what I would say, one of the great experiences of our lifetime. We were all right, kind of together with the CDC for National Academy of Sciences.

I mean, it was really a great exchange of scientific information. I think so. And, you know, when they found the BBC, a since then, there are a lot of publications that have come out.

And one of the interesting things that nobody really knows, because we haven't talked about it, is that we are able to detect with the immuno blocked species that they are discovering there, because we have had cases which were Lyme genus positive but are not microalgae or Duncan or the collier, but they are different species.

And now by sequencing, because we do culture and you know, if we're lucky we get cultures to work. There's never a guarantee that the culture is always going to be positive.

But when we do get it, we've been able to find that the is picked up on the immunobiology genus is a different species, the BCR that we have just discovered.

We don't know too much about it, but it's a different species. And the immuno blot is detecting it. So the point is the immuno blot at the genus level is really good at picking some unknown species of BCR data causing disease in humans, not just micro DNA.

Done kind of just like the deficiency. So is this possibly like a mog m01 kale? I mean, is it some of those species? Are we talking maybe some of the European species that we're not used to seeing here?

Do you know we don't know yet. Yes. It means don't have little information. We are trying to work this out. It looks like a Chinese. You know, it was discovered originally in China.

It looks similar to that at this point. And there's some other interesting findings that we need to conform. But, you know, this was to us this was exciting that we were able to find my sequencing species that are being detected on the immuno block.

So this means yeah. Right. So clinically this means for someone. So if for example I have a patient that comes in with malaria like symptoms, you're coming in with day sweats, night sweats, chills, flushing air hunger can catch my breath.

Cough I've ruled out hypothyroidism I've ruled out tuberculosis non-Hodgkin's lymphoma menopause. Right. Hyperthyroidism. All the things. Autoimmune disorders, things that would cause drenching sweats.

And you can't find it with the BBC micro D titer or uncanny titer. You're basically saying that immuno blot will pick up some of these other species that could be accounting for malarial symptoms, but we're we're not picking it up on the standard testing.

Yes, that is correct because these are the samples we were worried. How are we going to, confirm that this is really a Busia? That is one of our questions because I have Duncan in my eye.

If he is going to be negative, they are going to be negative. So this is why we are pursuing methods to confirm this other species, or at least say these are at the genus level, because our goal is to get an FDA approval for the immuno blots, which I think is very important.

In fact, we are trying to work with them and, you know, see how we can make this happen. It may take some time, but that's something we are working with FDA on.

Have you had some, input from them, as to what? And I think it's going to be a joint effort to get something like this on the market because there are no competitors.

There's nothing like this that we can compare with. And it's almost like what we had done for malaria fish, which was completely new, and it was working with them as a team to get those approved.

And we are hoping we can do the same thing for PCR with them. They've been very helpful and are willing to listen to what we have to say, and they have some really good scientists there that can give some advice and you know their thoughts as well.

And that's a wonderful. And you know, Justin, what's wonderful to hear about this is that I think a lot of times people have thought like, oh, it's not easy to work with the CDC or the FDA.

The rest now, I when I worked on the first round of the Tick-Borne working group, my experiences, these were wonderful people. We may have had our differences in some things with, I don't believe this or that, but it was an open minded scientific conversation going back and forth.

We both listen. You're saying the same thing. I mean, this has been very helpful. It's not like adversarial. It was actually let's work together, right, for the benefit of others.

And that's been your experience working with the FDA. And I actually had a great experience myself working with the governmental agencies when I was doing it also.

Right. Yeah. I think it's like nobody is going to agree to everything. We have to accept that science that is science. You know, we have our ideas. We believe it based on what we see.

They believe what they see, and then we have to provide data. And every day we are finding new things.

IgM, IgG, and Lyme disease staging

We might have said something ten years ago a week now, we would say is wrong, but that is what we knew at the time. For example, man 31 we all thought on the Western blot it was important and we were saying that till we found out that there was another marker underneath it, that 50% of the samples were false positives.

