

Episode 54: 2025 Diagnostic Trends and Innovations

Josh Casey: Hi, I'm Josh Casey. Welcome to *QuidelOrtho Science Bytes*, your trusted source for diagnostic insights and innovations. In this episode, we'll recap the year and cover the breakthroughs shaping diagnostics in 2025. From high-sensitivity troponin testing for faster cardiac care to noninvasive assays improving gastrointestinal health, rapid combo tests for respiratory surges and advancements in molecular diagnostics and informatics, plus a look at what's to come. These innovations are transforming workflows, guiding timely decisions and redefining patient care across the continuum. Today, it is our pleasure to sit down with Jonathan Siegrist. He is the Executive Vice President of Research & Development and Chief Technology Officer at QuidelOrtho. Jonathan is responsible for the company's global R&D strategy, driving innovation and advancing next-generation diagnostic solutions. He brings over 15 years of leadership experience in the biotechnology and diagnostics industries with a focus on molecular diagnostics, microfluidic platforms and biomedical engineering. Before joining QuidelOrtho, Jonathan served as chief technology officer and head of assay research and development at Cepheid, a Danaher company. Throughout his career, he's been recognized for his ability to lead complex multidisciplinary teams while fostering a culture of creativity and innovation. Jonathan holds a PhD and Master of Science in Biomedical Engineering from the University of California Irvine and a Bachelor of Science in Electrical Engineering from the University of California Los Angeles. Welcome, Jonathan. What a great year it's been. Thank you for joining us to talk about it.

Jonathan Siegrist: Yeah, thanks Josh. It's been a really great year. I think in our industry, lots of change as always, but also a lot of progress. So really appreciate the invitation today and I'm looking forward to our discussion.

Josh Casey: Awesome, great. Well, let's get started. So 2025 welcomed several new additions to the VITROS™ Clinical Chemistry Assay menu. Perhaps most notable was the introduction of high-sensitivity troponin. What does this test mean for clinicians and their patients hospitalized with cardiac conditions?

Jonathan Siegrist: Great question and love to be able to start on high-sensitivity troponin here on this discussion. So we've had a really nice strong product around high-sensitivity troponin outside the U.S. on our VITROS System for a while now and it's really nice to be able to talk about bringing that product into the United States next year, early 2026, now that we've got our FDA clearance in hand. So when you think about cardiovascular diagnostic tools, it's really about speed, accuracy and really delivering those results with confidence to the clinicians and our patients. High-sensitivity troponin is now a very established and very important tool in that cardiac diagnostics toolkit. With FDA clearance of that test on our VITROS System, our high-sensitivity troponin I assay, clinicians now can use the VITROS Systems in the U.S. to access high sensitivity, very reliable cardiac troponin testing and it fits really nice into a lot of different workflows. And what we continue to see, especially with our unique to our VITROS Systems, is we see them used in very interesting different workflows, including, for example, stat testing. So really excited as we deploy that test into the U.S. early next year to see all those different workflows and innovative solutions that our customers will bring to bear with those, with our, with our tests. So overall, really excited to get this test out. It's guidance aligned, you aligned with IFCC guidance. It's a really, really great test. Emergency rooms, acute settings, hospitals – excited to see this come to the market next year and a big win for us and a big win for patients as well.

Josh Casey: Great. So also in the area of clinical chemistry, QuidelOrtho partnered with BÜHLMANN this year to introduce fCal and fPELA Turbo Assays for the VITROS XT 7600 and 5600 Integrated Systems, as well as the VITROS 4600 Chemistry System. What is the significance of this for patients who may be suffering from inflammatory bowel disease and pancreatic insufficiency?

