Evolving Tests For Tick-Borne Diseases Transcript

(Transcripts are generated by AI and may contain errors)

Introduction to Lyme Testing Challenges

Hi, and welcome to another episode of the Healing Lyme Summit. I'm your host, Dr. Myriah Hinchey, keeping up with advancements and testing for vector borne diseases is essential, especially when dealing with the complex and often controversial diagnosis of Lyme disease.

And it's and its associated co-infections. Limitations. in testing when using conventional laboratories can really complicate the matter and lead to misdiagnosis of a lot of these infections.

So given the nature of these infections, which is often nonspecific and intermittent, coupled with a negative test result, this can lead to a lot of misdiagnosis, especially when the practitioner is not Lyme literate.

So you will hear me say time and time again, that vector borne disease is a clinical diagnosis, and I stand by that. But using special techniques by specialty laboratories is helpful in confirming the presence of Lyme disease and also figuring out what other co-infections are present, which can be essential to being able to use the appropriate, treatment for this specific infections in that person.

So here to talk with us today about the evolution of testing for vector borne disease is Jyotsna Shah, PhD. So Dr. Shah is the research and Clinical Director of IGeneX laboratory and has been since 2003.

She has over 40 years of experience in molecular biology, microbiology and immunology and she holds over 20 patents. Dr. Shah has dedicated her career to studying various tests and techniques for detecting parasitic infections, as well as other infectious diseases, and she is the world expert in the fish test, which you're going to hear about and is a way of directly testing, samples from patients.

So welcome, Dr. Shah. Thank you for your time. Please tell our listeners a little bit more about yourself and your work in developing testing for vector borne diseases.

Thank you, Dr. Hinchey, for inviting me today. to talk about, tick-borne disease testing. And where are we? What advances have we made in the last 20 years?

that is what I'm going to cover briefly today. Wonderful. So can we start by talking about tell us how many species of Lyme disease we are actually currently able to test for?

Well, different labs do different testing. Some labs say, you know, I've seen a list of up to 14 different Borrelia species just for Lyme disease. And it put on that test request form.

and we always says test for nine major species. Basically, there's also one has to understand between different Borrelia as they are quite closely related.

So some of the antigens we have designed, we pick up the remaining few species that we don't have on our list. So I think the testing we do is pretty comprehensive.

Pretty much can detect Lyme disease infection from anywhere in the world. We have demonstrated it very clearly in a study that, where we tested samples from Europe, Australia and US, also from South America, we had space specimens.

Mexico, we have covered Africa bio gold.

Borrelia Species and Global Test Coverage

So basically, we know that our test will pick up species that are found worldwide. Okay. And so you're saying your test for Lyme disease looks at nine species of Borrelia.

But then we also have the tick-borne relapsing fever species of Borrelia. Correct. And then that's another how many species? there are about 20 species known.

And of these in the US, there are six major species that are causing the disease. So the way we have designed that test is to detect all the species that are found in us that we know of.

But the way we design our test is I mentioned it will detect species in Europe, in Australia, in Africa. So this is how our test are designed to be very, very inclusive.

One of the things we have to remember when you are testing is a patient could get infected anyway. We all travel either for business or business and pleasure and ticks are everywhere we go to parks.

Hiking doesn't matter whether it's in US or in Europe. In Africa, Africa, you can get bitten by a tick and get Lyme disease or tick-borne relapsing fever.

So that is why when we think about a disease, we look at it from a worldwide point of view. Even though you don't get it in us, you are traveling so when you get back, you may have got it from somewhere else.

Right? That's a very good point. So can you tell us when we're talking about conventional labs? Right. And you, you have a Lyme test done. What specie or species are they looking at?

They only look at Borrelia burgdorferi sense a stricter, that is, on what causes Lyme disease mostly in the US. That is what it was thought. But we all know that that many species found in us as well.

There are publications, things that mean this is what we knew in 1994 that there was only one species that was causing the disease. Since then, many other species.

Just to give you a few examples, Spillman. Mahoney, that everybody has accepted exist. You they Spillman this Californians basically. just to name a few.

Guarini has been found here. Obscenity has been found here. So all the European species are also not being found in patients in U. S. And sometimes there are cases where they say they have never traveled anywhere, but they have the disease.

So it's important that we test for that. In a conventional lab, they'll only test for the main species, Borrelia burgdorferi. Strict, sense of stricter.

And because they do that the test itself. When you think about any test, you do look at the specificity. How good is the test and how many is it going to detect my disease.

So there's a balance. And the big labs the way they perform the test today. The two tier test that's accepted, is the gold standard by CDC. It first one is analyze the test.

So basically what is an Elisa test. It's a mixture of antigens put on a plate and then you test your serum against it. You can get positive and negative.

You are putting everything there so your specificity is not going to be high. The idea is it's a net where you collect all the positives. Plus negatives, some negatives, and then you go to the second test, which is very specific, and get rid of the non line in principle that is what it is.