And we that's why we developed a confirmation test for Ben 31. Yes. And with a immuno blot that problem is gone now. Yeah. And again, for people listening and the problem with diagnosing the three BS of Borrelia bibs and Bartonella is that there are so many species out there.

The problem is if you go to a local lab and you just get a Western blot, you're just basically checking one strain. Borrelia sensu strip two, you're not getting, you know, all of the since you lost two strains, including as you were talking about.

Absolutely. And Guarini and some of the European strains apart from California strains and the rest and that's ultimately it's Berlioz's right that's making people sick.

Just like part analysis. You can't just do Bartonella. Hensleigh Bartonella quinton of Bartonella maxilla form. You need elicit BFA. You need Vincent subspecies. Right.

It's really the broad range of organisms that the immuno blots are picking up that make it so useful. Yes. And I'm going to the nano. We are seeing a species that it's not the standard for species that, you know, really speaking everybody's looking at Quintana and hence the only my I agree, there are no other tests out there.

And there's a lot of cross-reactivity on the IEP. We have seen that. But on the immuno blots we are picking multiple species, that we would wish otherwise because we have tried to put 13 different species of Bartonella on the immuno block.

And we are seeing pattern sometimes, you know there is a cross between some species, sometimes is a very clear cut down. So you will get but they are clearly bartonella.

The specificity is so high of these recombinant immuno blots. We that's what we are trying to get through New York. First we are almost ready to submit our package are done everything that we need to do hopefully within less than a month, that package should be out, because I just wanted all the confirmations that are in the team here.

The research team is fantastic and the lab people, you know, I mean, they went backwards to get whatever needs to be done in a timely fashion. So we think we have everything and we are so lucky that we are able to culture everything in in-house.

The four species of Bartonella, we don't culture the other ones because we don't think it's necessary. And all the brilliance. We have cultures so we can confirm with the cultures as well, with the antibodies that we raise against them using these cultures when we want to do testing.

So I think we have been lucky with, everybody's help all over the world that we got all these collections here. Right? And ultimately now even the New York State Department of Health early on, right, might have been difficult.

Ultimately, they came around and said the test actually is accurate. We've gotten approval. And I think we're working more together now than ever since before now, a little bit.

What I'm seeing when people come in with these immuno blots, especially the tick-borne relapsing fever talk. Also a little bit about this, because it's a cousin of life.

It causes Lyme like symptoms. How many of these species you're picking up on the tick-borne relapsing fever immuno plus eight. Eight of them. Yeah. So what we have found recently that Borrelia is on the rise.

And we've got that on the East coast as well. We are very certain that that's what we are picking up on the East Coast. Another one we have found is tajika is quite common.

People don't talk about it. They, it's animal species. No, it is human species. I mean, that was the first species we found on the Western blockbuster Zika reactivity or Zika.

And in our mating, more violence patients as well. We had found two years ago, like in Texas. And we are finding there Zika Miyamoto is the other one.

And we read a few cases where we feel it's Parker Ray as well. And, you know, with the markers we are using, we can differentiate them and sometimes we can't.

But most of the times the patterns are becoming quite standard. Now that we understand what's going on, we debrief and we are finding that quite maybe not that much on the East Coast is we are finding in Midwest and in California, on the West Coast, it seems to be higher percent.

Yeah. The the interesting thing about tick-borne relapsing fever is these patients don't have the classical symptoms

of relapsing fever. Yes. And I think that is what it is very misleading when we try to talk to people.

They said no, you know relapsing fever is relapsing fever. You don't need anything except BCR. What would you say? I know I can tell you right now from my experience with it also, you know, I mean and you're right, I mean, what you're discussing is the classical textbook definitions like a bbca.

You have to have hemolytic anemia, renal failure, and elevated liver functions. Right. We don't see it. I've only seen two cases by the way of hemolysis in my patients and all these thousands of people.

And most of the time it's in hospitalized patients who have congestive heart failure and other serious issues. That's, by the way, that was the whole issue with the Chinese government.

It wasn't looking like and smelling like the bishop, but it's what you and I see which is like, no, the textbook definitions when you're mixing these organisms together, whatever you're reading in the textbook doesn't apply.

