Behind the Lab Door: Global Standards for Lyme Disease Testing Transcript

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Podcast Introduction and Episode Overview

It's important for patients to know that by adhering to global standards, their test results should be accepted across country or even even I can I dare to say state to state or province to province you know and 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 insurances 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 to empower the patients that this is the information that you can bring with you to say, don't disregard my test result and don't say it's a false positive or a false negative.

Hi, and welcome to the Lime Bites podcast, where we shine a light on the misunderstood science of Lyme and other vector-borne diseases, as well as the truths that many still miss.

I'm Dr. Mariah Hinchy, naturopathic physician and fellow of the Medical Academy of Pediatric Special Needs. I specialize in treating chronic Lyme disease as well as other complex inflammatory conditions.

In this podcast, we break down what's working and what's not. We share the facts that most people miss, we challenge outdated thinking, and we give both patients and practitioners the tools to heal smarter.

So let's get into it and change the way we heal Lyme. Hi, and welcome to another episode. I'm your host, Dr. Maria 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 Lyme and other vector-borne disease testing. Here with us today to navigate through this pretty tough topic is Dr.

Leona Gilbert. So Dr. Gilbert is a docent of cell and molecular biology and the CEO of Tested Oi. This university spinoff 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, Dr. Gilbert's several peer reviewed publications also demonstrate a thorough investigation of how a common virus or bacterium can contribute to an autoimmune disease.

Dr. Gilbert's Research Background and Lyme Testing Challenges

Dr. 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, Dr. Gilbert. Thank you so much for joining us. Well, thank you for having me. Absolutely. Tell our listeners a little bit more, how did you get involved in this?

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

And we noticed that actually the test kits that they were using for streptococcus cryogenous actually was failing the patients. because that bacteria was changing shape.

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 we should do better for the patients.

And that's what 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, out of all of the bacteria out there, Borrelia has to be one of the most fascinating to study because of the way that it changes throughout its life cycle.

And you have multiple different forms of it in the body at one time. Yeah, I agree with you. And also, it's a low abundance bacteria. And we keep forgetting that it is like, you only need a few copies of this to cause havoc on the system.

And compared to, like, the streptococcus progenus, it's highly abundant in the system. You can really detect it directly. But Borrelia is low abundance.

It clears the bloodstream so quick. you know, it finds its niche, it causes havoc, it causes 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.

low abundance and very, very slow growing. Yes, 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 Dr. 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 CLIA 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 these various clearings or approvals or certifications that all of these labs carry.

Okay. So I will start globally speaking. So the international organization for centralization, these ISO standards are harmonized standards. Okay. That 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 13485, 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 the really great quality management system in its production. And also making sure that it is in real time always being validated and performing as it should 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 13485, those characteristics should be minimal in this standard.

ISO Standards, CAP, CLIA, and FDA Test Approval

And those people adhering to this ISO 13485 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, to maintain this quality management system and to really demonstrate the validation analytically, clinically and clinically utility.

Then the other side to the clinical laboratories that are performing test kits. 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 results, and even sample preparations from the day one that their 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 under ISO. Those two ISOs come together and verify the consistent and accurate line testing that can be done globally.

stands for College of American Pathology. They verify, okay, unaccredited laboratories, okay, clinical laboratories under the ISO 15189. Okay, so CAP accredited under ISO 15189. So if you are adhering to this ISO, in a sense, there is equivalence to what CAP will accept, this body that regulates the performance of clinical laboratories.

And when I say performance of the clinical laboratories, it actually demonstrates 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, 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 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 a validated test like one manufactured under 13485 and in a CAP approved, accredited laboratory in Germany, it should be accepted in the United States 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 tongue-tying here, but it's an agreement that has many, many accreditation bodies from different countries signing to the equivalence of the standards.

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

And that really means really that test results coming out of 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 hear because in order for a test kit that is manufactured under 13485 to get that stamp of approval, okay, to be accepted internationally and also legally to sell it, 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. 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 to independently validate that test kit in their own lab and in order to maintain those ISOs and also because FDA requires that only validated test kits come into those labs but cap demands cap demands based on the ISO 1589 that these test kits be independently validated 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 shouldn't because legally speaking, a test kit cannot be sold 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 legally an inaccurate statement.