But we have problems with that here in us because the first test does. It is only made from the one species. So it's missing a lot of patients when you're trying to catch it in the net.

Right. and also so it's about 75 to 80% sensitivity at the best. And the specificity is around 80% at the best. So when you do that test, you miss some out.

Then you go to the next stage. And that is also not hundred percent sensitive. So when you combine that you could miss up to 50% of the patients just because the way the test is.

Of course newer tests have come out since then. This is in 1994. Now we have the two Elisa modified two tier test, which looks at two Elisa's. That test right now, the is more specific, but you know, you are still using one pathogen to design the test, so you are still going to miss a lot of patients.

And that is the problem. Improved the specificity by doing that but not the sensitivity. So the analogy that I like to use with my patients is that if I give them a box of crayons and you have all the basic colors, they're in the crayon box and I have them pick out a crayon and let's say they pick the green one.

And then I do a test that's only going to test for a red crayon. Obviously they're going to be negative. They're not. They don't have the red crayon. But I can't tell them they don't have a crayon. Right.

So it's like with lyme if you're only looking at the one species of Borrelia and you don't have it, that doesn't mean that you couldn't have one of the 20 plus other species of Borelli at that cause Lyme or tick-borne relapsing fever, which is very, very similar to Lyme.

You are absolutely correct. And that is why a lot of patients get undiagnosed. Right? Because, you know, we all go to LabCorp and quest.

Limits of Conventional Two-Tier Lyme Testing

That's the standard lab for other chemistries and everything. Doctors know that. Well, and that is what happens. This is why you need to go to a special dealer.

Now, when you talk about debrief tick-borne relapsing fever, there are no good good test out there. Yeah. Big labs only do homes. Yeah. Not you know, and or total antibodies.

none of the labs know for now they've started doing a PCR test for Miyamoto. but nobody is really looking at and looking at the serology in detail is we are right in that is very important to labs for the test for, tick-borne relapsing fever.

We do I, I Jen and vibrant does. But the quality of test varies drastically between the two labs. Our tests are very, very inclusive. I can only talk about what I know that and, I, I cannot say how good the other tests are, but from a scientific point of view, the way we have designed a probe, our targets, it's very inclusive.

We have tested it in Europe, US and Australia, these studies. And we detect tick-borne relapsing fever in all these places. In fact, in Ukraine, they didn't even know there was any tick-borne relapsing fever till we tested the samples for Lyme and then fatigue bone relapsing.

We will we were able to tell them that you have tick-borne relapsing fever in Lyme there and also tell about which species they were finding because they came to us and say the, you know, immune bloods they were using that are very popular new Europe.

We have used them, but our patients are negative. A lot of them. We know how we sick the disease, but they are negative. Please can you help us so we agreed to help those said look, first of all, send us your samples.

We'll test it for you to see what we are finding. Then we can guide you is what you need. And now that really well said, they can find Lyme. We also told them about Tick-Borne relapsing fever.

The lab does that as well in Ukraine. It's a very well established university lab for those diseases. No. So on top of

not looking at the species of Borrelia that cause tick borne relapsing fever and not looking for, you know, the other roughly eight species that cause just regular Lyme, what are the other reasons I want to stick with conventional labs for now?

Because that's what, you know, most people that don't know any better, and even physicians that don't know any better are using, why else are there so many false negatives?

So, let's start with talking about testing too soon, right? Like if you're using an antibody test to detect antibodies right after you were bit before, the immune system has had time to generate those antibodies.

And then can you talk about what you think, the other false, reasons for so many false negatives would be as well. Okay. So I think before we discuss diagnostic methods, we need to understand this, specter of the disease and what comes up.

And, so, say, when a person is bitten by tick, the first target, that it is the T cells of the, and, the T cells are the ones that detect it, that will go to foreign matter, and they'll start the reaction and in play and in return.

And they will also, initiate the IgG response. Okay. But most of us, when you're bitten with a target, this is very shortly the T cell response. We don't generally nobody uses that test at that point too early.

You Mr.. And the other test that will be paused even a few days because where you are bitten by, tick, they are going to deposit some reference Borrelia or the methods are going, the co-infections, infections, babies, whatever that particular tick is getting is going to get, into the bloodstream because they bite you and you see a rash where the, the tick has bitten.

But the problem with that rash is it can be anywhere. You may see it sometimes. Sometimes you don't see it because it's in a place you can't see. So about 35 to 40% of all cases you will see a rash is detected.

And you can define it. Now there. Right. Issues with the rash as well as we know that, it may not be Lyme disease. It could be something else. And you have a rash and you could be just, like, not misdiagnosed as just Lyme disease.

Positive. Then you could be having other co-infections in and you are not treated for that. So, you know, doing the right diagnosis is very, very important.

You have to look at the co-infections. For example, the bees, you know, is very high in us. It's well documented. Now in our studies we found that there are more cases of the bees.

Yet then of Lyme. Of course, the samples we get, a lot of patients have already been screened out for Lyme. But the other diseases, nobody's really looking.