Jonathan Siegrist: Yeah, thanks Josh. Another great question. You know, the area of gastrointestinal health and maybe more broadly, digestive health, super important area that arguably is underserved still by the tools we have today, especially on the diagnostic side. So really important area, I think, for everybody to focus on. This partnership with BÜHLMANN is a really important one to really expand our offering on VITROS in this space. We have a particular technology on VITROS called our MicroTip technology that's essentially an open channel that lets us partner as we have here with other best-in-class assays and bring that content onto our VITROS Systems. And that's exactly what both of these tests are for the VITROS Systems. Working with a world-class player and a big partner like BÜHLMANN has really been a pleasure and it helps accelerate for us and for patients getting these more important tests out on the market. The other thing I would say about at least the fCal test, the calprotectin, this is an inflammation, it's a protein, it's an inflammation marker that this test detects. And I think that's interesting because the immune system itself continues to be a renewed area of interest for diagnostics as well as pharma. We're learning more and more, both at the protein level and the nucleic acid level, how individualized or personalized our immune responses are, especially in these kind of chronic, longer-term diseases. So the fCal test is really neat because it's targeting one of those inflammation proteins that has to do with irritable bowel syndrome. So excited, exciting when we can bring these partnership assays to the market and continuing to kind of push this more proactive preventive test menu in our portfolio.

Josh Casey: Turning now to urgent care and rapid testing, QuidelOrtho announced in September the availability of the QUICKVUE™ Influenza and SARS Combo Test for professional use, just in time for back-to-school season. How does this test help manage the surge in respiratory infections?

Jonathan Siegrist: Yeah, so just in time indeed, right, as we're going into the next 2025/26 respiratory season. So first order, this test, our QUICKVUE, it's a Flu A, Flu B, SARS test. It's a visually read lateral flow test. Really nice test that delivers this combination of results in 10 minutes. It's really geared toward the frontline healthcare workers where it's the middle of season, patient flow is high and you need those quick but still reliable results and those decentralized or point-of-care settings. So this is gonna help a lot coming out on the market just in time. Continuing to see in the space more and more innovative and needed tools in the respiratory markets. And obviously we see the respiratory needs all the way from the hospital, all the way out to the most decentralized locations, including home, over the counter. We continue to see a need for different tools depending on the workflow, the situation, the environment and the patient. So this the QUICKVUE Flu A, Flu B, COVID Test, it really complements nicely our SOFIA™ Flu A, Flu B, COVID Test that's on an instrumented platform where patient volumes and needs are a little bit higher. And we continue, of course, to see molecular PCR tests playing in the space as well. So this continuum of patient needs, this continuum of different tools to serve those different needs, that's a recurring theme as we continue to see the space evolve and this QUICKVUE Test is a really important tool to that toolkit. Helps get the patients the right answers, helps

prevent or in some cases guide the right antibiotic treatment or antiviral treatment. As we sit here now in December 2025 having this discussion, the H3N2 flu A virus in particular, this new subclade K virus is circulating and it's the setup for potentially a perfect storm, if you will, around in the U.S. at least, historically low vaccination rates, not a very effective vaccine as happens from time to time, still useful but not as effective as we'd like. And then this new H3N2 variant all kind of circulating at once. So as always with respiratory season, we'll see how it pans out, but very happy to have this QUICKVUE Test as part of the offering as we go into the season. I think it'll make a big impact going forward here.

Josh Casey: Thank you for that explanation. Maybe the biggest news coming from QuidelOrtho in 2025 was the announcement of its intent to acquire LEX Diagnostics and its ultrafast thermal-cycling molecular testing platform. What will this advanced molecular technology mean for point-of-care diagnostics?

Jonathan Siegrist: Yeah, so LEX Diagnostics is particularly exciting, I think, for us. Big strategic shift in how we're thinking about the molecular offering that we might have as a company as we go forward. And this is one, of course, that we've discussed publicly our intent to acquire them upon their FDA approval. First things first, a reminder, LEX Diagnostics submitted their dual 510(k) CLIA Waiver application into the FDA in early June and they're continuing to work through the review process with the FDA. The reason we're really excited about the LEX offering is fundamentally two things, maybe three. So one is that the workflow just couldn't be simpler. It's a direct swab into their device, which is the first test being a Flu A, Flu B, COVID test as well. It's very high sensitivity. It's a true PCR chemistry inside of it, which differentiates it from other non-PCR molecular chemistry. So it's a true PCR gold standard, but it's very, very fast. You know, results in 10 minutes, positives can be delivered in less than 10 minutes. It is an extremely fast platform. One of the fastest true PCR platforms that exists. So we're very excited about the prospects around this pertinent to the other discussion we had earlier, very big help in the respiratory season, complements those span of call points from hospitals out to decentralized.

