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Global IVD: Barriers, Trends, and Future.
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Guest: Dr. Min Yu is a clinical faculty member in the Department of Pathology at Harvard Medical School in Boston, Massachusetts.

Bob Barrett: This is a podcast from *Clinical Chemistry*, a production of the Association for Diagnostics & Laboratory Medicine. I'm Bob Barrett. In vitro diagnostics [IVD] are used throughout the world to improve human health, helping to screen for, diagnose, and monitor a wide variety of disease states. During the COVID-19 pandemic, the general public became acutely aware of the importance of diagnostic testing and terms like "supply chain" and "regulatory oversight" worked their way into everyday conversation. While lessons learned during the pandemic have helped increase access to high quality testing, it is clear that many challenges remain when we consider the problem from a global perspective. Many areas of the world lack access to essential testing. Regulatory frameworks are not standardized, forcing manufacturers to navigate multiple complex approval processes to bring their products to the global market. Lastly, emerging tools like artificial intelligence and portable testing platforms are poised to revolutionize care in high- and low-income countries alike.

A Q&A article in the February 2026 issue of *Clinical Chemistry* brought together six experts from around the world to share their insight into the current state of the global IVD market and predict what changes the field has in store. Today, we're joined by the article's moderator. Dr. Min Yu is a clinical faculty member in the Department of Pathology at Harvard Medical School in Boston, Massachusetts. And Dr. Yu, this paper takes a broad global view of in vitro diagnostics. What motivated you to bring together these perspectives now?

Min Yu: Yeah, so what really motivated this paper was a sense that the diagnostics are advancing very rapidly. However, the access and impact are not keeping pace. So we have extraordinary innovation in biomarkers, molecular testing, point-of-care platforms, and digital integrations, yet the reality on the ground looks very different depending on where you practice or where patients live. So, what we kept coming back to was that a lot of existing work looks at the diagnostics in pieces, market size, individual technologies or specific regulatory frameworks. All of that is important, but it doesn't explain why, despite decades of innovation, access to high quality diagnostics still looks so uneven across the globe.

So what felt missing was a systems level perspective. Diagnostics don't fail because the science isn't there. They fail because the surrounding systems, regulation, infrastructure, workforce reimbursement are not aligned. This paper was really designed to synthesize those pieces and show how they interact in the real world, and that's also why it was important to bring laboratory leaders, global health experts, and industry voices into the same conversation. So each group sees a different part of the problem, but none of us sees the whole picture alone. But putting those perspectives together helps explain not just what the challenges are, but why they persist.

Bob Barrett: So, as you brought together these experts from different regions and sectors, what insights or tensions stood out to you the most?

Min Yu: Yeah, great question. One thing that stood out was how consistent many of the challenges are even cross very different regions. Whether we were talking about high income countries or low- and middle-income settings, the same things kept coming up. Regulatory fragmentation, slow moving healthcare systems, and chronic underinvestment in diagnostics as infrastructure. But what differed was where people felt the responsibility should sit. Some experts emphasize regulation as the primary bottleneck. Others point to reimbursement models, workforce shortages, all the lack of integration into clinical workflows. So that divergence is actually very important. It highlights that diagnostic sit at the intersection of multiple systems and no single stakeholders owns either the problem or the solution. What that means in practice is that progress requires coordination across groups that don't always operate in sync. And that helps explain why these challenges have been so persistent over time.

And what also struck me as a laboratory professional was how often diagnostics are undervalued despite the influence the majority of clinical decisions. And that disconnect between impact and investment keeps resurfacing across discussions. And it's a course in running through the paper.

Bob Barrett: Many of those tensions became especially visible during the pandemic. Rather than a list of lessons learned, how did COVID act as a real stress test of the global IVD ecosystem?

Min Yu: Yeah, COVID really put the entire diagnostic ecosystem under pressure in a way we hadn't seen before. So, on the positive side, it showed what's possible when alignment exists. We saw rapid test development, regulatory flexibility, manufacturers scale up, and an unprecedented level of public engagement with diagnostics that was entirely new. At the same time, it exposed how fragile the system can be. Supply

chains were stretched thin, access to testing was deeply unequal across regions, and quality oversight became much more challenging as testing moved into decentralized and home setting.

So many of those vulnerabilities didn't disappear once the emergency phase passed. The COVID proved that we can move faster and collaborate more effectively but it also showed that much of the progress was situational rather than structural. So the real challenge now is how we take what worked during a crisis and turn it into durable, resilient systems that function just as well outside the emergency. And that question carries directly into how we think about decentralization and digital integration going forward.

Bob Barrett: Well, decentralization and digital integration are major themes in the paper. How do these trends change the role of diagnostics?

Min Yu: Now, this is one of the most exciting shifts happening in diagnostics right now. Decentralization and digital integration are fundamentally changing diagnostics from something that happens quietly in the background to something that actively ships care in real time. The diagnostics are moving closer to patients, into clinics, pharmacies, community settings and even homes and that changes expectations. The tests aren't just about analytical performance anymore. They have to be fast, intuitive, connected and more importantly actionable. So digital integration is what makes that shift viable. Connectivity allows results to flow into clinical systems, supports remote quality oversight, and enables decision support at the point of care. Without the digital backbone, decentralization risks creating fragmentations and quality gaps rather than improving care.

So the role of diagnostics is clearly expanding. It's no longer just about generating results; it's about usability, guiding clinical decisions, supporting population health, and enabling care models that simply weren't possible before. So, as we can see, the opportunity is enormous but so is the responsibility to ensure those models improve equity and quality rather than widening existing disparities.

Bob Barrett: Well, finally Dr. Yu, as a laboratory leader moderating this discussion, how has working on this paper changed the way you think about the role of laboratorians in the global IVD ecosystem?

Min Yu: Yeah, if anything, this paper really reinforced me is that laboratorians are not just technical experts. We are system translators. We sit at the intersection of science, regulation, clinical care, and operations, and that perspective is incredibly important right now. The work on this paper made

it clear that many of the barriers to equitable diagnostics aren't technical problems. The assays exist. The platforms exist. Where things break down is almost always around alignment and implementation. And the way laboratories are uniquely positioned to see those gaps, whether that's regulatory friction, lack of integration into care pathways, or quality challenges as testing becomes more decentralized. It also changed how I think about influence. Lab leaders often underestimate our voice, especially when it comes to policy, regulation, or global strategy.

We tend to assume that those conversations belong to someone else, but laboratorians are the ones who understand what quality really means in practice, and that perspective becomes essential as models like point-of-care home testing and digital diagnostics scale globally. So, if this paper leaves people with anything, I hope it encourages laboratorians to think beyond their own institutions, to engage more actively in conversations about regulation, digital infrastructure, and equity.

The diagnostics shape most clinical decisions and we should have a stronger role in shaping the systems determine how diagnostics are used globally. Finally, this paper is a call to shift the conversation from 'what new test can we build?' to 'how do we ensure diagnostics actually reach patients and improve outcomes?' and doing that required alignments across regulation, infrastructure, digital health, and workforce. The last word I have here is, if diagnostics are central to care, laboratorians need to be central to the systems that deliver them.

Bob Barrett: That was Dr. Min Yu from Harvard Medical School in Boston, Massachusetts. She moderated a Q&A session in the February 2026 issue of *Clinical Chemistry*, describing the current and future state of the global IVD market. And she's been our guest in this podcast on that topic. I'm Bob Barrett, thanks for listening.