It is well, as we do, and that's why we detected that. But clearly that just makes a point. And a lot of patients can have multiple infections, not just Lyme.

It could be babies. Yeah, it could be Lyme babies. You know, any combination possible. So when you are thinking diagnostic I think we have to get away from Lyme disease alone and think about tick borne diseases, which includes Lyme babies.

Yeah. Which is a parasite. Borrelia bacteria and no plasma. elec. Yeah. And Rickettsia. Rickettsia is becoming very important. It's spreading. Recently, we had five deaths in California, due to rickettsia infections.

so that is also getting very important to diagnose and treat because that really, you know, is quite dangerous and it is spreading. so I just want to let people know that they should be thinking of the panel and not just Lyme disease.

Right? So we can't I think a lot of people think like, oh, I've been worked up for Lyme and, you know, using Lyme

interchangeably with tick borne disease where it's not.

Right. Lyme is just one of the many, many things, one of the many pathogens that the ticks carry. Yeah. So okay, so we started out and say that you are bitten by a tick. Now in the first week or so you PCR could be positive because it goes into the blood stream multiplies.

And that's and you will be able to detect it. Then the IgG response starts. But it takes about two weeks before you can physically detect it in a patient.

It may be there, but the amount is so low that you can so that start and you can detect IgG antibodies. And then that converts to IgG. And in some patients the AGM lasts for a very long time.

It a low level. Others it converts to G and years old. So that these patients with the AGM can last for a very long time. And therefore in chronic stage of the disease, we often see AGM and not ECG.

So and then PCR.

Why False Negatives Happen in Early and Chronic Infection

From our experience we say it's early disease, but in patients who may be immunocompromised or have some underlying diseases and may not make good antibodies, BCR can remain positive during that for a long time, from beginning to all the way to chronic stage of the disease, we have seen that.

So the thing is, when there are too much antibodies present, usually PCR is negative. That is our experience. So what we recommend when somebody doesn't know it, what stage of the disease they are, we would say do the immuno blots or do serology and PCR.

And you know we have found that by doing both in patients, because if you don't know where the patient is in the disease, PCR definitely helps their patients.

We find about 10% of the patients. I just PCR positive. Some would be PCR and a set of, serology positive. So that's our recommendation for any disease is to do a panel approach where you look at the immuno blots that are the best if it's available, otherwise IFP and PCI.

Okay. So for our listeners, I just want to be clear. So PCR is looking for the DNA or the genetics of the organism. It's considered to be a direct test where as Western blots, immuno blots, these other tests that we're talking about are looking at the person's immune response to the infection.

And so they're considered to be an indirect test just to make that differentiation. But I wanted to give, Doctor Shah the opportunity to just let people know how to find out more about testing for vector borne disease.

So go ahead, Doctor Shaw. Okay. So we again dedicate our lab to Lyme disease and tick borne disease testing only. That is all we do. And one of the things we do is make sure that we keep up with the literature and update our test as necessary.

If we find something that we think is important, we will incorporate that in our test. For example, really, Zika is a tick-borne relapsing fever when we first mentioned it that we are finding it in patients, we are told it's not a human disease, yet we kept on finding it and we just call it the species that that time in letting the doctors knowing patients were getting better.

Eventually, the CDC published a paper from patients. This was done by PCR culture and PCR. They detected Zika in patients as well. Now it's accepted that Zika motorcycle like, Borrelia is causing disease in humans.

Just to give you an idea about that. So if you need any information, you can reach us, by calling us at Hygin X. Our number is 1-800-832-3200. And as for customer service, they will be able to guide you as to what should be done,

what testing is available.

Secondly, if you go to our website I genex.com all the information is there. We have a portal for physicians and we have general information is read. Now if a physician wants to do testing with us, they can get their results directly.

There's more information on the physician physician's border. Once you sign off with us, there's no fee or anything. We can give you the portal for yourself.

So that's how it works. Each physician has their own border and they get the results. they can go in and download the results for their patients. Wonderful. Thank you for sharing that.

so, Doctor Shah, we were talking about immuno blots. So can you tell our listeners a little bit about so what is the difference between a Western blot and an immuno blot to start.

And then I want to talk about the difference between conventional immuno blots and what a specialty lab like hygienic does, and how their immuno blot is different.

Okay. So Western blot it is made from culture okay. So you have to grow the pathogen. In this case let's take lyme in example. It can be any one of them.

You have to grow it in culture. Then you lysate concentrate lyse it and then you separate the protein by size only by electrophoresis on acrylamide gene.

So once you have separated your proteins out, say they were 4000 proteins. Some of them are going to be of the same size. There's limitation to how much you can separate those out.

Once you have done that, you transfer the proteins that are on the gel onto a membrane. Okay. Once you get that membrane treated, you're ready. And that is what is used to test your serum.

So now what you're done is you transfer the proteins and separate them by size on this little strip. And then you test the, patient sample. You see a signal where the patient has if the patient has good antibodies.