Josh Casey: Great, thank you. Another really positive trend we've seen this year is the decline of overdose deaths related to opioids like fentanyl. How has testing contributed to the decline and what's on the horizon for drugs of abuse testing considering the recent rise in availability of synthetic opioids?

Jonathan Siegrist: Yeah, so this is also a really important area. I mean, one, while we've made good progress, so really kind of a sad area within healthcare. Obviously, some of the rapid treatments like Narcan, what have you, have made a huge impact on, especially on the fentanyl overdose situation, but we still need a really good test. This is still a really vital piece. Like any disease state or any healthcare condition, it's about a really good test and a really good treatment. So the diagnostic tool continues to be super, super important. Getting proper care to patients who have this acute intoxicated state, you don't always know that it's fentanyl. You need to do the right testing and the screening continues to be a big area. There's a lot of good tools that are out there. For example, some of them in mass spec, they're bigger and they take time and there's more cost to deploy and they're not necessarily decentralized or point of care. So while the treatments are helping a lot in this space, we need better tools. And I think one of the trends we're going to see as we continue to go forward is the push and pull for more point of care, kind of rapid testing in this space rather than some of the larger, more complex test methods to really fundamentally help patients and save lives. For us, more to come as we get into next year, but we're continuing to focus on certain tests in the toxicology space. We have a bit of an offering on the VITROS

as well as our TRIAGE™ Devices. More to come on what we've been working on our TRIAGE Platform in this space. But glad you brought it up. It's a really important, really important healthcare area that we'll keep focusing on.

Josh Casey: Okay, so now thinking of transfusion medicine, it isn't necessarily an area where we immediately think of innovation, but at AABB this year, QuidelOrtho announced FDA approval of its micro-typing systems' DAT card for direct anti-globulin testing. Why is this a noteworthy development?

Jonathan Siegrist: Yeah, very exciting development for ORTHO VISION™ System customers and for us as well. You know, from an R&D perspective, really big win to get this one out and FDA cleared for us. As you said, Josh, this DAT card really rounds out our offering in this space. It puts QuidelOrtho in a position where really the only complete gel-based solution for anti-globulin testing, so this DAT card really rounds out that offering. All of course on a single platform. We have a couple different flavors of the VISION Systems as well as our optics, helps bring that testing from polyspecific to monospecific test suite around the space. This particular card, the DAT card, leverages our gel-based column agglutination technology, which is tried and true, very high confidence results coming off of this device, feeds in with the automation that is enabled by our VISION Systems, and really just serves not only but primarily for the blood bank professional needs in the space. Minimal hands-on time, high confidence results, fits into the ecosystem of our current customers. And then, importantly, following the DAT FDA clearance, we also got clearance of our ELUTION™ Kit, and this really enables that seamless kind of end-to-end workflow for the customers, which is really important. So excited not only about the DAT card, but also the ELUTION Kit along in the space and sets us up for a really nice, you know, new product offering to be able to talk to customers early next year. So very excited about this. I think to your question, maybe a perception that innovation isn't alive in this space, but for us very much it is you know, a duty and excitement to continue adding to the offerings in this space and lot of innovation on this side of the business is alive and well here in QuidelOrtho and I'm super happy to be part of it.

Josh Casey: Okay, so shifting now from diagnostics to advancement in technology, 2025 was also a big year for informatics at QuidelOrtho with the launch of the RESULTS MANAGER™ System. How are informatics improving workflow, quality and performance in the lab and at the point of care?

