Exposing The Gaps In Lyme Disease Testing: What Every Patient Must Know Transcript

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Introduction to Lab Standards and Guest Background

Hi, and welcome to another episode of the Healing Lyme Summit 2.0. I'm your host, Doctor Mariah Hinchey, and today we're going to be discussing what is going on behind the lab door.

So we're going to talk about the global standards driving diagnostic accuracy when it comes to mine and other vector borne disease testing. Here with us today to navigate through this pretty tough topic is Doctor Leona Gilbert.

So Doctor Gilbert is a docent of cell and molecular biology and the CEO of Tested Oil. This university spin off company aims to get patients tested so that they can be treated and recover quicker.

She has her doctorate in biotechnology and a vast experience in bio innovation and bio business. In addition, Doctor Gilbert's several peer reviewed publications also demonstrate a thorough investigation of how a common virus or bacterium can contribute to an autoimmune disease.

Doctor Gilbert's research initiatives into complete diagnostic platforms and clinical profiling of patients for tick borne and autoimmune diseases will allow a better understanding of how chronic conditions can be established with infectious pathogens as potential underlying causes.

Welcome, Doctor Gilbert, thank you so much for joining us. Well, thank you for having me. Absolutely. So tell our listeners a little bit more like, how did you get involved in this?

How did how did this become your career? Know? Well, I actually did a postdoctoral fellowship at Penn State University College of Medicine under Doctor Stanley Needs in the rheumatology department.

And we noticed that actually, the test kits that they were using, for Streptococcus pyogenes actually was failing the patients because that our bacteria was changing shape.

And and when I left, my postdoctoral fellow and came back to Finland to start my own group, I had the opportunity and funding from an American philanthropist to actually investigate Borrelia and how it changes form.

And then that really led the research into, noticing that the test kits, okay, that was being used for Lyme disease, actually aren't recognizing that form.

So in my research group with my PhD students and my research team, we really showed that there's a chronic form of Borrelia. It's not being used in test kits.

And therefore therefore we should do better for the patients. And and that's what's kind of started me on this, kind of idea that we need to do better for the patients because the test kits were failing the patients.

And I would have to say, after all of the out of all of the bacteria out there, Borrelia has to be one of the most fast in eating, to study because of the way that it changes, throughout, you know, its life cycle and, you know, you have multiple different, forms of it in the body at one time.

Yeah, I agree with you. And also it's it's a low abundance bacteria. Then we keep forgetting that we, that it is like you only need a few copies of this to cause havoc on the system. And and compared to like, with streptococcus pathogen, it's it's highly abundant.

Okay. In the system you can really detect it directly, but really is low abundance.

How Borrelia Research Led to Better Testing

It's clear that the bloodstream so quick you know it finds its initial causes have it cause problems and long term problems. And no doubt it's difficult to, you know, detect it and to treat it because these test kits are failing and it's a low abundance.

So low abundance and very, very slow growing. Yes. Exactly. Exactly. Yeah. Okay. So for our listeners at home today, we're going to be talking about the International Organization of, standards for quality when it comes to testing.

So this is a little bit different than our other, testing talks that we've had where we've talked about, you know, direct and indirect and how to read these tests.

So we're actually going to be talking more about like the regulatory side of testing. So Doctor Gilbert, let's start by talking about ISO and really how these various international organizations apply to, you know, most of our listeners are here in the United States.

And then break down cap and clear and FDA cleared versus FDA approved. Let's just spend a couple minutes kind of like navigating through all of this language when it comes to, you know, these various, clearings or approvals or certificate motions that all of these labs carry.

Okay. So I will start globally speaking. So the, International Organization for standardization, these ISO standards are harmonized standards. Okay. That's countries all over the world can adhere to, conform to and should be accepted okay by other countries.

And henceforth ISO okay. And the two ISO standards that we use for testing are the ISO okay, let's say 1345 which is for medical devices. So medical devices that are being manufactured in whatever country, okay.

If they are accredited by this ISO standard, they can actually, demonstrate that their medical device is validated both analytically, clinically demonstrates clinical utility.

Has a risk assessment follows that really great quality management system in its production. Okay. And also making sure that it is in real time always being, validated and performing as it should for, for the patient.

So safety efficacy. So how efficient it is. So the whole robustness of that test kit, how it's performing. So we should not see high amounts or percentages of false positives or false negatives because under this ISO 1345 those characteristics should be minimal minimal in this standard.

And those people hearing to this ISO 13 485 for manufacturing that medical device, which these diagnostic kits are then covered under this ISO standard.

They are audited every year to maintain this quality, okay. To maintain this quality management system. Very and and to it really demonstrates the validation and likely clinically and clinical utility.