And depending on the pattern of the antibodies, you can see, you know, whether the patient is positive or negative. The problem with the culture is that it's going to be dependent on how the culture grows, culture conditions.

And then the protein expression can vary on that. Also the other variable that you have is your separating them by agar, by gel electrophoresis. And as I said, the culture can vary.

You can get some variations in the proteins as well. And the position of the protein, which keeps on changing slightly every time. Whereas an immuno blot this is advancement from a Western blot.

There are two big advantages. Number one, you are not dependent on the culture anymore. The proteins are synthesized. So you're making the protein of interest.

Once you know that and you have the sequence of the protein, you can manufacture it in the lab. And so once you have made it it's consistent. It does not very it's not culture dependent, temperature dependent or electrophoresis dependent.

So now when you make a blood immuno blot you can put any protein you want where you want on the strip. So you know exactly at what position, what antigen is present.

Now for the western blot if you want to dose western blot, for multiple species, it's going to be very cumbersome. It's going to be a big blot. Number one, you have so many variables.

Say you're trying to grow eight different cultures. They're going to be variables. Position everything. And the

amount of work you are going to require is tremendous.

So in terms of practicality it's going to be impossible to make a blot with nine species or Western blot. But when it comes to an immuno blot, you can do it because you are manufacturing these proteins.

Once you have made your lots of proteins, say you have 30 proteins, you and you know exactly where you are, spraying your proteins. You know the exact size.

And out of a big gel, which could be quite big, you end up with one strip, very three millimeter strip, maybe 12in long, and that will have everything on it.

All nine species. So now you converted it to a practical form. The variation goes away. You know exactly where it is. it's clean number two, because when you do a Western blot, multiple when proteins are migrating at the same place, for example, if there's a protein at position 31 kDa, which is very specific, you bro, you all know about or speed the first vaccine that was made against it.

And in addition there is a housekeeping gene that go migrates. There. So that is why 31 was never used. You know, to decide whether you are good line or not, because 50% of the times it could be negative, false positive on a Western blot.

But we know from our experience that. ospi. That is very Labrador free antigen acquisition. 31 kDa is very good marker for Lyme disease. And therefore, when we make an immuno blot, we can use it because now the background noise is gone because we just use the correct antigen.

That's how powerful an immuno blot can be.

Immunoblots vs Western Blots

And you just put it on that membrane, what you want, you decide not what the culture decides for you to look at. Those are the advantages. So the biggest thing is that with the Western blots, there can be a lot of cross-reactivity, like various viruses and like you said, you know, the the gene piece, but with an immuno blot it's cleaner.

So you know exactly what the antibodies are. React to if they're present. That is correct. Okay. So what is the difference between a and immuno blot that you could get from a conventional lab like let's say quest or LabCorp.

And for example, the immuno blot that I genex has a big difference. As we talked about, it's made from one species that is, worms is made from main species.

Right. But then you also have bands, right? You're looking at proteins that are not looked at as well. So you're looking at more species, but then you're also fully evaluating all of the proteins or the K-T bands.

Whereas the western blot, at least with quest, is looking at like ten K-T bands for IgG and only three K-T bands for IgG. That is correct. So we look at more bands, we look at five bands for IDM and six bands for it for reading our criteria.

So I in fact we have 12 bands for IgG and five bands for AGM, whereas CDC has three bands for AGM and ten bands. So we include 31 and 34 bands and we find they are very specific and they're very useful in the diagnosis of Lyme disease.

Just to give you an example, we recently did a study with CDC samples. These are well-qualified samples in a blinded fashion, 280 samples, out of which 90 were Lyme positive.

The rest were had other infections that can mimic Lyme disease symptoms. And our specificity with our criteria, where we look at three bands out of six was 100% in. And the comparing to what the the limited information we had, I Gen X performed the best in terms of sensitivity as well.

So we are you know, we think our plots are very good for detecting Lyme disease. Of course no test is 100% sensitive. We have to accept that. but it is, where it is in the top.

It's probably the most sensitive and specific immuno brought on the market. It's wonderful. And again, you know, with we can't always rely on a test, like you said, there's no test that is ever 100%.

So again, we have to go back and use our brains. And the tools that we have all been taught as, diagnostician is right. Absolute lay it. The tools are to be used with clinical symptoms.

and where you are staying, you know, sometimes nothing works. It could be a new strain. Nobody knows. So physician has to make the decision in the end, right?

They have the expertise and the knowledge, and they know their surroundings. So they can make the best diagnosis and provide the patient with the care they need.

Yeah. You know, another thing about specialty lab testing, too, that I like is, you know, with the conventional labs, it's either reactive or non-reactive.

And I like how how these specialty labs will give you, for example, with Iconix. Right. You either get, A-minus, as in it's not there or you will get an indie, which means there is an antibody response.

It's just a weak antibody response. And then you get your plus or two pluses or three pluses are four pluses. So in an infection that can suppress the immune system's ability to produce antibodies in response to it, as a clinician, I think it's super important to be able to see, you know, those I and D levels, which is showing a response.