Jonathan Siegrist: Yes, I love talking about the digital space and I think that the all these digital tools, whether they be AI or non-AI, continue to perfuse into our lives daily. So of course, this is a really important area for healthcare as well. It's also, you know, not such an easy area to crack the code on, so to speak, sorry for the pun, from a healthcare delivery perspective. Right. A lot of folks have and continue to try, rightfully so but, the tools and offering in this space are still very scattered. To take a step back, diagnostic tests fundamentally, they're delivering a lot of information. At face value, it's oftentimes just a number, at least from a blood test or a classic in vitro diagnostics, just a number or a positive, negative. But there's actually a lot of rich data behind that that gets delivered, as well as the physician or the caretaker making a decision for that patient in context of all the other things that are happening to that patient or around that patient. So that's a very complex environment, and certainly we're seeing more and more the ability for informatics and digital tools broadly defined to help streamline and increase patient outcomes in that space. The other area where informatics is playing well, Josh, you hit on with the question, is fundamentally the operational efficiency around how labs and diagnostic tests are

deployed. And at the end of the day, it's really about turnaround time, getting that result back to the patient quickly, where oftentimes minutes matter, so the right decision can be made at the right time. And a lot of these tools can help a lab director or an operator understand how things are moving through the lab from a patient's and a test perspective and help optimize fundamentally to get answers back to clinicians faster. So very excited this year to have our RESULTS MANAGER offering start to roll out our informatics solution, focusing on the clinical lab space at the moment. Our intent is certainly to deploy this ecosystem that we're building across our entire offering, whether it be more central lab testing or point-of-care testing.

Josh Casey: Very exciting stuff. So, okay, we've come to our last question and as we've talked about today, 2025 is really an exceptional year for QuidelOrtho and we're anticipating more exciting developments in 2026. What are some of the milestones we can look forward to in the year ahead?

Jonathan Siegrist: So overall, I really do think it's been a great year for the company, for QuidelOrtho. At a macro level, as I mentioned, the opening of our space, what a roller coaster of a year at the same time, right? We've all in the space and outside dealt with tariffs, the changes in the FDA, a lot of things happening. We've seen a lot of mergers and acquisitions in our space as well. So it's definitely been an eventful year in our space for sure, but on our side, just I'm really proud and happy of the things we've delivered into the hands of our customers and our patients this year. We talked about a few of them earlier, but really, really happy with how we've done that. And I guess if I take a step back, I can't help but think, it's a bit of a tangent, but leadership also really matters in this space, whether you're a health system, a company like ours, a startup company but I have to reflect as Brian Blaser, our CEO, president came in, you know, a little over a year ago, almost a year and a half ago, he's really helped drive us as a company forward in that sense, transforming how we focus on the patient, focusing on delivery of our products out. And I think along with that has been the opportunity to elevate leaders from within the company to help us set that vision as well as bring in additional leadership from outside the company. You know, just to note a few that we've talked about over the year, really, really happy and lucky to have Sergio join us as our head of clinical regulatory. Very ecstatic to have Devin here as head of our quality. And then most recently, Erich, joining us at the senior leadership level on strategy and business development. I think it's palatable inside the company, the new thinking, and some of the visions we're building together. Very exciting setup, I would say, for next year. Puts us in a really good position for 2026. So to that question, yeah, lots to talk about for next year. The launch of a couple of things that we spoke about earlier. We've got our FDA clearances in our hand, getting those products out to the market, high-sensitivity troponin in the U.S. being the biggest one, excited for that. We have been working on our newest VITROS System, the VITROS 450. That's our next generation, smaller clinical chemistry analyzer. Very excited to see that launch outside the U.S. early next year. Lots of anticipation on that one. We spoke about LEX earlier. And then last but not least, as we spoke about earlier, some really exciting informatics offerings coming in the year. Also, some of those associated with some automation offerings in our Clin Lab space. So lots of stuff to keep us busy, lots of stuff that I think will make our customers really happy. I think we're set up in a really good position to deliver on some cool stuff next year, so I'm really looking forward to it.



Josh Casey: So you all heard it here, stay tuned, much more to come. And that wraps up our final episode of 2025. Jonathan, thank you so much for your time and for sharing your perspective on these important innovations.

Jonathan Siegrist: Yeah, thanks for having me today. I had a blast and look forward to connecting again on a future episode.

Josh Casey: Awesome, thank you. And thank you all for listening in. Please be sure to review the sections and links within the podcast description. You can always go back and listen again if you'd like more details. Stay tuned for more conversations on how technology, science and innovation are transforming healthcare. And please subscribe if you haven't already to join us each month for the podcast brought to you by QuidelOrtho Corporation, where we are advancing the power of diagnostics for a healthier future for all. We'll see you back here next year. Until then, take care, everyone.

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