Okay. Then the other side to the clinical laboratories that are performing test kits, okay. There's another ISO called the ISO 15189. And this is really for medical laboratories to make sure that they are conforming with the quality standards in performing the test kits, maintaining the test, the test results, okay.

And even sample preparations from the day one that your sample comes in, how it's treated and how it's used, and how the reporting is for the patient or for the clinician.

So we have the medical lab, clinical lab under an ISO. And we have the test kit being manufactured in an array. So those two ISOs come together and verify the the consistent and accurate line testing that can be done globally.

Globally okay. Now cap cap is is stands for College of American pathology. They verify okay. And accredited

laboratories okay. Clinical laboratories under the ISO 15189 okay.

So Cap accredited under ISO one 15189. So if you are if you are adhering to this ISO, in a sense there's equivalence to what Cap will accept this body that regulates the performance of clinical laboratory okay.

ISO Standards, CAP, and CLIA Explained

And and when I say performance of the clinical laboratories, it actually demonstrates, you know, equality in the, efficiency and the quality of performance amongst all the Cap accredited laboratories.

And that really boils down to this ISO 158189. So in a sense, if a lab in Germany is Cap accredited, okay, they will have the same quality robustness equivalent as a Cap accredited laboratory in the United States.

Okay. And one level more. Then if those two cap cap, accredited laboratories use the same test kit that is manufactured under the other ISO, the 13485 for the medical device, then their test results should be equivalent and they should accept those test results.

This means fundamentally that if a test result that is using using, a validated test like one manufactured under 1345 and in a cap approved, okay accredited laboratory in Germany, if it's it should be accepted in the United States, okay, under the Cap accreditation.

And I'm only using those two as an example. But there are many countries adhering to, some agreements, like this international laboratory accreditation cooperation, mutual recognition arrangement.

It's an agreement. I know it's come down here, but it's think. Yeah, it's an agreement that has many, many accreditation bodies from different countries signing to the equivalent of the standards.

Okay. So they will they should legally accept, test results from other accredited laboratories. Okay. And there's, a few of these agreements out there and United States does, does signed to some of these agreements.

And and that really means three that test results, coming out of a accredited lab in Germany should be accepted in these countries that have signed these agreements.

But that's not what's happening with our Lyme disease patients. Okay? And I constantly hear these are false positives. It was performed in an uncredited lab or the test is invalidated.

Well, actually, those are common wrong and misleading narratives that I constantly here because in order for a test kit that is manufactured under 1345 to get that stamp of approval, okay, to be accepted, you know, internationally and also legally to sell it.

Okay, the test has to be validated, has to be analytically. So the performance has to be validated. And then the clinical validation. So it has to be clinically relevant.

It has to show clinically that it does properly diagnose for Lyme disease okay. And and so it's validated. Yes. At the manufacturer's level. But under the other ISO the 15189 that lab is legally obligated, legally obligated okay.

To independently validate that test kit okay. In their own lab and in order to maintain those ISOs. And also because because, after the FDA requires that only validated test kits, okay, come into those labs.

But Cap demands, cap demands based on the ISO 1589 that these test kits be independently validated, be before they're being used under that accredited lab.

So it's easy for people to disregard false, you know, our, test results. Okay. Because just by saying it. But they but they shouldn't because, legally speaking, a test kit cannot be sold, okay, under these accredited labs if they're not independently or analytically or clinically validated.

Okay. So that means that, by just a clinician disregarding test results and saying, well, that's a false positive, that's actually a legally an inaccurate statement.

Okay. According to these standards and legally selling these test kits, okay. In the countries now we we talked I know I'm talking a little bit longer than the two minutes, but, to get back to the FDA approved and FDA cleared test, so FDA cleared test actually refers to equivalence.

So one test is equivalent to the end it's performance than the other test kit. Okay. That is that is, cleared. Being approved means that a new test kit, okay, that doesn't have a predicate or doesn't have a comparison test kit comes into the market and it has it has to go and undergo more assessment because there is no comparative test out there to compare it with.

But cleared means it's just performing the same as, all the other tests. Okay. That's out in the market. All right. Yeah. And then what about clear? Yeah. So clear.

So this is the clinical laboratory improvement amendments. Okay. That's what it stands for. It is it is another a lower level than Cap accrediting body for clinical laboratories.

They do not verify to ISO 158189. They don't unfortunately. Okay. So there is not a demand as stringent as Cap okay. Like as stringent as ISO 15189. And and so like for example, some people will say that's clear doesn't demand this clinical validation okay.