But a weak response. Whereas this is another thing that in a conventional laboratory, like you would never see that. But I think when you say indie, indie means indeterminate, that the signal was there, it could be positive or negative sometimes.

What that suggest to you is that you need to retest the patient if they've just started making antibodies, and maybe if you tested them four weeks later, they'll be better.

Antibodies. If that was truly the case, it will help you confirm it by retesting 4 to 6 weeks later. we see that like, for example, you can take an early sample where you barely see a band or maybe see one indeterminate band, maybe 30, 23, for example.

That's an early marker for Lyme disease. And then if you test four weeks later, it turns out to be, you know, you see both the two bands, three bands and will be truly positive.

But so what you just said, looking at those bands really does help you. If you think the patient has it, you can retest or treat. I mean, as I said, the physician has to make the decision based on symptoms and signs.

Yeah, exactly. The what other technologies are there? can you tell us a little bit more about the new microchip technology? Sure. So the microchip technology is, as you know, vibrant, uses microchip technology where they can put up to 44 different antigens on a chip.

And they do look at Lyme disease and, and other diseases, that's what so that allows you. But it's really an Elisa at the end of the day, you are doing on a chip individual.

Eliza's in reading. there was a study done which is published where, the cheapest label is used. and what when they looked at the sample, the sensitivity, the specificity was pretty good, 97%, but the sensitivity was around under the best condition that they compared a set of CDC samples because that I can, you know, can use to compare other test was around 66.7% using the same set of samples.

because it's a CDC said, if I just look at the data and what we find in our test, we are far more sensitive than them

using the same data. So the immuno blots seems to be performing better than a chip assay at this point in time.

Now there is an FDA cleared test on a chip. Now why? We're amazed they come out with a two tier test, standalone test like the two tier modified Eliza, which is done on a chip.

And they do look at multiple antigens as well and report out a result as positive or negative. There isn't much more information on that except that it's cleared by FDA.

Now is a standalone test on a chip. SC and there is an IgG and AGM chip is read which differentiates them for Lyme disease that seems to be working similar to immuno blot.

Yet we don't you know, it's I don't have much information on the performance, but when I looked at the data that's published, it seems to be similar to the standard immuno blot.

Nothing special about it. Okay. So what would be the advantages to using, like this new technology? the advantages that is that you can do the test, multiple test at the same time in a shorter time.

But, you know, I think the way we are looking at the immuno blots right now, within a year, we expect that everything is going to be automated, just like in Eliza.

But with the sensitivity, specificity in all the details, we you currently will be able to do that. So at that point, yeah, we are there almost. But you know, we need to do a little more work before we said that we are ready.

But the data looks extremely promising for us. Well that's exciting. News. And yeah. So I think automation is the way to go. Then maybe once we get enough samples in this comparison.

But I feel that the technology we are using and with what we know, it seems to be working very well, and we'll be able to translate it to all the diseases.

That's wonderful. Yeah. So serology will be better, more practical we hope, as we move into automation. Right. And so obviously that's one of the challenges and limitations right.

How long it takes.

Specialty Lab Bands, Indeterminate Results, and Microchip Assays

Because you're actually growing it. And you're doing like this whole test where you know with the immuno blot. What other challenges would you say or limitations are there.

What current Lyme and co-infection testing? I mean, let's take the BCA, which is the second most common one. The problem is we do not have good testing, right.

currently there is only immunofluorescence assesses that in everybody all other labs can use there are no immuno blots. And those test also are dependent on the whole cell.

So depending on the quality and how and if it is, you know, you read it manually how good you are, the other auto fluorescence issues and things like that.

And since you need a technical person to read it, there's always going to be limitation to microscopic technique. So immuno blots get you out of that.

That's one big advantage. And the only lab doing immuno blotters such is us. the ACA is on the, vibrant microchips as well, but they have limited, antigens on that with the immuno blot.

I think we are very inclusive. And the data that we have is extremely, you know, promising. and we hope that, that

will, I think our test will be busier at the best.

We have a fish test. That's a it's a direct test. It's a test that only I can offer is for BCA. We developed it, in 19 I think 97, 98 timeframe. And it is considered one of the best test for the BCA when a patient doesn't make antibodies.

that test is going to be positive because it looks at the RNA, the pathogen itself. from what I hear from the physicians, they say that, you know, when everything else fails and they get a fish positive sample and they treat the patient, the patient always gets better.

So that says that that test, you know, works where other tests have failed. And it is well respected. Test in for the BCA. That's great. But unfortunately you cannot do this test for Lyme disease.

The reason is in Lyme disease the bacteria are very few in the bloodstream. So you are not going to be. The sensitivity of the test will not allow us to do that.

Whereas with the BCA the parasite is in the red blood cells. So you can see. Right okay. And so you know what that just made me think of something. So there is the ability to look right with a PCR at urine and test urine for Borrelia or Lyme disease.