Okay. According to the standards and legally selling these test kits in the countries. Now 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 in its performance than the other test kit. That is cleared. Being approved means that a new test kit that doesn't have a predicate or it doesn't have a comparison test kit comes into the market and it has to go and undergo more assessments because there's 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 15189. They don't, unfortunately. Okay. So, there is not a demand as stringent as CAP, like as stringent as ISO 15189. And so, for example, some people will say that CLIA doesn't demand this clinical validation.

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

And in order for them, minimum standard that they need to be accredited is this CLIA standard. So they demonstrate that that test kit is analytically validated in its robustness and its accuracy and its precision and 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 as the ISO 15189. So, there's a clear distinction between CAP accreditation and clear accreditation.

CAP is adhering to the ISO standard, the 15189 that demands clinical validation and clinical utility. not only analytical, but also that CLIA demands, of course, the analytical validation.

And, of course, you want to show some clinical validation, but the clinical utility demand is not there. So, there's a higher level of accreditation, a higher level of demand in the CAP accreditation, because it follows the ISO 15189. So for our listeners, 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. So everyone CAP accredited is what you would be looking for. And in the United States, most labs are CLIA. Yeah, like you have to be clear.

Yes, in my understanding, yes. And that allows them for you for that lab to bring on their in-house test kits called laboratory developed tests, LDTs.

Okay. LDTs. And we call them in-house test kits here on this side of the world, but it's a laboratory developed test. you have to be CLIA approved or accredited in order to carry and or to use your LDTs.

Most like 99.5% of all Lyme disease testing are LDTs in these specialty labs. And I'm not saying that the performance is less than CAP accredited. I'm not saying that at all, but I think we should be aware that there are quality management systems and global standards that influence the performance and how we should look at these test kits.

It would be so difficult to bring a test result from a CLIA approved test into a different country and say, accept this

because it's not adhering to the 15189 standard.

It's not adhering to the global standard. Yes. Legally, it's not. I'm not saying that they can't get CAPA approval, and I encourage that they do in this shift of what FDA is making these clinical laboratories go through with their laboratory-developed tests, but it's important for patients to know that that by adhering to global standards, their test results should be accepted across country or even, can I dare to say, state to state or province to province.

And that's the key thing that we need to empower the patients who think this, that it's actually, these are my test results. You cannot dismiss them. Or health insurances to say, no, we were not going to cover this.

Well, you should, because legally, this is, you know, it's accredited, it's validated test kit. 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 say, don't disregard my test result and don't say it's a false positive or a false negative.

Really, there are limitations to these tests. Yes, we understand, but they should be minimized because of these standards. Manufacturers don't want to give false results.

Hopefully. I think everyone listening or most people understand 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 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 to be able to properly work up a patient and test them and actually have them have that positive result for them to go off to say they're neurologist or rheumatologist or oncologist even, and have them say, oh, that test is, that's crap.

That's not a standard test. 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. It is just absolutely. devastating. So I think that this talk here is so important because you're 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 what actually is reality. So in addition to that, talk about what other benefits these global standards bring to testing and to our patients.

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Patient Advocacy and Benefits of Global Testing Standards

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This conference will arm you with the knowledge, clinical pearls, and practical solutions that you can implement immediately into your practice Monday morning that will literally change your patient's lives and get them on their

path to true healing.

So join us at Pompano Beach or virtually from anywhere. Register now at LymeBytes.com. That's L-Y-M-E-B-Y-T-E-S dot com. Yeah, I really think that by looking out for this, you're actually protecting the patient more, okay?

Because you're using really validated test kits. Like now they can use those words. Yes, if the test was manufactured under 13485, it's validated, okay?

So you're protecting the patient so that they will not get a misdiagnosis, okay? And they get the most accurate diagnosis possible. And if that test was then performed under this ISO 15189 accreditation, then you know, you can feel comfortable that that lab is performing that test kit as accurately as possible.

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

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

And at the moment, 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 to develop tests.

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 are manufactured under 13485. So, because that is, there's demands on performance there.

Also, the whole point too is because of these harmonized standards, it makes the market approval 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 say this credibly, a lot of those test kits are using, you know, just the Borrelia bedorferi and so stricto strain.

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

Okay. And that's the whole point that, that we need to do better. So, so streamlining with these ISOs and streamlining the regulatory approvals based on these ISO standards or these accreditation standards and on these international agreements, it should allow us to get in to 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 in countries that don't have good testing algorithms.

They're wanting better testing, better testing. Well, we have better tests. It's just we need those countries to honor these agreements, honor the ISOs, recognize and enforce these ISO standards and so forth.