I it's true. I don't see the classic tick-borne relapsing fever, relapsing sweats every couple of weeks. We don't see that what we're seeing in these sub clinical presentations in people.

And so yeah. So it's you're right. It's a very different kind of presentation, especially when all of these bacteria and viruses and parasites are mixed together.

It's changing the way the body's immune system and even the clinical presentations of how they're presenting. That's true. That's exactly what happened.

So the initial cases we found here in California, where we decided to just look because doctors would call me sometimes and say, hey, the patient is all the symptoms.

Why is my patient not getting a positive test? I said, I can't make a test positive or test is a test and I can only tell you what the results are. So that got me thinking. What can that be?

And then of course, in the literature they talk about relapsing fever being present. So we decided to look into that. And it started happening that these patients were really positive for relapsing fever and not for Borrelia.

Very clear pictures. And we would look at multiple species of Borrelia to see if it's one of the other species that they don't have on the West or Darwin detecting that.

Or are we detecting relapsing fever?

Broad tick-borne testing and global species detection

And I could blot that in if I just show you anybody who sees that test, you believe that this is really true because we've got quite a few of them with all these nine species of Borrelia on them and then multiple species of relapsing, three were on the other one.

And you compare the patient is one or, you know, doesn't have it. Some patients have Lyme, some might have mixed infection. We have shown that by culture as well, but mostly that.

But all of them had similar symptoms. Interesting. You know and also with hard tick relapsing fever. Brella Miyamoto I. Yeah. The people who are immunosuppressed usually are the ones who we know get the worse symptoms with all of this.

But it's not easy. Although they say, you know, you can get it on certain antibody tests or PCR IVs. We have a tough time picking it up right in the patients that I've really only found that your tick-borne relapsing fever blot right is is an easier way to pick it up.

But these are soft ticks. So I mean do people do any of the patients actually say they've seen the soft ticks attached? Because, you know, obviously in this part of the northeast we don't see it in the same way.

No, they haven't said it. Maybe it's for a short time for relapsing fever dissolve. Ticks are attaching that. We are not really seeing them. Or if they are, they don't think about it.

My other thought, I don't know whether that's true or not, because is it something in your locally not, you know, from which you are getting ticks like here we have a lot of squirrels, in California, are they getting the ticks and the soft ticks that are causing relapsing fever?

Oh who knows because it's quite common. We don't know where they're getting from. Maybe there is a different host that we are not aware of. Yeah. Because I mean, you know, when you look at the literature years ago, you would see like really Herm site infections in Arizona.

Kids would go camping in the woods in old cabins and the soft ticks would be there. Right? There were reasons why they were getting it. But it's clear that these things are under the radar.

Like a lot of these infections are starting to appear in people under the radar. And that's really the beauty of these immuno blots of being able to pick it up when when you just don't suspect it otherwise.

Right. So I and I think it's important we are finding there. So we always recommend do both. If Lyme is negative their symptoms up you must go for relapsing fever.

And that's something we are still what I mean it's there. But you know like every other test we continuously look at new markers to add on to that as we learn from the results what we are seeing.

But as I see it, it was quite a surprise to start seeing from the East Coast. We in fact had a patient who called me from the East Coast, a good friend of mine, and she said she got a tick bite and she had a rash.

She's like, and these patients, grocery cart grocery is one of the Lyme antigens. So she did the tests and it came back positive, and I got her blood.

She was positive for Bbca, not micro T or Duncan. Uncanny. And she was positive for dedicated. And what happened was it went to her. I had I got infected she she called me and says, you know I got this infection and they've given me a viral treatment.

It's not working. I said, well, I've just looked at all your results. You could be seen relapsing fever. You are not micro t done kind of. You have a different species.

And sequencing confirmed that it was way busier species. Yes. And she had to record it on the East Coast in Massachusetts. This happened. Right. So I mean, we're learning over time, kind of like this is the calving field, right?

I mean, it's all it's all kind of changing over time. Are there any other tests that you're doing right now for my genex that you think you want to tell people about that?