Can you talk about that a little bit. So in addition obviously this would be a great test to use in pediatrics. are there other times where this would be a good choice for patients or practitioners to use this test?

Okay, so what we have found just looking at the overall picture, sometimes the patient is negative. But every other test we always feel that we get more positive.

The immuno blots then followed by PCR. but then the just the regular serum whole blood PCR. There have been cases where everything else comes back negative urine PCR comes back positive.

There was an ALS patient who was naked doing everything else, was told, that he will have six months left of his life, is still alive after so many years.

Because he looked he did not believe it. He was a physician. He didn't believe it. So he looked and looked and then, you know, send the samples to us.

And the only test that came back positive was the urine PCR. We know the sensitivity specificity of that test is really very good. 90 greater than 99% sensitive is not very good.

We know. That's why we do not ask everybody to do the test. What is the sensitivity? I don't know because I don't have enough samples to really give you that answer.

But we recommend that if the the test fail, you should definitely do urine. Some doctors believes that it should be done after antibiotic challenge. Others will ask them to do it before they start the treatment.

I have no proof one way or the other. Which works better. There's no you know, it's a study we can't really do. and, so that's where it is. But it's a very useful test.

The test we have is very specific. So we know when somebody is positive, it's truly positive. Another test that's worthwhile really looking at that we don't really talk about much is the antigen test.

our antigen test is specific but not as specific is the PCR. But now we are more and we the system has been upgraded so we can see more and more species of meridia with that test.

It's quite works very well. And I would recommend that test is useful for pediatric patients with PCR to do the antigen test. it's noninvasive. And also we recommend that when a person orders Lyme PCR to include that test, we always recommend panel approach is I said different people different thing and behave differently.

So if you have both the test covered you're getting there's a better chance of finding it like we talked about then crayons if you your test picks one crayon you missed nine.

So here you are adding more. So you should pick up more. Both tests are very good. And what is the medium that's being tested for the antigen. It's at blood. Like what?

What sample we do urine sound. You do urine okay. We do urine samples for that. So it is a is it a culture from the urine. No. So I'm going to talk about no we don't do culture from urine.

It doesn't work for Borrelia. But we do have a culture test we introduced last year after working on it for multiple years, several years. It was not an easy thing to develop, but there was interesting developing the test.

The, so we decided we worked on it and we would our goal was to just develop a test for Lyme disease. so we started out with that. And then when we tested, would we develop the medium, we developed what we found was that we were growing all the pathogens in it.

We were surprised, which was yes, we were extremely surprised. And we were able to show that that culture can be used to grow bbca elderly get and Rickettsia tickborne, relapsing fever and Borrelia burgdorferi, a Lyme causing Borrelia.

So all of them. After doing extensive studies on about 100 patients, we started offering the test and it has turned out to be very useful. Sometimes the patient, you know, the physician thinks it's Lyme, that the patient has a problem.

They'll order one test. And since we all do, it was our first year of doing research. So we would test for all the pathogens and grow the cultures for everything.

we found that a lot of patients who were thought to be Lyme positive would turn out to be, they Busia or Alicea or Rickettsia positive. So based on that information, I am right now recommending that if you are doing the culture test, please consider doing tick borne disease panel, not just Lyme disease because you could miss out very important information.

We will not be doing this on all the patients anymore. We have done our research. We know what it is.

Direct Detection: PCR, Urine Testing, Antigen Tests, and Culture

So you know we physicians I would really advise them to when they order the test to the do the full panel, if you are going to do the culture test, you could miss out after spending so much not doing the right test, you could miss out.

And if you get the right answer, the patient gets well with the right treatment. Right? And that's all that matters. So, what can we look forward to? What other advancements do you see coming down the pipe in the future here for testing?

Okay, one of the big questions that we get is that sometimes patients have problems getting their blood drawn. if you are living in areas where it's difficult, sometimes they can't go out.

So I, X has just developed a test which will be coming out very soon where a patient, can draw blood himself or herself because with, you know, with the finger.

Finger stuck. Yeah. Fitness finger stick is there. Say we are coming out with you. Get a blotting paper. You do your finger stick and put drops of blood on the filter paper.

And then you do not need any special way of shipping it to us. You put it in an envelope and send it to us. So it's a dried blood SPI. Blood spot is what we have coming out and we will be able to.

We are going to start out by offering the Lyme test. The screening test, which would give you a you know, the specificity would be extremely high, the sensitivity would be there, but you would not be able to know where the serum it would be for the antibodies to start out with.

That's what we are going to offer. But at least that's a big advancement, because this test is going to be fully inclusive of all the species and everything.

It's great. We call it a screening test, and if you are positive by that test, you can reflex it to being without having to stand any more blood. And so is it like an Elisa or is it an immuno.

It is going to be a yeah. You know, or it's most of the first test is proprietary. Okay. You can test is immuno blots but it will give you specificity and sensitive.