That may be so. That may be so but it is it allows kind of like in-house test kits to be used in house test kits. Okay. So which means that that clinical lab could develop their own test kit, own test kit and use it in-house under their own roof.

Okay. And and in order for them minimum standard that they need to be accredited. Is this clear standards. So they should demonstrate that that test kit is is analytically validated okay in its robustness, in its accuracy and its precision in its sensitivity and specificity.

These are all words to describe the performance of the test kit. It doesn't have that demand of clinical utility okay, as the ISO 15189. So so there's a clear distinction between Cap accreditation and clear accreditation okay.

Cap is is adhering to the ISO standard, the 15189 that demands clinical validation and clinical utility. Not only analytical but also that that's, clear demands of course, the analytical validation.

And of course there you want to show some, clinical validation, but the clinical utility is demand is not there. So there's a higher level of accreditation, higher, higher level of demand in the Cap accreditation because it follows the ISO 15189.

So for our listeners, you need to be sure that the laboratory that they're using is following kind of like the highest global standard that would be looking to see that they are Cap.

Is it called certified like Cap. Accredited. Accredited. Accredited accredited. Yeah. So everyone Cap accredited is what you would be looking for. And in the United States most labs are clear.

Yeah. Like you have to be clear. Yes. In my understanding, yes. And that allows then for you, for that lab to bring on their in-house test kits called laboratory developed test.

Let's. Okay, let's and we, we call them in-house test kits here on this side of the world. But it's it's a laboratory developed test. You have to be clear. Approved okay.

Or accredited in order to carry and or to use your letters. All right. Most most like 99.5% of all Lyme disease testing are let's in in these specialty labs okay.

And and I'm not saying that the the performance is less than accredited. I'm not saying that at all. But I think we should be aware that there are quality management systems and global global standards, okay.

That influence okay, the performance and how we should look at these test kits. Okay. It would be so difficult to bring a test results from a clear proof test into a different country and say, accept this because it's not adhering to the 15189 standard.

It's a lot. Easier into the global standard. Yes yes yes it and but like legally it's not okay. I'm I'm not saying that they can't get coppa cap approval and I encourage that they do in this shift of what FDA is making the, you know, these clinical laboratories go through with their laboratory develop test.

But but it's important for, for patients to know that that by adhering to global standards, their test results should be accepted. Okay. Cross country or even even I can, I dare to say state to state or province to province, you know, and and and that's the key thing that we need to, you know, empower the patients who think this, that it's actually these are my test results.

You cannot dismiss them, you know, or health insurance is to say, no, we we're not going to cover this. Well, you should, because legally, this is you know, it's accredited.

It's validated test kits. There is no reason legally to disregard these test results. And that's what my message here for this interview is, is to empower the patients that, you know, this is the information that you can bring with you, you know, to to say, don't disregard my test result and don't say it's a false positive or, you know, or a false negative.

I'm like, really there there are limitations to to these tests. Yes, we understand, but they're they should be minimized because of these standards. And and we manufacturers don't want to give false results.

And hopefully I. Mean I you know, I think everyone listening or most people understand what what a terrible time most patients have leading up to their diagnosis of Lyme and other vector borne diseases.

A lot of times they have seen, you know, multiple, multiple doctors. They've been told that they're crazy. It's all in their head. They're making it up.

They've been misdiagnosed with chronic fatigue, fibromyalgia, I mean, some very serious diagnoses as well that are pretty grim. And then, you know, to be able to properly workup a patient and test them and actually have them have that positive result for them to go off to, say, their neurologist or rheumatologist or oncologist even, and have them say, oh, that that test is that's crap.

That's not a standard test. You know, that's a false positive or all of the narratives that I think we clinicians have seen over and over and over again.

And it's like that patient having like that glimmer of hope that they finally had a diagnosis that was, you know, able to be treated to then just be dismissed.

I mean, I've seen it happen over and over again. And it is just absolutely devastating. So I think that this talk here is so important because you are literally giving the listeners like the language and the understanding that they need to have to be able to take this back to, you know, that practitioner and nicely educate them that they're wrong, you know, and that what actually is reality.

So in addition to that, talk about what other benefits these, global standards bring to testing and to our patients.

Why Global Accreditation Matters for Patients

Yeah, I really think that that, by looking out for this, you're actually protecting the patient more. Okay. Because because you're using really validated test kits, like, now you they can use those words. Yes.

If the test was manufactured under 1345, it's validated. Okay. So you're protecting the patient so that they will not get a misdiagnosis okay. And they won't like they get the most accurate diagnosis possible.

And if that test was then performed under you know this ISO 15189 accreditation okay. Then you know, you can feel comfortable that that lab is performing that test kit as accurately as possible.