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 nicety of these patients and long-term consequences.

in these patients because we'll have the good diagnostics tests from the onset. And that's our hope in educating more on these ISO standards and these global standards.

And I'm not dismissing local standards because CAP is really a good local standard in the United States. 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, you know, different labs so that we have fair, equitable treatments and diagnosis and treatment for these patients.

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

So normally these accreditation bodies like CAP, there are national ones, like in the United States, there's a handful of them. And just like there's like CLEO is one, CAP is one, UAF is one, IAS is one, there's different accreditation bodies.

In Finland, we only have one, because we're a small country. It's called FINNAFS, Finnish National Accreditation Service. UK is UKAS, UK Accreditation Services.

In Germany, it's DOCS. So, in some countries, there's a handful of accrediting bodies, but in some countries, there's only one that stands out, like here in Finland.

So these accreditation bodies, like I said, are, 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, CLEA, they then assess the clinical laboratories in their performance.

And they are the ones that sign the international agreements that recognizes that they are conforming with the standards of ISO 15189. So CAP really is for accrediting alongside that they're verifying according to ISO 15189 for the medical laboratory.

But we have other auditors, if you call it that, other auditors for the ISO 13485. And these auditors, like Lloyd's Register, LQRA is one auditor, BSI is another auditor for the medical device manufacturing, that standard.

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.

But the ones that we are really interested, like we've been talking about in the last few minutes, are really the 15189 and the 13485. Those ones are top-level notified bodies or top-level accreditors, like CAP and FINAS and DOCS, and they are actually approved by governments to be accrediting bodies.

And here in Europe too, because we're a European Union, Finland is a part of it, we even have the EU looking at making sure that these governments are appointing good, notified bodies that can then approve approve legally for this IVDR on our side, which is the in vitro diagnostic regulation on our side.

Test Performance, Sensitivity, Specificity, and Intended Use

Okay. Cause 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. IVDR here in Europe and FDA has their approval system for tests for tests.

for tests. So FDA approves or clears for manufacturing tests and then IVDR approves for tests that can be sold in the European Union. And they themselves have their own harmonized kind of agreements as well.

And it boils down to also if the manufacturer of the medical device is following the 13485. So if you are accredited to to 13485 ISO, then FDA will accept it, your quality management, Health Canada will as well, I have to say TGA in Australia, and EU will accept it.

So the standards are important even to get legally your test kits sold. So we talked about crediting of laboratories and that's CAP and that's FinNAS and the Finland, UCAS and United States, 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 13.485 standard, the ISO standard.

And FDA is coming more and more closer to verifying the ISO 13.485 standard for its testing parameters as well. So it's, yeah, we didn't even go to that legal aspect, but there are legalalities.

Maybe in another episode. 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, 3485 and the 15189, I'm just saying them over and over and over again in case our listeners are trying to catch them and jot them down so they can look into it.

How do these ISOs address that? Yeah. So 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 kits. Okay. Accurately and robustly how through audit through audit.

through audits. So the ISO 15189, they are audited every year. CAP may audit every two to three years, but it's immense kind of demand in the beginning to get your approval and then they'll come back and audit you.

The ISO 13485, you're audited every year to maintain that credibility robustness of your test kit. So what it's audit is, are you using your quality management system?

So are you validating your test kit clinically and analytically? Are you constantly demonstrating that your test kit is doing as it should be doing? And you need to show this.

So you have to do a post-marketing surveillance follow-up. It's called report. So basically it's showing that it has clinical utility. It has not no, but it has very few false positives and false negatives.

You now have to demonstrate that it has very little cross reactivity. And you have to demonstrate with data that it is doing what it's supposed to be doing.

So it's not misdiagnosing, it's accurately diagnosing. And there's a lot more to it, but the test performances and the safety and the efficacy is the most important thing in this ISO 13485. Making sure that the patient is not at risk if your test kit does something wrong.

And that's why when I, we do have accurate, like I hear all the time, oh no, we don't have accurate tests. We don't have, we have poor testing. The algorithm that's used, the Modify2 system is outdated and the There's data to support this, but the test kits, there are test kits that are very good with great performance.

Okay. Great accuracy, sensitivity, specificity, but we have to use them at the appropriate time. And that's, that's the whole point with serology tests.

There are pitfalls with serology tests in all serology tests. It's not exceptional for… It's not conventional versus specialty. It's timing is the key thing.