It's not an analyzer. And when you say all of this species, do you mean all of this species for Lyme or for like an tick-borne relapsing for Lyme. we're just going to do Lyme and then we'll consider tickborne relapsing fever afterwards.

But at this point just like okay wonderful. So any go ahead I think then more work is needed with tick-borne relapsing fever. we are working on improving that test.

I mean, to be more inclusive than we are to we want to get it to the same level as the Lyme immuno blot. test. We are really, I think the immuno blots that we have a the best even the tick-borne relapsing for you.

Immuno blots are the top. But I think we can add more to it as well. And then comes Bartonella, which is really a big problem. We didn't know about. there are more than 22 species of Bartonella that's caused the disease.

And we have designed and immuno blot. I think this is the favorite of a lot that doctors like for Bartonella is a Bartonella test. It's one of the most popular test because it's very inclusive.

We thought that there was only one button species that was causing the disease, Martin and Hensley. But now we know there are multiple species that are transmitted by your pets, right?

Like dogs as well, not just cats that you are getting because they come in, bring ticks and you can get it from ticks or from mites or, you know, fleas that getting or from when they scratch you, you can get it if they're infected.

And a lot of patients, are having Bartonella infections, literally. They become very lethargic, they get very tired, and kids don't know what's going on.

But if you get the right diagnosis and right treatment, you can get your life back from Bartonella. Right? So that's something very important to look at as part of the panel.

And I think immuno blots are the best for that. I would highly recommend for Bartonella to do the immuno blots if that is suspected. So if someone were to do the Bartonella immuno blot through Iconix, how many species does the current Bartonella immunology validate?

Oh, at the genus level we look at 22 species. Wow okay. And we species up to four species on the block. So we'll tell you either genus it's it's a different species or is it Hensley Quintana.

which is the the Elizabeth. and so I agree and, and and we do and Sally Donna Elizabeth convincingly is that the most common species we can't do the other ones is where, you know, we are not reporting other ones simply because we do not have cultures to prove, because we need to know on our side like we know it.

But we have to prove it for the agencies and to convince everybody else that this is what we are detecting. So we just reported it species, not species any further.

The if you get a bartender a positive test, the patient has to be treated. Oh for sure. Yeah. And Bartonella can

cause so many psychiatric issues as well. Yes.

Oh that brings me back to so this is a very interesting fact that we have is that one of the physicians several years ago we were getting pediatric patients with neurological symptoms.

Right. So she she heard somewhere that there could be a call. So she started sending us samples from this patient. We don't know who samples we are getting.

We get them, they get tested and results get reported out. Suddenly she calls me and says, 50% of my patients are positive for fish. Are you sure your test is working?

And I said, I think so. I said, let me look at it. I mean, maybe there was a problem. Thank you for telling me. So I went in and looked at it. The samples were ordered a different time points.

It wasn't like all of them came with the same day anyway, and I looked at all the reports and everything else for those days, and it was pretty similar.

You might have 1 or 2 positives or, you know, on that day, or maybe, but nothing unusual that we had 15, ten positives or so I called it, and I said I don't find anything unusual on there.

Modern findings. Pretty normal. So she decided to send her own samples, thinking that, you know, that way she'll find out whether we are truly doing something right or wrong.

So we got our sample and it got tested just like it goes in the flow. So I don't even know sometimes. Then she calls me. My sample came back negative.

So now I believe you that you get the right results. I said we had no doubts because every sample from you when we get a fish positive sample for BCA, they confirm it by PCR independently.

For us, we have to send a positive sample for confirmation to New York State Department. Oh wow. That's good to know. Yeah, yeah. So that gets confirmed.

We've never failed. even when we did the proficiency, we never fail. In fact, we did a letter from them saying that, you know, they did it for us for ten years. We are the only lab doing it.

But they still provided us with the proficiency testing. And after ten years they said, you don't need our help anymore. You never fail anything you can do.

Your internal proficiency is from now onwards. Yeah that's great. So yeah, that fish test is a pretty good. So what else do you think the listeners should know about testing and tick borne disease.

Or I should say vector borne disease. I think to be alert and look at more things, not just be nearer. If you get a tick bite, just don't look at it in a narrow fashion with those, you know, you need to look at the broad, picture and consider all the other common ones and also the area.

If it's something that happens locally, look at what's out there when you're testing to be sure you include the common, diseases in there. I mean, viruses can be exposed as well.

So we need to include that in the picture.

Future Testing Advances and Broader Tick-Borne Disease Awareness

sometimes we see by, we see that it's a virus but has a Lyme like symptom or flu like symptoms. Then ALS patients, you know, misdiagnosing als when they could be Lyme patients.

Rheumatoid arthritis can be mistaken. So you need to look at, broadly. We don't look at it in a narrow fashion is, oh, this is rheumatoid arthritis. Can't be anything else.

It could be you do infection and you can treat it and the patient gets better. this is very interesting. This happened with, one person who had twins.

So when the twins were very young, they were told that, sorry, they got rheumatoid arthritis. And they'll be limited to what they can do. This is very young.