Okay. And and and that's the whole point that, that mitigate the risks for the patients. Okay. And hopefully then, the patients, will be managed more or more directly and more positively and more accurately because we're we're reducing the risk of mis misdiagnosis.

So we have then, ultimately less false negatives, you know, less false positives. Okay. And and hopefully this will lead to a better kind of understanding of, reliable diagnosis.

Okay. And at the moment, I, I'm not dismissing any clinical lab that has clear accreditation because I think that's a great start and it's needed for the laboratory develop test.

But if we are going to compare okay, between labs we need to get to that ISO 158. Now for these labs and also use test kits that that are manufactured under 13 485.

Okay. So because that is there's demands and performance, there. Also the whole point to it, because of these harmonized standards, it makes the market approvals streamlined.

So we can get into those markets faster. Like right now the testing scheme in Australia is very poor because a lot of those test kits and I see this, credibly, a lot of those test kits are using, you know, just the burly border fees and so stricter strain okay.

You can increase the sensitivity okay. And parameters of diagnosis by just putting the other two strains. Absolutely. Greenie in there okay. And use, you know test kits that have those three strains okay.

And and that's the whole point that that we need to do better. So, so streamlining with these ISOs and streamlining the regulatory, you know, approvals based on these ISO standards or these accreditation standards and or in these international agreements, it should allow us to get into those markets, you know, faster for the patients.

So that's good for the labs, and it's good for the clinicians, because there's a lot of clinicians, you know, in countries that don't have good testing algorithms, you know, they're wanting better testing, better testing.

Well, we have better tests. It's just we need those countries to, you know, to honor these agreements. Okay, honor, honor the ISOs, you know, honor these, you know, recognize and enforce these ISO standards, you know, and so forth.

So and also, the whole long term benefit, with these ISO standards and embracing them legally more so and empowering, you know, patients and clinicians to utilize this.

It's actually really, having an influence on minimizing chronic Lyme disease patients, you know, the whole chronic necessity of these patients and long term consequences in these patients, because we'll have, you know, these good diagnostics, tests from the onset.

Okay. And and that's our hope, you know, in educating more on these ISO standards and, and these global standards. And I'm not dismissing local standards because Cap is really a good local standards in, in the United States.

And but we have to really think about, you know, what's the benefit of the patients and making sure that the standards are embraced. Okay. Amongst, amongst, you know, different labs so that we have fair, equitable treatment and diagnosis and treatment for, for these patients.

Yeah. Okay. So in the United States we have Cap that's looking at that. So 13485 as well as the ISO 15189. But outside of the United States, what organizations and laboratories also comply with.

But so so so normally normally these accreditation bodies like cap okay. There are national ones like in the United States, there's a handful of them.

Okay. And just like there's, like clearance one cap is one, you at UAF is one, is is one. Okay. There's different accreditation bodies. Okay. In Finland, we only have one because we're a small country.

It's called for NF. Okay. Finnish national Accreditation Service UK is Ucas a UK accreditation services in Germany is docs. Okay. So so in some countries there's a handful of accreditation bodies.

But in some countries there's only one that stand out like in here in Finland. So these accreditation bodies like I said, are they're they're approved by the government, the overall government.

Okay. And they do the assessment of these clinical laboratories. Okay. And and they are the ones these these notified or sorry, these accrediting bodies like Ucas, cap College, they then assess the clinical laboratories in their performance.

And they are the ones that signed the international agreements. Okay. That's recognizes that, you know, that they are conforming with the standards of ISO 15189.

Okay. So Cap really is for accrediting, along alongside that, they're verifying according to ISO 15189 for medical laboratories. But we have other auditors.

If you, if you call it that, other auditors for the ISO 13485. Okay.

International Bodies and Regulatory Approval

And these auditors like Lloyds Register Lcra is one auditor, BSI is another auditor for the medical device manufacturing that standard. So so some of these standards like the ISO the fundamental one, the ISO 9001, that standard is for management of offices.

Okay. There's different auditors for those standards. Okay. But the ones that we are really interested like I, that we've been talking about, in the, in the last few minutes are really the one five, one eight, nine in the 1345.

Those ones are top level notified bodies or top level, creditors. Okay. Like captain find us and docs and they are actually approved by by, governments.

Okay. To be accrediting bodies. Okay. And here in Europe too, because where European Union we Finland is part of it. We even have, have the EU looking at making sure that these, these governments are appointing good to notify bodies that can then approve approve legally for this EVD on our side, which is the in vitro diagnostic regulation on our side.

Okay. Because that's another that's the law that we have to follow. What we have been talking about are just standards okay. But the law is okay. IVD here in Europe and FDA has their approval system for tests, for tests, for tests.