During the infection. Absolutely. Yeah. Yeah. And that's the thing that we keep saying, because I hear it, like, all these great groups, you know, that support chronic line 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 that's what I'm trying to say is that let's use these good tests that are validated, that are performed under accredited labs.

Let's use them on the patients and change the narrative because we do have good testing. We do. So there's no test that's 100% ever, right? Do you know what the efficacy is for a lab that has the 1, 3, 4, 8, 5 ISO?

What is the amount of error that's allowed? Well, I would say that if we can talk sensitivity specificity, if I can say that because that relates to the error.

Explain to our listeners, because we're not all medical professionals, what do those two words mean? Break that down and then continue. Are you suffering from Lyme disease or another complex chronic illness and aren't sure who to trust when it comes to herbal supplements?

Hi. I'm Dr. Mariah Hinchey, founder of Lime Core Botanicals. As a naturopathic physician specializing in complex, chronic, infection-driven illnesses like Lyme disease, I needed herbal medicine I could truly trust.

That's why I formulated Lime Core Botanicals, where our herbal tinctures are handcrafted in small batches right here in Connecticut. We use the whole herb, never isolates, to preserve the full spectrum of medicinal compounds.

Every single step from sourcing to extraction is done with precision to ensure maximum purity, potency, and consistency. These are the same herbal formulas I used to heal myself and have used for years to help my patients and family members heal, too.

And now I'm making them available to practitioners and patients everywhere. Lyme Core Botanicals, herbal medicine you can trust from a doctor who lives this work.

Learn more at Lyme Core Botanicals. That's L-Y-M-E-C-O-R-E dot com. Okay, but I will, but I would just say to start this, I would say that how well the test is performing is what the parameters should be looked at in the context of the patient and the clinician.

So is it specific enough? Is it seeing what it should? And it is sensitive enough to see the negative So sensitivity and again, a little jack-mike here, but making sure that you're picking out the Lyme disease patients over the non-Lyme disease patients.

And specific enough that you can differentiate between the negative, like people that are not sick compared to those people that are sick. And I know every, and I've 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 40% 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 their 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.

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

So a sensitivity 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 95 or 98 is good. These legal authorities and accreditors will not allow a sensitivity here and one of these would I, because we're audited every year, would not allow a poor performance test kit to be able to be sold.

And what that is, well, in the United States, 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 Eigenic said it was 70. Their IFU says it's 75% is their sensitivity, specificity, I didn't see

that in their instructions for use, and FDA accepted that.

But I know here in Finland, that would not be 75%, sensitive would not be acceptable. And so we have a demand to make sure that our sensitivity and specificity is higher than 90%. That's our demand here, not only our company, but it's 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 dial. document. That's what FDA allows it to be disclosed.

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

And then, because this is never given out, these instructions for use. But if you ask for it, they legally have to give it to you. And this is empowering them patients to be more aware and the clinician to be accurately comparing the test kits.

Because the instructions for use will also tell other parameters of the test kit. Stability, 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 Borrelia burgdorferi, right?

So it's like, again, your test might say that it is 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 are we up to now, 18 or 19 different testable species of Borrelia that cause, quote unquote, Lyme disease.

And it certainly isn't going to test for all the species of Babesia or Bartonella or Anaplasma or Ehrlichia or Mycoplasma or Rocky Mountain spotted fever, Brachycea, et cetera, et cetera, et cetera.

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 like with what you just said.

Exactly. And that's what it encompasses that what the test is testing for.

Immune Markers, False Negatives, and Clinical Context

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 in there.

I absolutely like support exactly what you said. So when I, 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 kits unless they have the same 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 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. You can't compare microscopy to serology tests.

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 the serology testing, 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 negatively 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? And I think that's such an important point. Yeah, because having one Borrelia species in a test kit compared to the three most prominent ones, like global ones, they may not catch the other two species of Borrelia.

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, a Borrelia species in them. We do have those test kits that, you know, test for multiple tick-borne diseases.

We do have this, but we should not, and we need to stop comparing these tests. And then I just want to bring up one other point about false negatives and false positives.

We are seeing in these patients, chronic Lyme disease patients, there are negative patients, which means that they're not producing antibodies, you know, because their immune system is dysfunctional at some extent.

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

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

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

This can be seen in other chronic patients as well, that there are seronegativity in these diseases. And that's something that we need to publish more on 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 the immune system is compromised and they're not being able to build up those antibodies.

Right. And it makes sense because so many of, I mean, really, I come back to, for me, the fundamental, like, why does Lyme become chronic? How does it become chronic?