Yes. Sorting for them. So the other test which we find quite useful is the, culture test. And it's working really well. We got some data. This is like really?

We thought it will only grow Borrelia. That's what we started out with. But once we started getting, the cultures growing, we had a study going on for over 100 patients that we followed for months, up to four months.

And we found that in some of them. So we said, okay, four months, what are we going to do? The best thing is to palate the cells. And then, make Western blots with that palate.

So whatever it is there, we can put on a blot and then test it with different antibodies. That we had rabbit antibodies to different pathogens. We did that for Lyme, Tiberius, the BCR and Bartonella.

And when we tested that, we were able to detect, antibodies by antibodies. The antigens were just like our own, a Western blot. So from cultures, we were making Western blots from patients culture and testing them.

And my dad, you can see really that's something they're going to publish sooner or later. But there you can if you have tested a patient's, culture by certain antibodies, suddenly you might see one in some patients grow.

And I was showing all the bands to one particular, pathology. And like, maybe we might see two Lyme. We might see two homes. Yeah. For example, two Bartonella.

And we got this data, which was very surprising because we thought we will only be able to grow Borrelia and not by Busia, but the Busia du Bartonella grew TB.

I guess we expected to grow because Lyme and TBR have a similar. But that was very encouraging to see. And we're also seeing in real cultures, Rickettsia grows very well in our culture, media.

But the most interesting thing is we are finding things that we would never think of, when we culture like we found a different species of anal plasma in a patient that has only two cases reported from South America play die.

And the treatment is different. And when we send out for sequencing, what, the one that was positive for in plasma, it turned out to be black Cat and we didn't know what that was.

We searched and it was from South America that that two cases. So we informed the doctor this was under research. And we found when we're doing babies are looking for babies, yet babies are primers cross-reactive with Globo pedia.

That is. And this is something that, this is a published paper where they were looking for babies in horses. So using those primers, they did PCR. And in that sequence 50% of the horses were infected with Globo pedia.

And what about ciliary? You know, you see it over time in the literature. And I've always wondered whether some of these patients that, you know, are negative by standard testing.

It's not really they don't really talk much about the area, but it's in the literature. Are you finding, like any of that getting in?

Tick-borne relapsing fever and culture testing

We haven't found any culture positive fertile area at this point, but there could be reasons we our cultures might not be working. They may not, you know, but that's something we haven't found is yet in any other way but global PDA.

I mean, there were two cases reported from immunocompromised patient. We have already found three patients positive for proper PDA culture here in US.

So that's something that is, you know, positive in patients that we are finding. And you've gotten around some of the, you know, for those of us who've been in the field as long as I have, over 40 years, you've gotten around some of these problems with the culture testing that was described years ago.

You don't have the same problems that were discussed years ago with it. No, we don't, because I think one of the things when you do culture, you got to be very careful how it is done.

Contamination is your biggest problem. So the way we do it, we this method is very simple. We are not using slides or anything that you would contaminate things because the original culture method that was done by advance, they had to put a special slide in it coated with something so that it would work.

But then you peel it off from there. So, you know, the handling part was really messy for, clinical use the way it was done. And that didn't work well in our hands because we originally got the recipe from them, what they were doing on the license, and we tried it for two years.

In the end, we gave up and we said, we can't do it because what was being sure, what they were calling positive. I had a hard time believing anything because on the IFP slides, every sample I could not see a single thing that looked like Borrelia, and they were calling that a defeatist culture.

You have to see a proper Borrelia in the culture. If you can't, then there is a problem and at the end I said, I'm sorry, but I don't think your test is working.

So we we are giving back your baton. You know, it was expensive a I had. That's fine. It's done with. But that's our answer and we continue doing our own culturing because we were already culturing all the brilliance pure culture.

So we said, why can't we see what will work? Well, we can play with that. When we did. And in fact, we grown at least 3 or 4 tubes for each patient. And we do culture. It's not it's simple.