So the father did not accept that because they lived in Lyme endemic area. he surgeon. So then the samples came to us, we tested them and they were positive.

So that was reported. That was the end of it, I think when the kids were about 12 years old, I met the father and he said, thank you. I said, why would have done?

You said, you saved my kids. this is what that's when the story was told me. Says when they were told that rheumatoid arthritis, they did not headline, they could treat it.

They are fine. They go hiking everywhere, outdoor. Both of them are outdoor. But, people enjoying life. but things like that happen. So just I think as a physician, you have to be alert and think of all the possibilities where the disease looks similar.

Just don't, Except yeah, I mean, it's the great mimic. right. And it infects every single cell in the body. Therefore it can mimic or bring out any of these other diseases too.

So I firmly believe it should be in every single differential diagnosis for every illness out there. I think it's more that I agree with you, but I think specially in the endemic areas, children should be screened for these diseases regularly because they are the ones when they are not diagnosed properly, they have cases where they were not diagnosed properly.

The doctor thought is flu. Yeah. And then of course they didn't get treated. And you know, young kids, they have good immunity so they don't feel it is bad in the beginning.

But it hits them slowly and they get worse and worse. So they wouldn't be able to play games. Or they come home and go to sleep. Right, because they're so tired.

And you ask, have you done anything? Why are you so tired? They're tired. And what we found was these kids had with BCA infections. So the BCA was causing all these symptoms in these kids.

This is locally in California. We are seeing that. And once they were treated they are fine. They got their life back and they were not tired. Or Bartonella was the other cause of that.

I know, getting tired, going to sleep. Once it's cured, the patient is fine. So the, you know, it's multiple things that you have to look for, right? And I think that, you know, that's a good point too.

I was going to bring up the, you know, the leg pain. Right. And it's always been just growing pains. And I can't tell you how many patients. It's like, you know, they're oh, it's just growing pains.

It's just growing pains. But it's like, okay, but when it's growing pains and fatigue and, you know, anxiety and stomach pain, right? When it's when it's all of these things and we see like these patterns.

Right. So it's pattern recognition. Right. That's the big thing. Right? Especially in kids. They shouldn't have a multitude of different symptoms that are intermittent and cyclical.

And so it's really knowing the pattern and not putting a different part of the body in a different box. Right. And trying

to treat it separately. Right.

So that I think that's the problem. We've got specialists here. Yeah. You know, we need somebody who can put things together, not just pieces. As we we have done here in us.

The medicine has changed so much. Yeah, we need it as in combination people. All the physicians should be working in not we do specialize and forget everything else. Yeah, hopefully that happens.

At least the family doctors are aware of that. So that's a big plus. Yeah. You know you bring up the screening in pediatrics I couldn't agree more. I also think it should be part of prenatal care.

You know we're still looking for those torch infections right. Like that's in the prenatal. Oh you want to get pregnant. Let's look for these things. You know, testing for syphilis but not testing for Lyme disease.

It's it's mind blowing, you know? Yes. Especially when Lyme can be, you know, transmitted through the placenta in pregnancy. And you, you know, you can have a child born with congenital Lyme, but also it can cause a lot of issues with pregnancy and, in fertility, you know, exactly does. Right.

Because I we're talking to some physicians who do women's health. And they say that a lot of change is hormonal changes, issues with people. Women cannot become pregnant and associated with the imbalance which is due to Lyme disease.

And once she can fix that, they get their life back. They can have kids, they're fine, normal. So, these diseases, these pathogens as something else. She they really are.

We really, really, really care of it. I think that's the important, that to be aware. Yeah. Everybody should be aware that if these symptoms are there to include this is you said I can't agree more with you on that, that they have to get them tested, not at the big labs.

That's the problem. Problem. Okay. So we I mean I would love to accept insurance, but the insurance people have their they don't allow you to get in the network.

Right. that's a whole nother conversation. Yeah. So it's right. By the insurance. Company I know. So those are the issues. I know, you know, but test having good test is expensive because it requires a lot more than just putting a sample in, walking away and getting an answer, which doesn't mean much.

Right. And patients can take their receipts and they can submit them to their insurance for out-of-network laboratory reimbursement, correct? Yes, we do it for them.

Patients can tell us and we'll do it for them, and we do not charge anything for it. Oh, and Medicare. Right. So Medicare as well. And insurance, whatever they get out of network we send them a check goes directly to them.

We take nothing. We do this as a free service because, you know, we want to help patients. And sometimes if the check comes here, it goes straight to the patient.

So that's something patients can use. And you know what. Sometimes they got more than their what they're paid is I mean depending on your insurance it goes from 0 to 100%.

And it's wonderful. So that's something we can always help. Good. That's good to know. I'm glad we just brought that point up. Yeah. So, Dr. Shah, thank you so much for joining us today.

And, thank you all at home for listening. And I hope that we see you soon on another episode. I hope all of the information that you gained today was valuable and helps you on your path to healing from Lyme.

Take care.