Okay. So FDA approves or clears, okay. For tests, manufacturing tests and then IVD approves and clears or sorry approves for tests that can be sold. So in the European Union okay.

And they themselves have their own harmonized kind of agreements as well. Okay. And and it boils down to also, if the manufacturer of the medical device is following the 1345.

So if you are accredited to, to a 1345 ISO, then FDA will accept it. Your quality management, Health Canada will as

well. I have to say TGA in the United or sorry in Australia.

Okay. And the EU will accept it. So so the standards are important even to get legally your your test kits sold. Okay. So we talked about you know accrediting of laboratories and that's cap.

And that's for us in the Finland Yukos and you know state that's accrediting for the laboratory. But legally speaking, even before you can sell a test kit, it has to follow the laws.

And here in Europe, it follows the 1345 standard, the ISO standard. And FDA is coming more and more, closer to to verifying the ISO 13 485485 standards for its testing parameters as well.

So it's yeah, we didn't even go to that legal aspect, but there are legal allergies. Maybe in. Another episode. Yeah, exactly. Yeah. Okay. So for those who might still doubt the accuracy of the Lyme disease test.

Yeah. You know, beyond the FDA and all of this accreditation, like how does ISO, how do the two different ISOs, the 13485 and the 15189? I'm just saying them over and over and over again in case our centers are trying to catch them and jot them down so they can look into it.

But how did these ISOs address that? Yeah. So it you have to think that these two international standards are demanding real time, performance of what they're doing.

Okay. Like, the clinical laboratory has constantly have to demonstrate that they're performing the test kit, okay, accurately and robustly. How do you audit through audits.

Through audits. Okay. So so the ISO 115189 they are audited every year okay. Cap me audits every 2 to 3 years okay. But it's it's immense. Kind of, demand in the beginning to get your approval and then they'll come back in order to you, the ISO 1345, you're audited every year to maintain that credibility, robustness of your test kit.

So what it's audit is, is are you using your quality management system. So are you validating your test kit clinically and analytically? Are you are you constantly demonstrating that your test kit is doing as it should be doing okay.

And you need to show this. So you have to do a post-marketing surveillance follow up. It's called to report. So basically it's showing that that it has clinical utility.

It has no no not no, but it has very few false positives and false negatives. We now have to demonstrate that it has very little cross reactivity. Okay.

And and you have to demonstrate okay with data, okay, that it is doing what it's supposed to be doing. So it's not misdiagnosing it's accurately diagnosing okay.

And and and there's a lot more to it. But the test performance is in the safety and the efficacy is the most important thing in this ISO 13 485 making sure that the patient is not at risk if your test kit does something wrong, okay.

And that's why when I we do have accurate like I hear all the time about no we don't have accurate test. We don't have we have poor testing. The algorithm that's used the modified system is outdated.

Okay. And that and there's data to support this and and but the test kits there are test kits that are very good okay. With great performance okay. Great accuracy vision sensitivity specificity.

But but we have to use them at the appropriate time.

Test Performance, Sensitivity, and Specificity

Okay. And that's, that's the whole point with serology tests. There are pitfalls with serology test in all serology test it's not exceptional for right.

It's not conventional versus specialty. It's timing. For. Everything during that infection. Absolutely. Yeah. Yeah. And that's the thing that we keep saying because I hear like all these great, groups, you know, that support chronic Lyme disease patients saying that we have bad testing.

No we don't we have good testing. We're just using the test wrong. We need to start using it accurately. And and that's what I'm trying to say is, is that that let's use okay.

Let's use these these good tests that are validated, okay, that are, that are being performed under accredited labs. Let's use them on a test on the patients and, and, and change the narrative.

Because we do have good testing. We do. Yeah. So there's no tests. That's 100% ever, right? No no no no. What to what would do you know how like what the efficacy is like for a lab that has the 13485 ISO.

Like what is. Yeah of error that's allowed. Well I would I would say that if we can talk sensitivity specificity if I can say that because because I can relates to the error like oh.

Pain to our listeners. Yeah. Because we're not all medical professionals. What can those two words mean. Break that down and then continue, please. Okay. But I, I will in one. Okay.

But I would just say I would just say to start this, I would say that, how well the test is performing okay is what the parameters should, be looked at in, in the context of the patient and the clinician.

So is it specific enough? It's it's seeing what it should and it is, sensitive enough to, to see the negative, cases. Okay. So sensitivity and and again, a little jack like here, but making sure that that's you are picking out, the Lyme disease patients, over the non Lyme disease patients.

Okay. And you're and specific enough that you can differentiate between the negative like people that are not sick compared to those people that are sick.