It's pretty complicated. And then we run pieces on it. That is why the test is expensive because there's a lot of work that goes in to make sure that when we give a result we know what's absolute.

We are sure that it's correct. We don't provide sequencing information because it's just too much, but we just tell them at the genus level and species level what we are finding.

So when would someone use, for example, you also have a lymphocyte transformation test. And Elizabeth asked culture when would someone decide? Because in general I have found the immuno blots and fish testing to be most of what I need.

When would somebody need to do a culture test or nella spot with a lymphocyte transformation test? I when they are immunocompromised, for example, they are going to be negative on the antibody test that might that is when it's useful.

Sometimes people want to know species or know that it's useful. It's not something if you I find the immuno blots and immuno give you most of the information.

Then if you want to know, some people are doing is taking some medication and they want to see if it's cleared. That is when they're using culture to see if it's cleared out completely or not.

Okay. So you can use it there. And some people just want a confirmation of what it is. So they order. Now what's very interesting is most people think that you just need to order tests for Borrelia.

When we are culturing a lot of scans, what we found is a patient is negative for Bria but positive for Rickettsia, for example of in a plasma and people don't think about it, that those are the things you are finding, I don't know.

Rickets seems to be quite a common problem. And we are finding different species of rickettsia, you know, cultures, have this kind of interesting because we never were thinking of doing it against.

Yeah, but it happens to grow extremely well in our culture. Media got it. So. And and of course, we're not just talking Rocky Mountain spotted fever, rickets.

You were kept saying North fever in the Brunetti you're talking or even typhus you're talking other species of Rickettsia, like you're talking even like the Swiss agent that they had discovered in Europe years ago.

Haven't found that. But, you know, we don't always go and sequence them because that was what we do for a but now for clinical samples, which is reported as rickettsia. Yes.

Okay. That's very good. Yeah. Good. So so it's mainly these people that either you want to prove like with by culture that we've really eliminated it.

Apart from clinical symptoms, immunosuppressed patients you could use the LTT but but otherwise for the most part you're what I'm doing with the immuno blots and fish I'm finding is really going to be the majority testing that we need.

And the other test is the T-cell test. Now we are looking at the data that we collected. We found that it's useful in patients who are literally negative for by immuno blocked.

So again, immunocompromised people, you know, in the stage where very, very early stage, we find the elite sport works extremely early or late in the disease.

It works where the patient has very little antibodies. But when the patient has lots of antibodies, T-cell test does not work in our hands. That's what we saw that patients were bothered by.

T-cells were had very low amounts of antibodies. Most of them were negative by that immuno blot. Some might have been positive by PCR. That's what we found.

Now, there's something very interesting that we published very recently. This is to show the importance of ospi in patients all stages of Lyme disease.

You know, usually if somebody gets a second infection, one of the first microbes that shows up is band 31. It's also antibodies to a spare. And we did a study where we just we looked at patients, just on Western blots at the time.

And, who were PCR positive. It was very interesting observation that a lot of them had 31 band in them. So we recently did a study with immuno blots, took this PCR positive patients and ran then on immuno mode blots.

And we found a lot of these patients that were positive on the immuno blot for or spare antigen from different species, and they didn't have any other markers.

This was very interesting. Only thing we saw was Osprey. A few had, usb-C that we considered to be early disease, probably with AGM, but a lot of them had only or spare what we are talking about late stage.

Maybe chronic for patients who were having it. Very few bands, but they were positive either on IGI or AGM. One of them, but very interesting that we were able to show that importance of 34 in all these patients.

Future Lyme screening and home lateral flow assay

So is this going to be a problem like it was years ago with the VA, the VLA 15, the new lime vaccine that's coming out, which earlier on in the Dearborn, they took out the 31 and 34 bands because they didn't want them Cross-Reactive is this going to be another issue?

Again, we're going to be dealing with now of not being able to tell whether it's a vaccine induced us, pay us B or it's from an actual infection. How is this going to work?

That's going to be very interesting, right? Because 31 is a Ospreys or Osprey and this is what we are seeing. So it's always bothered me when it comes to 31 and 34 being used as vaccines, because patients also have antibodies to this even in late stage.