How does it evade the immune system? Because it breaks the immune system. And so, you know, almost everybody, it imbalances it, to say the least. But then when you have patients who have 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. 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 bloodstream and kind of goes to the extracellular matrix and 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 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 have to take all of that and bring it into the clinical picture and into that one person sitting in front of you and work them up clinically to get your diagnosis.

Yeah, I agree. Our test kits that we make as a manufacturer is only there to help and aid in this clinical diagnosis. The full picture of the patient should be taken into consideration.

And I reiterate that, including also immune fitness testing. because that's the whole picture of the patient. There are very standard tests for this and for the immune fitness and we tend to overlook the whole picture of the patient and only want yes-no answers.

I know that's easy to react with, yes-no answers, but we're not dealing with yes-no bacteria, we're dealing with a chronic or a complicated bacteria. One of the things that for the listeners, let me just interrupt for a sec.

So what Dr. Gilbert is talking about is you can have an assessment of your immunoglobulins. So you can have like your total IgG, your total IgM, and also IgA and IgE.

But I would say, you know, when you're looking to see if you're making antibodies in a normal looking at IgG's and IgM's 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 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 Igenics will give you an indeterminate or a one plus two plus three plus, et cetera.

You know, and so if you have low IgG or borderline low IgG and let's say, you know, you get an IDN as your result, that IDN has to be taken extremely seriously, right?

Conference Announcement and Contact Information

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 what you're 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, CD8, you know CD57, CD56 like these are coming out anyways 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 there are publications to demonstrate the correlation in to chronic chronic Lyme disease patients that have lower CD57s and so forth.

So the point is that that all gives a picture of immune fitness and we need to employ those tests to say, okay guys, come on, this is anyways being done.

Let's look at that and correlate that with the test results and think cleverly that the immune system isn't one fit all for everybody. It's everybody's individualized.

Okay. 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 and support what you just said as well.

Well, thank you so much for joining us. 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 7th of 2025, so this year. 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 a little slow right now getting that official website, but it will be on our website, on the company's website.

So www.tztd.com. It'll be there first, and then we'll have our own SIPP website as soon as we can. we can get that up and running. But thank you 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, can be other infections, infections that are attributing to chronic diseases.

And I think we're seeing a lot of similar traits amongst these patients that have chronic infectious diseases and pathologies. And even the science is demonstrating the common traits as well.

It's data-driven. This is a scientific conference where your tagline is, show me the data, but that's the main focus. But I want to reiterate that this conference is unique in itself that we want to make sure that it's impactful for the three major stakeholders in our area.

And that is the patient, that is then the clinician or the practitioner, and that is the scientist. So we will have impact statements and we'll embrace all three stakeholders because without the three, we feel that we cannot progress further into having workable, tangible action points 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 or only for clinicians, maybe clinicians and scientists together, or then we'll have patient-orientated conferences.

But we are absolutely trying to embrace All 3 stakeholders and that's what we want to push in this conference. That's everybody that presents everybody that comes out.

Hopefully, it'll come in and provide impact for all patients, scientists and clinicians or practitioners. Wonderful. Thank you. Conference. Actually here.

So here is Yuvascula, Finland. Yuvascula, Finland. And it's a great time of 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 berry 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 be here in Uvascula.

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

So I'm encouraging you yourself to submit an abstract with the data 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 scientists, credible for the clinician.

And it doesn't have to be peer-reviewed data, it can be preliminary data. This isn't to encourage PhD students, master students, postdocs, early career scientists, as well as medical students and so forth, or even just stakeholders that want to come and let's say they analyze the surveys, patient surveys, or analyze policies, 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 outcomes for patients, scientists, and clinicians.

That's the point. So show us the data. Well, thank you. One more time, tell our listeners how to contact you or learn

more. Yeah. So you can, you can email me at leona.gilbert.

So L E O N A dot Gilbert G I L B E R T at tested T E Z or Z T E D dot com. You know, I'm a Canadian when I say Zed. Yeah. So you can email me at leona.gilbert at tested.com or go to our website www.tested.com.

So T E Z. So T E Z. Yes. Yeah. All right. Well, thank you again for joining us. Thank you too 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. We'll see you at the next episode. If this episode gave you an answer, brought you new insight, or made you think differently, subscribe to the Lime Bites podcast and share with someone who's ready to take control of their healing journey.

And if you can, please leave a review. It helps others to find the show. Thanks for listening and we'll see you next time.