Okay. And and I know every and I seen this in conferences last year. They're saying that we only have a, 60% sensitivity rate. Okay. Sensitivity rate, 60%.

That means like 60% of the chance you'll catch the cases, okay? And 42% chance you're going to miss it. All right. But that depends on what test you're using.

Yeah, I know, but they're using that in their in their presentation. But that data is from scientific articles. Articles that are like 15 years old okay.

You need to look at the instructions for use the instructions for use for the test kit. Is there legal document that demonstrates the sensitivity and specificity?

Those two parameters are the ones that you should be looking at. So that shows how accurate this test is. So if it has a sensitivity of 98%, there's a 2% chance that it will not pick up as it should. Okay.

And if it's in specificity, it means that that's it's, it's differentiating the negative people, compared to the positive people. Okay. So those are the two parameters that we should be looking at.

So a sensitive 50 of 98, like I said, 2% that they're not catching the positive people. Same thing, 98% of specificity. They're not picking up the negative people 2%.

They're not picking up. So those parameters are good. I would think that a sensitivity of 99, 95 or 98 is good. Okay. These these legal, authorities and a creditors will not allow okay, a sensitivity here, here in Finland at least would I for it because we're audited every year.

We're not allow a poor performance test kit to be able to be sold. And what that is well, in, in you know, it's says it's

this, FDA approved or cleared test.

So the sensitivity and specificity, what is, acceptable at the FDA level. You need to look at those cleared tests. Okay. And right now I think I genic said it was 70 there.

I if you says it's it's 75%. Is there sensitivity specificity I didn't see that in there are instructions for use and FDA accepted that okay. But I know here in Finland that would not be 75% sensitive would not be acceptable.

Okay. And so we have a demand to make sure that are sensitivity and specificity is higher than 90%. That's our demand here. Not only our company okay.

But it is definitely a demand that we want to keep. But we have a legal obligation to make sure that those sensitivity specificity numbers are actually in the instructions for use.

So I encourage every patient and every clinician to demand this legal document, the instruction for use of the test kit. And look at those parameters, because that's the parameter.

It's not the scientific peer reviewed publications that are being it's in the instructions for use. That's the legal diet document. That's what FDA allows it to be disclosed.

This is what the European Union allows us to disclose. And our if it asks here, our regulatory body here in in Finland, that's the legal document. So that's what we should be looking at.

Okay. So in and then because this is never given out this instructions for use. But if you ask for the legal you have to give it to you okay. And this is empowering them patients to be more aware.

And the clinician clinician to be accurately comparing the test kits, okay. Because the instructions for use will also tell other parameters of the test kits.

Okay. Stability. Okay. The clinical utility, the analytical utility, all the validation parameters should be on this instructions for use. It's a legal document. It has to be there.

And I don't know why we're not doing that. I don't know either. I think right now it's also important to bring back up the fact that your test is only testing for what it says it's testing for.

So we cannot say that we're testing you for Lyme disease and have that encompass all of the various species of Borrelia, as well as those species of Borrelia that also can cause tick-borne relapsing fever, which gets lumped into the Lyme diagnosis.

If we're using a test that is only testing for Borelli for Borrelia burgdorferi, right. So it's like, again, your test might say, you know, that it is, you know, a certain sensitivity and specificity.

But if you're only testing for one species, you cannot then extrapolate that and say, I don't have Lyme because you haven't evaluated like the other. What what are we up to now?

18 or 19 different testable species of Borrelia, not cause quote unquote, Lyme disease. And it certainly isn't going to test for all the species of the Baeza or Bartonella or an a plasma or liquid or Mycoplasma or Rocky Mountain spotted fever, Rickettsia, etc., etc., etc..

Right. So know what the test is actually looking for. In addition to knowing, you know, its various, efficacy and accuracy ratings. I agree exactly what you I like with what you just said exactly.

And and that's what it encompasses that what the test is testing for like the legal term is the intended use of your test kit. Okay. So the scope of your test kit. Absolutely.

It doesn't have all the species as you just said, a Borrelia there. I absolutely like support exactly what you're said. So when I as a as a medical device manufacturer, I am constantly asked, well this test result on this test was positive, but you're negative on here.

Why you can't compare the two test test kits unless they have the same. The same. Okay proteins in that test kit. Unless they're testing exactly the same species, you cannot do a comparison.

And it is actually really, damaging for the patient to do that or even even not only like if you're talking serology tests, if you talk about indirect tests in a direct test and comparing them, you can't do that, right.

You can't do you can't compare microscopy to serology test. You shouldn't compare PCR with serology. You cannot do that. And even in the serology world, I go back to my first point.