I mean, that is why we wanted to show the importance of 31, and we know 34 is equally important. Just like 31. In fact, 34 might be even more important than 31.

That's our preliminary data that we have collected. Is markers. We will be talking more about it once we know exactly what's going on with that. So we we may I mean, I wouldn't necessarily say this, and it's not in my

population, but in people who are thinking of getting the VLA 15, this new Lyme vaccine, they may actually want to get tested and find out what their immuno block looks like before they actually take the vaccine, so they understand what their banding pattern is before and afterwards, because otherwise it might be a little bit confusing.

Yes. And again, it's going to depend on what test schedule. Because if they do the standard bloods 31 is never there. So that you never see 31 and 34 on any of those blots.

Right. So that's going to be a big, big pro I think that is one of the problems that we've had forever. Yeah. Yeah. Now this is fascinating. Just so this was great.

Do you have anything else you'd like to add to just tell people? I mean I think we've gone through a lot of the testing. Anything else you think it's important to share with people?

No, I don't think so. At this point, I think we've covered mostly everything. Great. Only thing I have to say is thank you to all the physicians, all the patients who have been supporters.

And I think it's the team. As a team, we have made progress. There's no way one group or one person can make, this difference that we made for the life and other tick borne disease patients.

So I would like to thank everybody and let's all continue working together to even, you know, continue answering questions that come on. Yeah. No, that's great.

And I agree. And honestly, I think it has been a godsend. It from the very beginning of my clinical career, I could not have helped the thousands of patients I've helped without.

I genic. So I want to personally thank you from the bottom of my heart. I did tell this to Nick when he was around. You guys have been great. You've been the front runners of the lab testing, really helping with this worldwide epidemic.

And, it's been wonderful working with you and publishing with you and doing everything. And I really look forward to great things ahead. And in fact, when we finally get adoption trial, a randomized trial, I look forward to working with you on that trial. Also.

Oh, there's something I want to mention, and I need everybody's help on it. Because we have developed a home lateral flow assay for Lyme. Okay. And it seems to be working very well.

The idea is to put it in doctor's office in the beginning with the reader. So there is no subjectivity in it. The preliminary data is very encouraging.

You do a finger prick requires five microliters of whole blood. You put it on the cassette, walk away with three drops of the buffer, walk away after half an hour, stick it in the reader.

You get an answer, yes or no, and it seems to be quite a good, marker. And, that would help just to, you know, like a screening test. Yes. And then, of course, all the other things would have to be done, but that's something we are developing with or in some, you know, eventually to be able to use at home is where the data looks interesting.

We are ready to start our clinical trials now, and we are looking for people to help us collect those patients, and provide us a data. That's great. And of course, because we expect, you know, many thousands of people to be watching this Lyme summit.

For those of you who are listening, if you'd like to participate and help with this very, very important study, what is the best way for them to contact?

You just need to get in touch with you. I think the best way is if they can send an email, do I genex and say they want to participate because, you know, it's only going to happen in doctors office set offices because we can't do

this with tens of hundreds of sites because of the IBS and all the regulations that we have to follow.

We will be helping the doctors get the IBS, and we are looking for doctors who can give us at least, you know, 30 to 40 positive patients at least, so that we get the numbers that we require to get to file for FDA.

Great. So so what exactly? It's the best email exactly to get in touch with you. Okay. Just a JCI digest.com. I'm sorry. So spell it out for people again.

Jennifer Jones s h h ed I genex I g e and next.com. That's great. Joseph, thank you so much for taking the time today. This was great. For those of you who've been listening, we've been interviewing Doctor Justin.

A shot for my genetics. She's been on the front lines with, line immuno blots and Lyme diagnostic testing for decades. At this point, I want to thank you for taking your time.

And again, for those of you who've been tuning in, my name is Doctor Richard Horowitz. I'm co-host for the Healing Lyme 2.0 summit with Doctors Talks.

Thank you for joining us. I look forward to seeing you again in another episode soon. Bye bye.