Even in that serology testing, the the different tests you can have the same person being tested over against like five different tests and the correlation or how they compare.

Okay. This is called like positive agreement or negative agreement. How they positively compare with positive samples, how they compare against like that ranges from 72 to 98% depending on what is inside of the test.

What are your proteins? What are you actually testing for in. In such an important point? Yeah, because like having one Borrelia species in a test kit compared to the three most prominent ones, like global ones, that's the they they may not catch the other two species of Borrelia, you know.

So so that's the whole point of why we need to do better. We do have these test kits that have the most global, you know, Borrelia species in them. We do have those test kits that, you know, test for multiple, you know, tick borne diseases.

We do have this, but we should not and we stop. We need to stop comparing these tests.

Interpreting Lyme Tests in the Full Clinical Picture

And then I just want to bring up one other point about, false negatives and false positives that we are seeing in these patients, chronic Lyme disease patients, a negative, patients, which means that they're not producing, you know, antibodies, you know, because their immune system is is dysfunctional at some extents.

Okay. And it it could be many reasons. Right. And and there are many hypotheses in many studies to demonstrate this. And that's why we have false negatives.

Okay. And we have to understand that, that in those chronic patients this is occurring okay. Not in typical healthy human that, you know, has, you know, working immune system that can elicit like, build up, can make antibodies.

Okay. We won't see that in those people. But when we were dealing with chronic patients, we are definitely seeing this. And this is not exceptional to chronic Lyme.

This is this is can be seen in other chronic patients as well that there are certain negativity in these diseases. And that's something that that we need to publish more on.

Okay. To substantiate that. But that's something to keep in mind that when we're having a negative result, it may not indicate that they are not suffering from Lyme disease.

It's just that their immune system is is compromised and they're not being able to, you know, build up those antibodies. So once because so many of I mean really I come back to for me the fundamental like why does wine become chronic?

How does it become chronic? How does it evade the immune system because it breaks the immune system. And

so, you know in almost everybody it imbalance it to say the least.

But then when you have patients who have, you know, impaired B-cell production and they literally cannot make antibodies against it, and then we come along with these indirect tests and they're called indirect because that means they're not testing for the bacteria itself, but they're testing the immune response to the bacteria, i.e.

the antibodies. Right. And so you know, it almost it's like it doesn't make sense. Like why would we use a test like that? And it's like, well, when it comes to Lyme or Borrelia, because of the way that it hates being in the bloodstream, and it gets out of the, the bloodstream and kind of goes to the extracellular matrix in the collagen so that it can eat, and evade the immune system more deeply.

It's very, very hard to get a direct test, which measures like the actual genetic information of the organism. So it's you know, it's kind of like the the best in a bad scenario, right, is looking at the antibodies.

But again, you know, coming back to Lyme is a clinical diagnosis. And all of these tests can be helpful if they're done at the right time with the right methodology, looking for the right organisms.

But again, it's like, you know, you have to take all of that and bring it into the clinical picture and into that one person sitting in front of you. Right.

And and work them up clinically to get your dietary. Yeah, I agree, our test kits that we make okay as a manufacturer is only there to help and aid okay.

In this clinical diagnosis, the full picture of the patient should be taken into consideration. And I reiterate that in including also an immune fitness okay.

Testing because because that's the whole picture of the patient. So so and there are very standard tests for this and for the immune fitness. And and we do we tend to overlook the whole picture of the patient and only want yes no answers.

I know that's easy to to react with. Yes no answers. But we're not dealing with, you know, a yes, no bacteria. We're dealing with a chronic, you know, chronic back to or a complicated bacteria.

Okay. And one of the. Things that for the listeners, let me just interrupt. So what doctor, Gilbert is talking about is you can have an abscess ment of your immunoglobulins so you can have, like your total IgG, your total IgG, and also IGA and IgG.

But I would say, you know, when you're looking to see if you're making antibodies, in a normal response, looking at ECGs and exams would be important.

And it's something that you can get done and is accurate at pretty much any laboratory. So that way if you're within the normal range, then you can probably take your, your test results, your indirect test results.

You know, more seriously, if it's done with a credible lab, versus like, you know, if you're very, very much on the low end with either of those, then you would want to look at that when you're looking at your test result.

And again, not just looking at positive or negative, but looking at, you know, depending on the lab, like vibrant gives you an actual number. I, Gen-X will give you an indeterminate or a one plus two plus three plus, etc., you know, and so if you have low IgG or borderline low IgG and let's say, you know, you get an ID and as your result that Id1 has to be taken extremely seriously.

Right. And the ones where you. So anyways, I think everyone understands what I'm saying, but I just wanted to kind of break that down for the listeners so they understand why talking about.

Yeah. And I would like to add to that too, that even standard, you know, blood counts like for your immune cells.

Okay. Like like CD4 and CD8, you know, CD 57, CD 56 like, these are coming out anyways.

And if they're doing, you know, blood counts. So along with the antibodies, like those are just standard tests that are normally performed. So let's look at those biomarkers okay.

And and there are publications to demonstrate the correlation in you know a to chronic chronic Lyme disease patients you know that have lower you know, city CD, 50 sevens and so forth.

So, so so the point is, is that that all gives a picture of immune fitness. And we need to employ those tests to say, okay guys, come on.

Conference Announcement and Closing Remarks

This is anyways being done with look at that and correlate that with the test results and and think cleverly that, you know, and that's an immune system isn't you know one fit all for everybody.

It's everybody's individualized okay. And and the immune system can have flares and come down and and and we see that in patients too. You know, they have good days, they have bad days or they have good weeks and bad weeks.

And most likely it's it's, you know, the immune system partakes in this. So so that's the point. Yeah. Just to reiterate why in support what you just said as well.

Well, thank you so much for joining us. So I want to make sure everyone hears that you are having the first annual conference of Chronic Infection Pathologies.

This is going to be September 5th through seventh of 2025. So this year and what is the website that, people can go to to learn more about your conference?

Yeah, it will be first because this is the first. And we're, we're we're a little slow right now getting that, official website, but it will be at our website on the company's website.

So we tested teased TED.com. It'll be there first. And then we'll have our own, step websites as soon as we can. We can get that up and running soon. But thank you for for mentioning that.

Yeah, we're excited about it because it's chronic infection pathologies. And it's not only just tick borne related, but it also of course can be Covid.

It can be other infections and infections that are contributing to chronic diseases. And and I think we're seeing a lot of similar, traits amongst these patients, that have chronic infectious diseases and pathology.

So and even the science is demonstrating the common traits as well. So. So any data driven like this is this is a yeah, scientific conference where, you know, your tagline is show me the data.

So that's exactly the main focus. But but I want to reiterate that this conference is unique in itself that we were on to make sure that we it's impactful for the three.

Major Straker stakeholders in our area. And that is the patients. Okay. That is then the clinician or the practitioner and that is the scientist. So we will have impact statements and we will we will embrace all three stakeholders.

Because without the three we feel that that we cannot progress further into having workable, tangible action. You know points for E, for the patient, for the practitioner and for the scientists. And we're unique in the sense of this conference because we're embracing all three.

Traditionally we see only for scientists, only for clinicians, maybe maybe clinicians and scientists together, or then

we'll have patient oriented conferences.

But we are absolutely trying to embrace all three stakeholders. And, and and that's what we want to push in this conference that everybody that presents, everybody that comes out hopefully will come in and provide impact for all patients, scientists and clinicians or practitioners.

Wonderful. Thank you. Welcome to that conference actually here. So here is you vascular Finland okay. You vascular Finland. And it's a great time of the the year because we will not have mosquitoes, but we will be able to see the northern lights hopefully on clear sky.

Yeah. It's still very, very season. So picking season in the forest you can go and pick mushrooms as well. And so it's a great time of the year to to be here in you vascular.

So it's basically 300km north of Helsinki. And it's a great place to, you know, to experience. So I encourage you all to come in and abstracts will be open probably next week for speakers.

So I'm encouraging you yourself to, to submit an abstracts with the data and the and we say show the data because because we want to make sure that everything that we do is credible for the patient, credible for the scientist, credible for the clinician.

And it doesn't have to be peer review data can be preliminary data. This isn't to encourage, you know, PhD students, master's students, postdocs, early career, you know, scientists as well as medical students and so forth.

Okay. Or even just stakeholders. Okay, I want to come and let's say the analyze the, you know, surveys, patient surveys are analyzed policies, you know, but they have some data to show.

So the whole point is really show us the data, to make changes in treatment, diagnosis, science and, and outcomes for patients, scientists and clinicians.

That's the point. So show us the data. Yeah. Thank you. One more time. Tell our listeners how to, how to contact you or learn more. Yeah. So you can you can email me at Leona Dot Gilbert.

So Leo and Gilbert Gilbert at tested T, Z or Z TED.com. You know, I'm a Canadian when I say that. Yeah. So you can email me at leona.gilbert@tested.com or go to our website.

We tested.com city Z TED.com. So ttd. TV. Yes. Yeah. All right. Well thank you again for joining us. Thank you two for having me. My pleasure. For all of our listeners at home.

Thank you for joining us. And I hope that this information is helpful to healing from Lyme. Take care and we'll see you at the next episode.